
Til: Jeppe Kramer Jørgensen (EM-DEP) (■■■■@em.dk)
Fra: Lene Laursen (■■@medicoindustrien.dk)
Titel: SV: D4/5/6: Final MedTech Europe political letters
Sendt: 05-01-2024 15:33

Kære Jeppe,

Intet at beklage – og godt nytår til dig også!

Vi skal nok følge op, som vi hører mere.

Mange hilsner
Lene

Lene Laursen
Vicedirektør

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Følg os



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Fra: Jeppe Kramer Jørgensen (EM-DEP) <■■■■@em.dk>
Sendt: 5. januar 2024 13:05
Til: Lene Laursen <■■@medicoindustrien.dk>
Cc: Stellan Nørreskov Wulff <■■■■@medicoindustrien.dk>; Maria Larsen <■■@medicoindustrien.dk>
Emne: SV: D4/5/6: Final MedTech Europe political letters

Kære Lene

Godt nytår.

Tak for orienteringen – og beklager sent svar.

I må endelig sige til, når/hvis der opstår noget nyt om D4, D5 og D6, som jeg bør kende til og evt. kan være behjælpelig med at håndtere.

Med venlig hilsen



JEPPE KRAMER

Specialkonsulent
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Fra: Lene Laursen <████@medicoindustrien.dk>

Sendt: 15. december 2023 11:03

Til: Jeppe Kramer Jørgensen (EM-DEP) <████@em.dk>

Cc: Stellan Nørreskov Wulff <████@medicoindustrien.dk>; Maria Larsen <████@medicoindustrien.dk>

Emne: VS: D4/5/6: Final MedTech Europe political letters

Kære Jeppe,

I forlængelse af vores dialog for noget tid siden vedr. stofferne D4, D5 og D6, vil jeg blot dele de vedhæftede breve, som Medtech Europe har sendt til de tre relevante kommissærer. Kort sagt beder vi om alignment mellem Stockholm Conventionens udmøntning og REACH, således at vi fortsat kan levere medicinsk udstyr til patienter og sundhedsvæsenet.

Mange hilsner – og god weekend, når det bliver tid!
Lene

Med venlig hilsen,

Lene Laursen
Vicedirektør

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Mrs Stella Kyriakides
Commissioner for Health and Food Safety
European Commission
Rue de la Loi 200
B-1049 Brussels

Brussels, 04-Dec-2023

Potential nomination of siloxanes D4, D5, and D6 to the Stockholm Convention on Persistent Organic Pollutants (POPs): securing patients' access to medical technologies

Dear Commissioner, dear Mrs Kyriakides,

On behalf of MedTech Europe, the European trade association representing the medical technology industry, I am contacting you today to raise your attention to the **significant implications that a potential nomination of the siloxanes D4, D5 and D6 to the Stockholm Convention would entail for the medical technology sector, healthcare practitioners and patients** who depend on continuous, uninterrupted supply of life-saving and life-sustaining medical technologies to satisfy their daily healthcare needs.

- (1) MedTech Europe is concerned with the significant risk posed by such a nomination on the vital use of D4, D5 and D6 in the manufacturing of silicone polymers, which are essential for the manufacture and use of many medical technology applications, including both medical devices and IVDs.¹
- (2) Additionally, the three siloxanes have been the subject of multiple regulatory measures in the European Union (EU) since 2017 by virtue of a REACH² Restriction proposal³. Currently, there is a recommendation by the EU Chemicals Agency for an EU REACH Authorisation proposal on these substances as well as a draft REACH Annex XVII restriction amendment proposal, which is pending for vote by EU Member States. A nomination of these siloxanes as POPs risks rendering the pending draft amendment of REACH Annex XVII practically void, which - after lengthy and time-consuming data gathering, evaluation and assessment - includes the proposal for setting a number of targeted derogations for critical medical technology uses of these substances and silicone polymers. Legal certainty for medical technology manufacturers would be compromised.
- (3) Finally, considering the highly complex, time consuming and multifaceted process of implementing the Stockholm Convention at the global level, a POPs nomination represents significant risks of deviations of any final global measure from the soon to be adopted draft REACH Annex XVII restriction amendment and the medical technology specific derogations included therein. Any such inconsistencies between global and EU measures would further engender legal uncertainty in the sector at the ultimate expense of patients and healthcare practitioners.

¹ Some examples such as medical devices (including the device part of an integral drug device combination) for the prevention and treatment of scars and wounds or for the care of stoma; syringes; needles, as well as applications in cardiovascular implant therapies. Other use applications include *in vitro* diagnostic (IVD) assays/mixtures for infectious diseases, blood screening, cancer, cardiac, metabolic and clinical chemistry tests; coating for the wiper ring component in a cartridge from an IVD analyzer; antifoaming mixtures, etc.

² [Regulation \(EC\) 1907/2006](#) of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency

³ <https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade>

Should the Commission proceed with a nomination of these substances to the Stockholm Convention, MedTech Europe urges at least a full alignment of any Commission proposal and final global measure with the medical technology-specific entries included in the draft REACH Annex XVII restriction amendment. Such an alignment would have to be applied to both the scope of the derogations and transitional periods to allow for:

1. **Continued access to life-saving** technologies for patients and practitioners
2. **Legal certainty and absence of double-regulation and/or contradictory requirements** for manufacturers
3. **A realistic transition pathway** to non-silicone alternatives for which no alternatives exist today
4. **Continued availability** of critical components and materials used to manufacture medical technologies.

MedTech Europe shares the ambition of the Chemicals Strategy for Sustainability⁴, as well as the United Nations' Sustainable Development Goals⁵, to spur innovation of chemicals that are both safe and sustainable by design. The sector is committed to the highest standards of chemical risk management measures and collaborates with its suppliers to continuously improve the performance of its products and processes. At the same time, the specificities of the medical technology sector must be considered and the timely availability of lifesaving and life-sustaining technologies for patients and practitioners must be ensured. In the EU, medical technologies are regulated under stringent sectoral legislation⁶, which establishes requirements for the design, safety, quality, performance, alternatives assessment and validation of medical devices (including the device part of an integral drug device combination) and IVDs. These are processes that require a significant amount of time and investment, in addition to the continuous search for alternatives where chemicals have been proposed for phase-out at EU and global levels.

We remain at your disposal in case of any further questions or information needs and thank you for your consideration.

Yours sincerely,



Oliver Bisazza

Chief Executive Officer, MedTech Europe

⁴ European Commission, Chemicals Strategy for Sustainability, available at: https://environment.ec.europa.eu/strategy/chemicals-strategy/implementation_en

⁵ United Nations, Sustainable Development, the 17 Goals, available at: <https://sdgs.un.org/goals>

⁶ Ibid.

Mr Virginijus Sinkevicius
Commissioner for the Environment,
Oceans and Fisheries
Rue de la Loi 200
B-1049 Brussels

Brussels, 04-December-2023

Potential nomination of siloxanes D4, D5, and D6 to the Stockholm Convention on Persistent Organic Pollutants (POPs): securing patients' access to medical technologies

Dear Commissioner, dear Mr Sinkevicius,

On behalf of MedTech Europe, the European trade association representing the medical technology industry, I am contacting you today to raise your attention to the **significant implications that a potential nomination of the siloxanes D4, D5 and D6 to the Stockholm Convention would entail for the medical technology sector, healthcare practitioners and patients** who depend on continuous, uninterrupted supply of life-saving and life-sustaining medical technologies to satisfy their daily healthcare needs.

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⁵ United Nations, Sustainable Development, the 17 Goals, available at: <https://sdgs.un.org/goals>

⁶ Ibid.

Mr Thierry Breton
Commissioner for Internal Market
European Commission
Rue de la Loi 200
B-1049 Brussels

Brussels, 04-December-2023

Potential nomination of siloxanes D4, D5, and D6 to the Stockholm Convention on Persistent Organic Pollutants (POPs): securing patients' access to medical technologies

Dear Commissioner, dear Mr Breton,

On behalf of MedTech Europe, the European trade association representing the medical technology industry, I am contacting you today to raise your attention to the **significant implications that a potential nomination of the siloxanes D4, D5 and D6 to the Stockholm Convention would entail for the medical technology sector, healthcare practitioners and patients** who depend on continuous, uninterrupted supply of life-saving and life-sustaining medical technologies to satisfy their daily healthcare needs.

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⁵ United Nations, Sustainable Development, the 17 Goals, available at: <https://sdgs.un.org/goals>

⁶ Ibid.

Til: Dorte Bjerregaard Lerche ([REDACTED]@mim.dk)
Fra: Jeppe Kramer Jørgensen (EM-DEP) ([REDACTED]@em.dk)
Titel: Bidrag til ERU alm. del - spm. 48 og 49 vedr. PFAS
Sendt: 21-11-2023 16:01
Bilag: Svar på ERU alm. del - spm 48 stillet efter ønske fra Betina Kastbjerg (DD).docx; Svar på ERU alm. del - spm. 49 stillet efter ønske fra Betina Kastbjerg (DD).docx;

Kære Dorte

Tak for samtalen.

Som aftalt kommer hermed de to ERU alm. del spørgsmål i EM's skabelon. Jeg vil meget gerne bede om KC-godkendt bidrag senest fredag kl. 10. Som nævnt i telefonen må bidraget meget gerne skitsere den hidtidige proces og de næste skridt, som du også nævnte over telefon. Det gælder formentlig særligt spm. 48 og om muligt et mindre bidrag til spm. 49, men det må I hellere selv vurdere 😊

Vores del af besvarelsen er som nævnt lettest at indarbejde, når jeg har modtaget jeres bidrag. Når jeg har modtaget jeres bidrag, vender jeg derfor hurtigst muligt retur med vores del af besvarelsen. Herefter kan vi lægge op til parallel godkendelse. I den forbindelse må du meget gerne afklare niveauet for godkendelse hos jer.

Vores interne godkendelsesfrist er den 4/12. Lad os derfor gå efter at igangsætte parallel godkendelse tirsdag den 28/11 – det burde give os tilstrækkeligt med tid.

På forhånd tak.

Med venlig hilsen



JEPPE KRAMER

Fuldmægtig
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Folketingets Erhvervsudvalg

ERHVERVSMINISTEREN

Besvarelse af spørgsmål 48 alm. del stillet af udvalget den 13. november 2023 efter ønske fra Betina Kastbjerg (DD).

ERHVERVSMINISTERIET

Slotsholmsgade 10-12
DK - 1216 København K

Spørgsmål:

Hvad er ministerens holdning til, at et totalforbud mod PFAS i medicinsk udstyr og produktionsudstyr til medicinsk udstyr og lægemidler kan have store konsekvenser for dansk life science og risikerer at rykke en del af produktionen af medicinsk udstyr og lægemidler ud af Europa, jf. Altinget-artiklen »PFAS-forbud vækker stor bekymring i medicinalindustrien: »Store dele af produktionen vil flytte ud af Europa««, den 7. november 2023?

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Svar:

[Tekst]

Med venlig hilsen

Morten Bødskov

Til: Jeppe Kramer Jørgensen (EM-DEP) (████@em.dk)
Fra: Stellan Nørreskov Wulff (████@medicoindustrien.dk)
Titel: SV: Møde ml. EM/Medicoindustrien
Sendt: 20-09-2023 14:12
Bilag: 230907_MedTech_Europe_PFAS_Position_Paper_final.pdf;

Kære Jeppe,

Jeg vender lige tilbage ang. PFAS, da vores europæiske søsterorganisation MedTech Europe netop har færdiggjort et position paper omkring PFAS med input fra branchen, herunder også os. I materialet er også en række eksempler på, hvor kritisk en rolle PFAS spiller i noget medicinsk udstyr. Som det fremgår, er det en kompleks sag, når det kommer til brugen af PFAS – og her har vi en alvorlig bekymring om, hvorvidt der politisk er tilstrækkelig forståelse for, at det vil have alvorlige patientsikkerhedsmæssige implikationer, hvis ikke medicinsk udstyr undtages – eller som minimum får en mellemlang udfasningshorisont (med undtagelse af enkelte særligt specificerede udstyrskategorier).

Samtidig arbejder vi på europæisk niveau videre omkring D4, D5 og D6 – og her forventer jeg, at vi også kommer til at forme et endeligt position paper eller i hvert fald et lidt mere konkret input.

Med venlig hilsen,

Stellan Nørreskov Wulff
Chef for Politik og Kommunikation – Director of Public Affairs & Communications

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Fra: Jeppe Kramer Jørgensen (EM-DEP) <████@em.dk>
Sendt: 3. september 2023 15:16
Til: Stellan Nørreskov Wulff <████@medicoindustrien.dk>
Emne: SV: Møde ml. EM/Medicoindustrien

Kære Stellan

Tak for opfølgningen og den udførlige gennemgang. Det er meget gavnligt.

Lad os vende i løbet af ugen og evt. kort i morgen til vores fælles møde.

Mvh.
Jeppe

Fra: Stellan Nørreskov Wulff <████@medicoindustrien.dk>
Sendt: 2. september 2023 21:02
Til: Jeppe Kramer Jørgensen (EM-DEP) <████@em.dk>
Emne: SV: Møde ml. EM/Medicoindustrien

Kære Jeppe,

Her kommer som aftalt en update omkring D4, D5 og D6, som er væsentlige i noget medicinsk udstyr, hvorfor det er vores vurdering, at et forbud vil have negative patientsikkerhedsmæssige konsekvenser. Ligeledes følger info omkring PFAS, som er et væsentligt opmærksomhedspunkt for os i øjeblikket.

D4, D5 og D6:

Kort om D4, D5 og D6:

- Inden for medicinsk teknologi bruges stofferne som silikoner i medicinsk udstyr, i IVD-tests samt i ar- og stomiprodukter.
- En fordel ved cyclosiloxaner er, at de er kemisk stabile og biokompatible, hvilket betyder, at de sandsynligvis ikke vil forårsage allergiske reaktioner eller medføre andre negative bivirkninger i kroppen.
- De er samtidig hydrofobe, hvilket betyder, at de ikke blander sig med vand og på den måde kan forhindre dannelse af biofilm.

Status omkring udfasning af D4, D5 og D6:

- Der er lagt op til, at begrænsningen skal gælde for fremstilling, markedsføring og brug af D4/D5/D6 på grund af deres PBT- og vPvB-egenskaber. Der er dog blevet foreslået en undtagelse for "Placing on the market of D5 and D6 for use as medical devices, as defined in Directive 93/42/EEC or in the Regulation (EU) 2017/745, for the (i) treatment/care of scars and wounds, (ii) prevention of wounds, and (iii) care of stoma." Har man ikke øje for disse undtagelser, vil det selvsagt kunne være problematisk i et patientsikkerhedsmæssigt perspektiv, ligesom det vil have en negativ effekt for producenter og leverandører af disse teknologier.

PFAS

Et andet – meget vigtigt - opmærksomhedspunkt er PFAS:

- Det er ikke nogen hemmelighed, at der er et stort fokus både nationalt og europæisk på udfasning af PFAS. Det kan få meget alvorlige konsekvenser for branchen, hvis ikke medicinsk udstyr undtages, da PFAS – ligesom i pharma – har stor betydning for produkternes funktionalitet og patientsikkerhed.
- I lovforslagets nuværende form er der tre mulige udfasningshorisonter for PFAS:
 - Den korte med 18 måneders overgangsperiode
 - Den mellemkorte med 12 år + 18 måneders overgangsperiode
 - Undtagelse fra udfasning
- Det er umiddelbart kun API'er (pharma), som er helt undtaget. Medicinsk udstyr opdeles i stedet efter udstyrskategori i den korte og mellemkorte udfasningshorisont (se tabel E.109 s. 327 i vedhæftede).
- Tilgangen, hvor der tages stilling til hver enkel udstyrskategori, er i vores øjne dybt uhensigtsmæssig, da listen for udstyr med mellemkort tidshorisont er ufuldkommen. Til trods for en høringsproces i samarbejde med vores kollegaer i MedTech Europe og deres netværk bliver vi løbende kontaktet af medlemmer, hvor deres udstyr ikke fremgår af listen for mellemkort sigt. Hvis lovforslaget stemmes igennem i sin nuværende form, har disse medlemmer kun 18 måneder til at udfase PFAS i udstyr og produktion, hvilket ikke vurderes til at være realistisk og derfor kan få dybt alvorlige konsekvenser for patienter og medicobranschen.
- Der er blandt vores medlemmer forståelse for, at industrien har et miljøansvar, herunder at bidrage til minimering af PFAS i naturen, men dette ansvar må ikke udvande patienthensynet. Ved en så simpel tilgang til PFAS-udfasning, som der lægges op til, risikerer udstyr at udgå af markedet inden for to år med de alvorlige konsekvenser til følge, som er skitseret ovenfor.
- I stedet mener vi, at man skal gå andre veje:
 - Alt medicinsk udstyr bør undtages – ligesom pharma - eller som minimum få mellemkort sigte ift. udfasning med undtagelse af enkelte specificerede udstyrskategorier.
 - I relation til ovenstående punkt skal det bemærkes, at det er vores vurdering, at en mellemkort frist er innovationshæmmende, da virksomheder kan være tilbageholdende med at bygge produktionsanlæg til eksisterende udstyr, såfremt PFAS indgår i udstyr og/eller i produktionen, og virksomhederne ikke kender til PFAS-alternativer på nuværende tidspunkt.
- Grunden til, at branchen er afhængig af PFAS er, at stofferne har unikke kemiske egenskaber (herunder coating, ligesom det degenerer kun ved meget høje temperaturer), som er vanskelige at erstatte inden for få år – hvis overhovedet. Ifølge MDR skal substitutioner af materiale / stof i udstyr som minimum have tilsvarende (helst bedre for at det giver mening for virksomheden) risikoprofil, før en substitution i udstyret kan godkendes.
- Som du formentlig er orienteret om, er der i regi af Miljøstyrelsen nedsat en taskforce omkring PFAS: [Eksperter skal sætte retning for PFAS-indsats - Miljøstyrelsen \(mst.dk\)](#). Sammensætningen af denne task-force bestående

udelukkende af forskere illustrerer meget godt, at fokuset rent politisk pt. ligger på det miljømæssige og knap så meget på det sundheds- og markedstilgængelighedsmæssige. Det bekymrer os.

Ser frem til at drøfte nærmere omkring ovenstående.

Med venlig hilsen,

Stellan Nørreskov Wulff

Chef for Politik og Kommunikation – Director of Public Affairs & Communications

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Følg os:



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Fra: Jeppe Kramer Jørgensen (EM-DEP) <[REDACTED]@em.dk>

Sendt: 22. august 2023 16:59

Til: Stellan Nørreskov Wulff <[REDACTED]@medicoindustrien.dk>

Emne: SV: Møde ml. EM/Medicoindustrien

Yes, sorry. D4, D5 og D6 ☺

Fra: Stellan Nørreskov Wulff <[REDACTED]@medicoindustrien.dk>

Sendt: 22. august 2023 16:56

Til: Jeppe Kramer Jørgensen (EM-DEP) <[REDACTED]@em.dk>

Emne: SV: Møde ml. EM/Medicoindustrien

Hej Jeppe,

Perfekt – vi ses d. 4. september ☺

Du hører fra os ang. REACH – det er D4, D5 og D6, right?

Mh.,
Stellan

Med venlig hilsen,

Stellan Nørreskov Wulff

Chef for Politik og Kommunikation – Director of Public Affairs & Communications

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Fra: Jeppe Kramer Jørgensen (EM-DEP) <[REDACTED]@em.dk>
Sendt: 22. august 2023 16:53
Til: Stellan Nørreskov Wulff <[REDACTED]@medicoindustrien.dk>
Emne: SV: Møde ml. EM/Medicoindustrien

Kære Stellan

Ingen problemer. Vi kan desværre ikke kl. 9 - så lad os holde fast i kl. 10.

Vi kan tales ved, når det nærmer sig. Jeg hører som nævnt også meget gerne fra dig, hvis I skulle have bemærkninger til begrænsningen af D3, D4 og D5 i REACH-forordningen – tak.

Mvh.
Jeppe

Fra: Stellan Nørreskov Wulff <[REDACTED]@medicoindustrien.dk>
Sendt: 22. august 2023 16:32
Til: Jeppe Kramer Jørgensen (EM-DEP) <[REDACTED]@em.dk>
Emne: SV: Møde ml. EM/Medicoindustrien

Kære Jeppe,

Beklager de interne uenigheder om tidspunkt. Vi holder fast i kl. 10-11 (medmindre I kan allerede kl. 9 eller 9:30) og kommer alle tre fysisk 😊

Mh.,
Stellan

Med venlig hilsen,

Stellan Nørreskov Wulff
Chef for Politik og Kommunikation – Director of Public Affairs & Communications

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Fra: Jeppe Kramer Jørgensen (EM-DEP) <[REDACTED]@em.dk>
Sendt: 22. august 2023 14:29
Til: Stellan Nørreskov Wulff <[REDACTED]@medicoindustrien.dk>
Emne: SV: Møde ml. EM/Medicoindustrien

Hej Stellan

Vil I vende internt, om mødet skal rykkes, eller om vi skal tage det over Teams eller uden Peter? ☺

Mvh.
Jeppe

-----Oprindelig aftale-----

Fra: Peter Huntley <[REDACTED]@medicoindustrien.dk>
Sendt: 22. august 2023 14:26
Til: Jeppe Kramer Jørgensen (EM-DEP)
Emne: Afslået: Møde ml. EM/Medicoindustrien
Hvornår: 4. september 2023 10:00-11:00 (UTC+01:00) København, Stockholm, Oslo, Madrid, Paris.
Hvor: EM: Fælles mødesale - Mødesal 4

Hej Jeppe

Denne mandag er ikke god, da vi har bestyrelsesmøde, hvor jeg gerne skulle være lidt forberedt.
Et TEAMS-møde er muligt, da vi kan spare transporten og dermed få tingene til at hænge sammen.

Mange hilsner,
Peter

MedTech Europe Position on the Proposal for A REACH Universal PFAS Restriction

7 September 2023

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Executive summary

MedTech Europe shares the ambition of the EU Chemicals Strategy for Sustainability¹ to boost innovation for chemicals that are both safe and sustainable by design. The sector is committed to the highest standards of chemicals risk management measures and is working with its suppliers to continuously improve the performance of its products and processes. At the same time, the medtech sector is ensuring the timely availability of lifesaving and life-sustaining technologies to satisfy patients' health needs. Medical technologies are regulated under stringent sectoral legislation, i.e., Regulation (EU) 2017/745 on Medical Devices (MDs) and Regulation (EU) 2017/746 on In-Vitro Diagnostics (IVDs)², which has been adopted after enacting the EU REACH Regulation 1907/2006. These sector specific regulations lay down requirements for the design, safety, quality, performance, alternatives assessment and validation of MDs and IVDs, which are processes that require a significant amount of time and R&D, in addition to the continuous search for alternatives for chemicals proposed for phase-out at EU level. The proposed EU REACH Restriction of per- and polyfluoralkyl substances (PFAS) is one such example. In addition, the PFAS Restriction proposal is of unprecedented scale not only in terms of number of substances in scope, but also their varied physical, chemical and hazardous properties, and the amount of essential medical technologies impacted.

PFAS uses in the medical technology sector or its supply chain occur due to their combination of different and essential properties including chemical resistance, heat resistance, durability, lubricity, low dielectric constant and/or biocompatibility. PFAS substances play a key role in achieving the required high performance and durability of the technologies critical to precision and reliability of medical applications, especially in the light of the above mentioned sectoral legislation.

Given the need for such a combination of essential properties, there is often no alternative available to the use of PFAS in many medical technologies, their (sterile) packaging or upstream manufacturing processes. Often, the only proposed alternative is another type of PFAS. In addition, any alternative must also fulfil all other regulatory requirements for use in medical technologies, including, required validations, aging tests, change of tooling and production processes, biocompatibility tests, clinical trials for certain devices, regulatory approvals and registrations, according to sector specific legislation (i.e., MDR and IVDR). Without successful completion of such required regulatory assessments and the necessary time to carry them out, a potential alternative material is neither able nor allowed to replace a given PFAS for use in MDs or IVDs.

Consequently, MedTech Europe's primary preoccupation with the unique PFAS Restriction proposal in terms of its enormously vast scope combined with tight timelines is geared towards **preventing any supply shortages of medical technologies to the detriment of millions of patients** when considering a gradual transition to PFAS-free alternatives wherever technically feasible, MDR/IVDR proof and capable of ensuring the intended purpose of the medical technology to the continued benefit of patients.

¹ European Commission, Chemicals Strategy website, available at: https://environment.ec.europa.eu/strategy/chemicals-strategy/implementation_en

² [Regulation \(EU\) 2017/745](#) of the European Parliament and of the Council of 5 April 2017 on medical devices and [Regulation \(EU\) 2017/746](#) of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices

The current PFAS Restriction proposal would result in **significant impacts on the quality and availability of treatments for patients in the EU**. Due to the unavailability of suitable alternatives to PFAS some products would have to be removed from the market. Certain diseases and conditions could no longer be treated at all or no longer be adequately treated, such as for example, by devices required for minimally invasive interventions. If these devices disappeared, the alternative options would be open, maximally invasive surgeries, which vulnerable patients often cannot undergo or do not survive. For certain patients, there are no alternatives to interventional procedures with subsequent impact on their lives.

Companies have been working with their suppliers to map PFAS uses in medical technologies and continue to find further use cases as time goes on. Due to the sheer number of substances in scope of the Restriction proposal and highly complex multitiered healthcare supply chains sometimes involving thousands of suppliers, there is the high risk that uses of PFAS that have not been identified by the end of the ECHA consultation period would fall outside the scope of derogations and would therefore not be permitted for use.

Finally, **the medical technology sector is constantly looking for ways to innovate state-of-the-art technologies**. PFAS offer many benefits in medical technologies, due to the unique combination of properties they offer in a single material. The Restriction of this entire class of substances risks halting future medical technology innovation. Industry needs clarity and legal certainty regarding research priorities for alternative substances, since the discovery of viable alternatives to the thousands of different PFAS substances, cannot be accomplished and incorporated into medical technologies at the same time.

For the way forward with the PFAS Restriction proposal, MedTech Europe recommends:

1. **An overall patient-centric approach** whereby patient safety needs are considered when transitioning away from PFAS (where technically and economically feasible).
2. **A realistic transition pathway to non-PFAS alternatives** that are reliable and feasible for medical technologies (including their manufacturing and supply chain) to avoid shortages of medical technologies for patients and practitioners. Sufficiently broad derogations should allow sufficient time to first identify all PFAS uses in medical technologies, and to subsequently move to alternatives where these are proven to be technically viable, available and in conformity with the sector specific MD and IVD Regulations as well as fit for the intended purposes of the medical technology. A realistic timeline must consider the sector's complex supply chain dependencies as well as the long development timelines and steps to ensure compliance with the sectorial legislation (please see MedTech Europe response to ECHA consultation³).
3. **A differentiated approach to high risk and low risk PFAS** in line with Article 68.1 REACH, which requires a proof of "unacceptable risk" for enacting a REACH Restriction: high risk PFAS should be targeted first. Fluoropolymers have a proven history of use and safety in medical technology applications and differ distinctly from the broader PFAS group. They should therefore be subject to a more flexible approach including an at least 13.5 year derogation and transitional period in medical technology applications and a review possibility for its prolongation where duly justified.

³ MedTech Europe's response to ECHA public consultation, Part 33 is available here:
<https://echa.europa.eu/documents/10162/28562aa5-2396-c7fa-efc3-f9ba60a30ff9>

4. **A safeguard mechanism** for cases where no alternatives will be available, and for newly identified non-derogated cases or potentially missed use cases to ensure quality and continued access to essential medical technologies containing PFAS or requiring PFAS for their manufacturing, as well as their upstream supply chain.
5. **An inclusion of upstream suppliers and manufacturing in medtech derogations:** Where medical devices and IVDs are granted the necessary derogations, these need to include the materials and components supplied to the medtech sector as well as manufacturing processes and process aids to be workable.
6. **An enabling R&D framework** that supports medical technology manufacturers in the unprecedented challenge of finding numerous use-specific, fit-for-purpose alternatives to PFAS medtech applications that are also satisfying MDR/IVDR regulatory requirements without compromising patients' lives or health.

In this paper, we substantiate our requests by providing further background information regarding:

- PFAS use cases in the medical technology sector ([Chapter 2](#), [Annex 2](#) and [Annex 3](#)),
- The sector's specificities in terms of supply chain complexities and sector specific, regulatory environmental, human health and safety considerations ([Chapter 3](#)),
- MedTech Europe's suggested key building blocks for a workable transition pathway ([Chapter 4](#)), as well as
- Underlying case studies ([Annex 1](#)),
- An overview of the redesign steps in practice ([Annex 4](#)) and
- A scientific PFAS and Fluoropolymers Emissions Bibliography ([Annex 5](#)).

Chapter 1: Uses of PFAS in the medical technology sector

PFAS are used in medical technologies due to their combination of specific properties, including, but not limited to, chemical resistance, heat resistance, durability, lubricity, and biocompatibility. PFAS uses in medical technologies can occur:

- either in a component or coating of a component of the final medical device (MD) or in vitro diagnostic device (IVD);
- or as a processing aid used during device or upstream manufacturing and testing;
- or in the device part of an integral drug device combination;
- or as cell replacement therapies;
- or in their packaging.

PFAS substances play a key role in achieving the required high performance and durability of the technologies, which are critical, e.g., for precision and reliability of medical applications, especially in the light of the applicable sectoral legislations, i.e., Regulation (EU) 2017/745 on Medical Devices (MDs) and

Regulation (EU) 2017/746 on In-Vitro Diagnostics (IVDs). These regulations lay down strict requirements for the design, safety, quality, performance, alternatives assessment and validation of MDs and IVDs to ensure the protection of patients' lives.

A non-exhaustive list of the various uses of PFAS in medical devices and IVDs can be found in [Annex 1](#), and a non-exhaustive list of the different types of PFAS used in medical technologies can be found in [Annex 2](#) of this paper.

Chapter 2: Challenges in finding alternatives in the medical technology sector

Given the need for such a combination of essential properties, there are either no alternatives, or only "proposed options of alternatives" available to the use of PFAS in many medical technologies, their (sterile) packaging, washing, upstream or manufacturing processes, which could potentially deliver similar functionalities. The challenge is that the technical properties based on inertness (such as oil, water, thermal, biological, chemical and fire resistance) are the very reason why PFAS are also of concern in the environment (mainly its persistence). Because of the unique properties of PFAS, often the only proposed alternative to a given PFAS use is another type of PFAS.

To identify an alternative for a PFAS use, first, a proposed alternative is assessed by material scientists for its possibility. If a possible alternative is identified, the whole development cycle has to be followed from analysis and (in silico) evaluation, early feasibility assessment and test, to physical verification and validation including aging testing, biocompatibility tests including extractable and leachable tests, pre-clinical and/or clinical evaluation as required by the stringent sector-specific legislation. When that has been successful the regulatory steps have to be taken before the product can be placed on the market. Until the very last step in the development cycle of/for a potential alternative, it is possible that the use may be not deemed acceptable in the medical technology and a new alternative would have to be considered. For more details of the steps of the design cycle, please see [Annex 4](#) – "Overview of the design cycle steps required for a medical technology".

Product, material and chemical innovation is a constant and integrated process. New products often include clinical improvements, improved treatment methods, and sustainable innovations (e.g., substitution of the most hazardous chemicals where feasible). The product life cycle of medical technology, due to its development time and required regulatory obligations, varies between years to decades, while the chemical and sustainability agenda in the European Union installs changes at an ever faster pace. This misalignment can be improved by properly taking into account the differences between new medical products and existing products already placed on the market, when setting sustainability requirements (including chemical restrictions). This will integrate the medical and sustainable innovation and ultimately bring new healthcare products more efficiently to patients.

As regards indirect uses (i.e., a PFAS used by a supplier to manufacture a supplied part) the described process can only start once a supplier declares the presence of a PFAS in a part to the medical device manufacturer.

An insufficiently broad framing of derogations or insufficient time to find suitable alternatives to current PFAS uses in medical technologies are likely to have consequences for patients, such as:

- **Potential patient death.** Percutaneous interventional procedures rely on the guidewire device to the target lesion. Without guidewire, there will be no life saving procedures. For example, stenting is needed for a severe heart attack patient, or dialysis for chronically ill patients to save his/her life.
- **Longer procedure times or increased stress to the patient,** e.g., PFAS coatings of catheters and PTFE contained tubes allow for their smooth insertion into the vasculature. Without the PTFE coating or PTFE tubing, clinicians may confuse the wire sticking to the vessel for a larger, more critical vessel blockage and not be able to differentiate in the severity of the issue. Guidewires that “stick” to the vasculature can cause thrombosis and patient harm.
- **Negative impacts on the quality of treatments:** Medical device procedures (such as endoscopic procedure) being replaced with much **more invasive and higher-risk procedures** (such as open-heart surgery), which would significantly increase patient trauma and may be detrimental to vulnerable patients, such as elderly, multi-disease patients. Invasive procedures often lead to increased or repeated hospital stays, longer recovery times, increased cost for the patient, and delayed re-entry into the workforce if applicable. Subsets of patients with pre-existing conditions and/or comorbidities may not even be eligible for open surgery.
- **A discontinuation of life-saving technologies and services** (e.g., procedures for stenting, heart valve repairing and replacement, catheters, implants, life-saving replacement therapy in case of organ failure, and capital equipment used in related procedures, leading to patients being untreated or suboptimally treated) and IVD uses (e.g., instruments, diagnostic testing kits), leading to undiagnosed conditions, whereby e.g., the lives of patients suffering from organ failure will be at risk.
- An **increased incidence** of puncture wounds, thrombosis, inability to deliver the device to the targeted lesion, device malfunction and/or the inability of the surgeon to sufficiently visualize the surgical site.
- **Complications during treatment and other negative impacts on the patient’s wellbeing,** e.g., no or improper interventional procedure at cardiac emergency, vein complications and tissue damage during interventional access, and improper healing in the case of hernia meshes. This may cause patient death or delay the patient's treatment and adversely affect post-treatment life. Additionally, the increased treatment times and complications will not only adversely impact the patient's overall health, but also the economic state of the patients and their families and the health system.
- An **inability to manufacture or source critical components** for medical technologies, e.g., humanitarian medical devices. It may cause suppliers to terminate their production and hence disrupt the distribution of medical technologies within the EU. Additionally, a shortage of possible alternative materials (e.g., the same category of the materials, but from a different supplier) may arise due to a sudden high demand from several manufacturers.

Chapter 3: Specificities of the medical technology sector

Medical technologies are strictly regulated under sectorial legislation for performance, safety, and risk management. Therefore, medical technologies containing PFAS are considered safe for the patient and user,

due to the rigorous validation processes and biocompatibility tests they are obliged to undergo. In addition, certain requirements exist for the justification and labelling of chemicals used in medical technologies. Where changes in the chemical or material composition occur, long and comprehensive validation processes are triggered (see [Annex 4](#) – “Overview of the design cycle steps required for a medical technology”).

It should also be noted that the multiple regulatory initiatives running in parallel to PFAS in the chemical's domain (e.g., BPA + BoSC, DEHP, microplastics, lead, etc.) also lead to alternative substitution requirements and collectively are creating a heavy burden on industry R&D resources. When many material and design change dossiers are submitted to regulatory bodies around the world simultaneously, they will be overwhelmed by the volumes resulting in probable delays in marketing the product in the EU. Resources may be better allocated towards new medical technology innovation, rather than phasing out chemical uses from approved safe technologies that are essential for many patients. Human resources that would otherwise be dedicated to treating new disease states, seeking solutions for new patient populations, and solving unmet clinical needs would likely be displaced to research in PFAS-free alternatives for existing products. European society, especially patients, will suffer due to dependence on old medical technologies or missing and reduced treatment options.

Supply chain complexities

The medical technology sector represents over 500,000 products, services and solutions available on the Union market. Individual devices differ greatly in terms of complexity. It is not uncommon for routinely used devices to have hundreds and thousands of components. Supply chains can be up to 30 tiers from materials to the final device. A single component of such products being banned due to a missed identification of its PFAS relevance or due to a too narrow or too short derogation (exact wording) can make the concerned devices and medical treatments unavailable for patients.

Given to the broad relevance of PFAS in industry and the unprecedented scope of the proposed Restriction, the current disclosure requirements, such as via safety data sheets, SVHC declarations or other means are insufficient to build the basis for identification and evaluation of all relevant PFAS uses in time within the expected legislative timeline.

In the absence of a workable regulatory obligation to disclose whether the provided products, components and materials contain PFAS or use PFAS for their manufacturing, there is a high likelihood that the medical technology sector is not yet aware of all uses of PFAS in components they use, or in the manufacturing of these components. Right now, there are also no single standardised analytical methods for all PFAS available. Against this background, it is questionable whether the proposed Restriction could be adequately enforced in connection with the import of PFAS containing products from third countries.

A Restriction of PFAS containing substances within the EU may cause suppliers to terminate their production and hence disrupt the distribution of medical technologies within the EU. Additionally, a shortage of possible alternative materials may arise due to a sudden high demand from several manufacturers.

In the end, all these aspects affect patients and customers, because the provision with the respective devices could not be ensured.

A strict sectorial regulatory system: human health, environmental protection and safety aspects

Human Health protection

Risk management is conducted in line with medical technology regulations (e.g., EU MDR and IVDR) and (harmonized) standards, as well as local governance biocompatibility studies and toxicology studies.

The existing regulations (e.g., EU MDR 2017/745 Chapter VI; EU MDR 2017/746 Chapter VI) require that manufacturers shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements, as well as provide requirements for conducting of clinical investigations. Existing international standards (e.g., EN ISO 14155) address good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical technologies.

In addition, manufacturers have established risk management systems (in accordance with EN ISO 14971). As part of the risk management, all known and foreseeable risks, and any undesirable side-effects, are minimised and need to be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. Furthermore, in order to ensure patient safety, the use of device materials must undergo rigorous biocompatibility testing in accordance with the ISO 10993 series on “Biological evaluation of Medical Devices, as part of standard medical device risk management requirements”, as part of the standard risk management process.

To illustrate, fluoropolymers and perfluoropolyether biomaterials are commonly used in medical technologies and other biomedical industries. The usage of these materials has been well-proven to be biocompatible and safe for patient use (over 45 years on the market) and well-regulated (EU MDR approvals and other regions' regulatory approvals).

Environmental protection and safety

Main PFAS emissions within the control of the sector are primarily emissions during manufacturing and end of life management.

As regards emissions during manufacturing, EU Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control)⁴, which has just been revised, applies on manufacturing sites of the sector in the EU. Besides, many companies' manufacturing processes are for example governed by the ISO 14001 standard, an established and internationally recognized management process for minimizing environmental impact in manufacturing. PFAS is an exceptionally broad term used to describe thousands of distinct chemicals with a diverse array of properties and uses in society. There are clear and important distinctions between the chemical, physical, and toxicological properties of various types of PFAS materials, which need to be acknowledged in the proposed Restriction. Certain PFAS have a high molecular weight, which generally makes them too large to be bioavailable and they are not mobile in the environment, posing a low environmental risk. Measuring environmental emissions should be based on the type of PFAS generated/manufactured in certain facilities.

⁴ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), available at: <https://eur-lex.europa.eu/legal-content/EN/TEXT/?uri=celex%3A32010L0075>

As regards end of life management, the sectorial legislations (e.g., EU MDR 2017/745, Annex I, Section 14.7; EU IVDR 2017/746, Annex I, Section 13.6) rule that devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. Instructions for safe disposal are provided in the individual medical technology's Instruction for Use (IFU) (e.g., EU MDR 2017/745, Annex I, 23.4 (v)).

If the device does not have specific disposal requirements due to the manufacturer's risk assessment or another applicable material regulation (i.e., electronics disposal under the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), the IFU commonly instructs to dispose of the product in accordance with the locally applicable legislation and the healthcare facilities' biohazard waste procedures.

The medical technology sector uses mainly PFAS-containing materials that are applied in articles used in the healthcare environment and laboratory settings (e.g., hospital biohazard disposal is typically treated via incineration).

Degradation emissions of PFAS to air from the incineration of fluorinated polymers is highly dependent on the waste treatment conditions⁵. Control of amounts of such emissions, if any, would be also subject to the European Industrial Emissions Directive 2010/75/EC.

Besides, the medical technology sector has been very active in exploring novel methodologies in a highly regulated environment. R&D talent is exploring **chemical recycling, modular medical technologies, recycled sterilizable packaging, and even re-use of certain medical devices**. These resources are also evaluating **more sustainable manufacturing practices** (such as electronification), carbon footprint reduction, invention/investigation of new biomaterials, and many more.

Different levels of risks: The case of fluoropolymers

The majority of medical technology manufacturers are not producers of the underlying chemicals or resins that form the fluoropolymers in their finished devices. These device manufacturers receive materials as polymeric products or intervening component parts in chemically stable forms, which are then used to manufacture or assemble medical technologies. Therefore, the use case of these fluoropolymers is either for a manufacturing aid or the material remains in the final medical technology product, where the material may or may not be patient contacting. Furthermore, uses may be in the up-stream manufacturing of those components or manufacturing aids. The use is subject to strict control measures and external certification under the MRD and IVDR.

The fluoropolymers used in medical applications meet the criteria set out by the OECD for polymers of low concern⁶. They do not present toxicity concerns and are not degrading into perfluoroalkyl acids (PFFAs). They are not bioavailable, not bioaccumulative, are not mobile in the environment and pose no potential for long-range transport (LRT). Thus, fluoropolymers do not impact drinking water, plants, or crops.

Fluoropolymers have unique physicochemical properties that constitute a low concern distinction within the PFAS group as they are "chemically stable, biologically stable/inert, negligibly soluble in water, non-

⁵ Wahlström, et al., 2021. Eionet Report – ETC/WMGE 2021/9, Emissions of PFAS to air from the incineration of fluorinated polymers, page 60

⁶ OECD, Data Analysis Of the Identification of Correlations Between Polymer Characteristics and Potential for Health or Ecotoxicological Concern, page 10, January 2009, available at: <https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf>

bioavailable, non-bioaccumulative; and non-toxic”⁷. Emissions during the manufacturing processes of medical technologies are controlled and meeting local regulatory requirements.

Per Table 1 of the PFAS Restriction proposal, annual polymeric PFAS used in the medical device industry make up only 2.75% of the total (mid) estimated amount used across the major use sectors. The emissions percentage is even lower for medical devices, at 0.38% of all polymeric PFAS emitted to the environment across all major use sectors.

Furthermore, because of their long history in the highly regulated healthcare field, fluoropolymers have an extensive biological safety testing history and long track record of clinical safety. This stands in contrast to certain classes of low molecular weight PFAS that have been the key focus for public health concern. Fluoropolymers (and their applications in implantable and invasive medical devices) have been extensively studied, especially regarding biological safety.

If the PFAS Restriction proposal were enacted as suggested, R&D resources in corporates are likely to be focused on seeking a fluoropolymer alternative and withdrawn from other R&I areas. In addition, enacting the Restriction as proposed would contradict the goals of a circular economy, as products in use would have to be scrapped earlier than necessary due to a lack of spare parts and the implicit ban of refurbishment and repair.

There should be a differentiated approach to high risk and low risk PFAS in line with Article 68.1 REACH, which requires a proof of “unacceptable risk” for enacting a REACH Restriction: high risk PFAS should be targeted first. A more flexible approach including an at least a 13.5-year derogation period in medical technology applications and a review possibility for its prolongation should be applied to fluoropolymers. Their history of use and safety in medical technology applications are proven and they differ distinctly from the broader PFAS group.

Chapter 4: A workable PFAS transition pathway for the medtech sector

The timeline required for a transition to PFAS-free materials for medical technology depends on various factors:

- A multi-tier supply chain and the medical technology sector’s main role as a downstream user of chemicals and components. As for most PFAS, there currently is no workable regulatory obligation for relevant information disclosure in the supply chain. The medical technology sector is likely not yet aware of all PFAS uses in components they use or in the manufacturing of those components;
- A proposed alternative is not the same as a validated alternative;
- Medical technologies are regulated under stringent sectoral legislation, which lays down requirements for their design, safety, quality, performance, alternatives assessment and validation. These are processes that require a significant amount of time and R&D, in addition to the continuous search for alternatives for chemicals proposed for phase-out at EU level;

⁷ Henry, et al., 2018. *A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers*. Integrated Environmental Assessment and Management 14(3): 316-334. <http://dx.doi.org/10.1002/ieam.4035>
See also Plastics Europe, Association of Plastics Manufacturers, *Fluoropolymers Product Group, Fluoropolymers vs. Side-Chain Fluorinated Polymers*

- Additional factors are the high complexity of products containing PFAS components, and the high number of products that a company will have to substitute concurrently.

To ensure the availability of vital medical technologies, MedTech Europe recommends:

1. **An overall patient-centric approach** whereby patient safety needs are considered when transitioning away from PFAS (where technically and economically feasible).
2. **A transition pathway to non-PFAS alternatives for medical technologies** (including their manufacturing and supply chain) based on realistic timetables that allow sufficient time to first identify all PFAS uses in medical technologies, and to subsequently move to alternatives where these are proven to be technically viable, available and in conformity with the sector specific MD and IVD Regulations. A realistic transitional timetable to non-PFAS alternatives needs to be reliable and feasible to avoid a shortage of technologies for patients and practitioners. A realistic timeline must consider the sector's complex supply chain and dependency on the supply chain, as well as the long development timelines and steps to ensure compliance with the sectorial legislation. Due to the large amount of medical technologies and their variety in terms of complexity, chemical design, and material design, there is no one-size-fits-all solution to the length of transitional time for all PFAS. The derogation periods vary due to the high level of uncertainty, such as:
 - Whether proposed alternatives meet the required functional properties;
 - The variety of products, its risk profile and the function of the PFAS containing material in the medical technology;
 - The different level of risks of PFAS used in the medtech sector, such as high risk PFAS and fluoropolymers;
 - The uncertainty of the future regulatory outlook and the application of the essential use concept, when the PFAS Restriction will enter into force or when the proposed derogations expire.
3. **A sufficiently broad approach to the derogations for IVDs and MDs to prevent imminent supply shortages:** As we work on the proposed PFAS Restriction, we are continuously identifying new PFAS uses. A detailed list of derogations at this stage can only be non-exhaustive and therefore runs the risk that applications will be missed. There is the risk that many of the PFAS uses in the sector are not known yet and will therefore not be taken into account at this stage.
4. **A safeguard mechanism for cases where no alternatives are available, and for newly identified non-derogated cases** to ensure quality and continued access to medical technologies containing PFAS or requiring PFAS for their manufacturing, as well as their upstream supply chain: For some of the medical technology uses of PFAS, the 13.5-year transitional period is not sufficient to find and validate a potential alternative, also considering the material and product design cycle and time for change implementation (please refer to [Annex III](#) – “Non-exhaustive list of types of PFAS used in medical technologies”). A 13.5-year transitional period creates the misleading assumption that an alternative will be available once this time has elapsed. This can however not be taken for granted considering the reasons mentioned above. As the technical conditions, regulatory requirements etc. differ significantly, the feasibility of PFAS substitution in one case does not mean that substitution is possible in other cases. In some cases, even if there is an alternative, it may have inferior benefit/risk assessment and/or performance. Besides, a similar mechanism for newly identified non-derogated cases is necessary to

ensure continued access to essential medical technologies containing PFAS to patients and practitioners (e.g., see complex supply chain section).

5. **A differentiated approach to high risk and low risk PFAS** in line with Article 68.1 REACH, which requires a proof of “unacceptable risk” for enacting a REACH Restriction: high risk PFAS should be targeted first. Fluoropolymers have a proven history of use and safety in medical technology applications and differ distinctly from the broader PFAS group. They should therefore be subject to a more flexible approach including an at least 13.5-year derogation period in medical technology applications and review possibility for its prolongation in the absence of a suitable alternative.
6. **A realistic transitional timetable to non-PFAS alternatives that are reliable and feasible** to avoid a shortage of technologies for patients and practitioners. Due to the large amount of medical technologies and their variety in terms of complexity, chemical and material design, there is no one-size-fits-all solution to the length of transitional time. A realistic timeline must consider the sector’s complex supply chain and dependency on the supply chain, as well as the long development and regulatory approval timelines and steps to ensure compliance with the sectorial legislation.
7. **Derogation extension for upstream suppliers and manufacturing:** Where IVDs and medical devices obtain the necessary derogations, we rely on our suppliers to also have derogations for the materials and components they supply us with, but also for the manufacturing processes and aids. Otherwise the derogations for our “end uses” would become mostly obsolete, discriminating EU-based manufacturers. Furthermore, where an alternative material/component to PFAS should be made available, that material/component would then need to undergo validation processes under sectoral legislation to ensure patient safety and quality and performance of the finished product. If a time limited derogation is granted for the PFAS use in the supply chain of the medtech sector, the newly supplied material would nonetheless still need to be tested, validated and approved for use in the respective medical technology, and therefore sufficient time would be needed.
8. **An enabling R&D framework** that supports medical technology manufacturers in the unprecedented challenge of finding numerous use-specific, fit-for-purpose alternatives to PFAS medtech applications that are also satisfying MDR/IVDR regulatory requirements and not compromising patients’ lives or health. Research priorities with respect to phase-out substances should be clear.

Chapter 5: About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, please see: www.medtecheurope.org.

Annex 1: Case studies⁸

MedTech Europe list a few examples of case studies illustrating the challenges for medical technologies with the PFAS Restriction proposal in its present form:

1. Implantable and invasive medical devices

Among the implantable and invasive medical devices, there are interventional cardiac occluders and endoprotheses, surgical vascular grafts, cardiovascular patches, surgical sutures, implantable ophthalmic applications, hernia mesh, endoscopes or cleaning solvents, to name a few. Fluoropolymer-containing or coated medical devices have been implanted in patients for 45+ years safely and effectively. Fluoropolymers are biocompatible, bioinert, are stable when implanted, durable, non-toxic, chemically and heat resistant, provide a low coefficient of friction, allow tissue growth, and are strong and flexible. Currently, there are no alternatives that meet all these properties and/or have the successful clinical history of fluoropolymers. Replacement of materials used in implantable [and invasive] medical devices (and their manufacturing processes) is a drastically more complex and resource-intensive undertaking than in most other applications and industries. It is estimated that development, validation, clinical studies, and regulatory approval of a material substitution in implantable medical devices would take ~20 years for a single device. For patient contacting and implantable devices, special requirements for carcinogenic, mutagenic and reprotoxic (CMR) and endocrine disrupting (ED) substances apply. The usage of CMR and/or ED substances requires justification, which includes a risk-benefit analysis. Currently, over 1,200 CMR/ED substances need to be addressed under Section 10.4 of MDR. Fluorinated polymer processing aids (PPA's) as well as the upstream supply chain need to be derogated to allow the manufacturer to continue medical device fluoropolymer manufacturing.

2. Complex equipment – e.g., equipment for organ replacement (active medical devices), packaging and spare parts

One example of concerned complex equipment are devices, which are used to replace essential body functions in case of acute or chronic organ failure, keeping hundreds of thousands of patients alive worldwide. Spot-checks by a single manufacturer already identified more than a hundred different components, consisting of several different fluoropolymers. Uses include e.g., parts of valves that must be biocompatible. Further parts, which are common industry standard like O-rings, batteries or electronic components, certainly exist and will further increase the number of concerned parts. Besides, the above-described active medical devices, PFAS are also relevant for manufacturing and packaging of needed single-use disposables. Qualification of potential alternatives must be done for each concerned component individually, considering the specific technical and regulatory conditions. In the majority of components, a material change would also impact the tools used in production. This significantly increases the time and efforts required. Besides design of current and future devices, also the already phased-out products must be considered. Concerned devices are investment goods, are intended to be used in clinics and hospitals for several years. Thus, the availability of spare parts for maintenance and repair of devices must be ensured for the whole use phase, i.e., approx. 10 years after stop of production. Each change of the product design and related tools must follow strict rules

⁸ For more case studies, please refer to MedTech Europe's response to ECHA public consultation, Part 33, available at: <https://echa.europa.eu/documents/10162/28562aa5-2396-c7fa-efc3-f9ba60a30ff9>

and processes to comply with applicable quality, safety and regulatory requirements. Experiences with past substance replacements (which were less complex and affected less numerous changes of materials) already indicate that a substitution of PFAS, if feasible at all, would take a significant number of years. Needed internal and external resources for technical qualification, bio-compatibility assessments and regulatory affairs for the required number of parallel substitution projects within such short timeframe are currently not available. Furthermore, such analysis of potential alternative materials, design changes, change of tools etc. could only start after identification of a component containing PFAS. The active medical devices consist of thousands of components and materials, partially designed and manufactured in-house, partially, especially in case of electrical components, manufactured and supplied in a multi-tier supply chain. Due to the broad scope and low threshold values of the proposed PFAS Restriction, existing PFAS disclosure and resulting data is incomplete and mostly limited to obvious cases, e.g., if fluoropolymers are the specified material of a supplied mono-material component. Experience with RoHS showed that generation of reliable and complete material compliance data takes years. In case of spare parts for products, availability of needed detailed PFAS data and willingness to invest in evaluation and re-design of components by concerned suppliers is highly questionable.

3. IVD reagents

PFAS substances are used in IVD devices such as IVD testing kits for hemostasis products (at an extremely low concentration and volume) which detect blood coagulation. They are used as well as heat-transfer agent in IVD clinical chemistry diagnostic testing instruments, which is essential to the functioning of the instrument. The PFAS substance is needed to maintain the temperature of the reaction cuvette. It ensures that the reaction which detects the disease or condition occurs under the correct conditions for a correct patient result. Manufacturers of IVD reagents and systems fluids are required under specific regulations to adhere to design change procedures that can take between 3 to 12 years to complete in order to meet the requirements for reasons of safety and performance. They are also subject to regulatory approvals in every country where sold (can be up to 42 months). This is for one substance only. When considering that a group of PFAS could be banned which may include up to thousands of PFAS substances, the redesign may take more than 12 years when for multiple products. The minimum approval time in case of materials with contact to blood or similar criticality is approximatively 3 years and can further exceed this range, e.g., if local registration updates require additional clinical studies. In case of materials with contact to high aggressive (THF, Chloroform and Acetonitrile) or similar criticality, the minimum approval time is approximatively 3 years and can further exceed this range. Additional use of PFAS in IVDs include that of trifluoroacetic acid (TFA) as identified in section A.3.10.1.14. of Annex XV of the proposed Restriction as an additive to the mobile phase in high-performance liquid chromatography applications and as an ingredient. Additionally, polymeric PFAS materials are widely used in IVD manufacturing process, including tubing, O-rings, Teflon stir bars, greases, water treatment, etc., i.e., essential uses of PFAS not ending up in the finished IVD. Unfortunately, no derogation has been given for these use cases. The reason for using these PFAS materials is primarily the same reason for uses in the IVD reagents which includes material compatibility, inertness, low coefficient of friction, etc. Not having a derogation to produce IVDs using PFAS materials could have a significant impact on the supply of IVD reagents upon the effective date of the Restriction.

4. Prefilled syringe stopper - A device constituent of an integral drug-device combination

Glass prefilled syringes are today widely used within the Union market for health treatments. We estimate that approximately 200+ marketed drugs in prefilled syringes⁹ are sold across the European Union annually. Due to their sensitive nature many of these drugs (in prefilled syringes) use a PFAS (ETFE) coated stopper. Examples of indications of these drugs include but are not limited to multiple sclerosis, rheumatoid arthritis, and neutropenia. The PFAS coated stopper plays a key role by providing a barrier effect against extractables from the rubber, minimizing the risk of interaction between the rubber stopper and the Drug during its shelf-life (up to 3-5 years). A well known-example for which a non-coated stopper (PFAS free) resulted in an adverse health effect is the “Eprex” case for which interaction with rubber extractables led to an increased incidence of pure red cell aplasia¹⁰. For sensitive Drugs substitution of PFAS coated stopper by PFAS free stoppers is not immediately possible. Even if redesign efforts have been initiated there is today no PFAS free stopper available on the market that has the same properties as the PFAS coated stoppers with regards to extractable impurities. With existing PFAS free stoppers, the risk of adverse health effect for sensitive drugs is high as impurities can extract/leachate from the rubber and interact with the Drug through the 3-5 years shelf life. With no derogation the impact of European citizen health will be critical as it will result in Key Drugs shortages (200+ Biologics sold on the EU market with PFAS coated stoppers). No derogation will also have a high impact on innovation and future new drugs launches on the European Market. We estimate that there are approximately 100+ biologic drugs¹¹ in clinical trials across the European Union that are expected to be launched in a prefilled syringe device with PFAS coated stoppers. A 12 year derogation is at minimum needed as redesign is mandatory and Glass prefilled syringes are highly regulated products: requirements of both, Medical Device Regulation (EU 2017/745) and Human Medicine Directive (2001/83 EC) have to be met when making a change leading to long timelines. Redesign efforts have been initiated but we estimate that more than 12 years are needed for substitution, including, among other, the following steps:

- Stabilities Studies by pharmaceutical companies¹²
- Manufacturing qualification
- Regulatory approval from the device side¹³ and the drug side¹⁴
- Industrial ramp

We estimate that 240 to 480 millions units of PFAS coated stoppers are used on the EU market for marketed drugs and clinical trials across EU. Transformation of this supply capacity will require significant time and investments as all manufacturing equipment will have to be converted to produce PFAS free stoppers, this includes rubber stopper manufacturers and pharmaceutical filling drug lines that will have to be upgraded.

5. Blood Glucose Meters (IVD) for diabetes treatments

Diabetes is one of the big health topics with an incidence of one in eleven adults in the EU. Blood glucose measurements are one of the most important pillars of the therapy, usually performed by the patient. Therefore, many home-use self-analysers, such as the blood glucose meters (BGMs) are designed as affordable appliances. Alternative materials, since they are quite rare, can be very cost intensive, and -

⁹ From IQVIA database (<https://www.iqvia.com/>) -detailed report can be shared upon request

¹⁰ "The increased incidence of pure red cell aplasia with an Eprex formulation in uncoated rubber stopper syringes"-Kidney International, Vol. 67 (2005), pp. 2346–2353

¹¹ Estimation was made from Global data 2023 (<https://www.globaldata.com/>) and IQVIA (<https://www.iqvia.com/>) databases- detailed report can be shared on request.

¹² ICH Q12 Technical and regulatory considerations for pharmaceutical product lifecycle management - Scientific guideline

¹³ Notified body Opinion on Annex I of (EU) 2017/745 shall be obtained on the device side of the integral Drug device combination.

¹⁴ Variation to the existing marketing authorization approval

together with lengthy design change and development periods - increase the cost of manufacturing immensely. Identifying a non-PFAS containing alternative, will make the distribution of affordable medical devices for all patients even harder. Patient safety is the first and foremost responsibility of a medical device manufacturer. Therefore, as for basically all medical devices, the design change processes required to change materials are extensive and lengthy. Even if a material with comparable properties is found, the process until it can be registered on the different markets can take several years. This does not include the time of the registration process with the countries itself, which is also time consuming. This again would influence the cost for patients and customers, as well as the healthcare system. Since medical devices make up for a rather small part of material usage worldwide, a restriction of PFAS containing substances within the EU may cause suppliers to terminate their production and hence disrupt the distribution of medical devices within the EU. Additionally, a shortage of possibly alternative materials may arise due to a sudden high demand from several manufacturers. In the end, this affects the patients and customers, because the provision with the respective devices cannot be ensured.

6. Flame retardant properties in patient monitoring equipment

Medical devices are required by the EU MDR to comply with EU safety standards, which include a requirement that plastic parts that are associated with electrical circuits are flame resistant. The choice of plastic is limited as medical devices such as patient monitors and patient ventilators need to be tough and must not easily be damaged by for example impacts from hard objects or by being dropped. Impacts can easily occur in emergency situations. Plastics commonly used for medical devices therefore require flame retardants. PFAS such as PTFE are used in plastics as flame retardant and drip protection. The requirements from standards such as IEC 60601-1 and UL-94 in relation to fire resistance and flammability specify maximum temperature in case of skin contact and have special considerations for oxygen-rich environments due to patients receiving oxygen. Research by members has not found a suitable replacement that is available with the same performance and which is not a regrettable substitution, in particular for material thickness of less than 1mm. The search for alternative materials is a lengthy process and includes obtaining samples of PFAS-free polymers and extruding for testing, redesigning parts, verification and validation, and undergoing comprehensive technical and clinical testing. EU MDR requires strong evidence that new designs do not have a lower level of patient safety or a reduction of clinical benefits as a result of new materials used in the devices. A realistic timetable is needed to allow sufficient time to move to alternatives in conformity of medical regulations.

7. Other case studies illustrating the specific *redesign* challenges

Guidewire for coronary and peripheral interventional application

Guidewires are an integral part of vascular intervention. They are utilized to access target vessels, cross lesions, and deliver other devices that can administer therapy to the target region of the vessel or treat the diseased vessel. Without guidewires, both coronary and peripheral interventional procedures cannot be conducted. Though there are many design requirements for guidewires dependent on the lesion type and clinical presentations, one requirement is universal for all guidewires, i.e., low friction, which allows the guidewires to travel through tortuous vessel to the target lesion without damaging patient tissues. At the distal end of the guidewire, hydrophilic coating can be applied to reduce the friction. However, at the proximal portion of the guidewire, a hydrophobic dry/wet lubricious coating is needed, because the physician needs

to manipulate the wire with their hand during an interventional procedure. The physician cannot manipulate a wire with a fully hydrophilic coating, which either is too slippery when fully hydrated or tacky when the coated surface is not wet. Alternatives to the use of PTFE as the coating on the proximal end of the guidewire have been evaluated multiple times over the past 10 years. In each case, a suitable replacement that could maintain the friction performance of PTFE could not be found unless it is another PFAS coating. The performance evaluation included direct friction measurements as well as in-vitro bench testing where the alternative materials demonstrated inferior performance relative to PTFE coated controls. Percutaneous interventions are premised on accessing and treating a diseased segment of vessel through an access point a distance from the diseased segment. The guidewire is the fundamental tool used by interventionalists to establish the pathway from the access site to the diseased segment. Any redesign of the guidewire coating still needs to meet the basic requirement of guidewire deliverability with minimum resistance in tortuous anatomy and in the delivery of therapeutic devices, while maintaining low profile. Any increase in friction could limit the ability to access complex anatomy or the delivery of therapeutic devices which will limit treatment options for a significant portion of patients that can be treated today. Therefore, a redesign of the guidewire coating will not meet the customer need without a dry lubricious coating.

Printing inks for markings on medical devices and on the device part of an integral drug-device combination

Fluorinated wax is used, by itself or in combination with other waxes as an anti-rub and slip additive in printing inks. These are required for the properties such as slip or lower coefficient of friction, scratch resistance, rub and abrasion resistance, matting effect and hydrophobicity. Printing inks are used to create markings for identification, scale, measurement, size, and other functional attributes on medical devices and on the device part of an integral drug-device combination. The alteration of any of the above listed properties will result in fading away and removal of marking on the device. In case of medical devices such as syringes, inaccurate markings or lack of such markings will result in errors in the medication provided by the healthcare provider because they will not be able to know if the right quantity of the drug has been given to the patient. This will adversely impact the health of the patient due to inaccurate amounts of drug administered. The consequences could be lethal. Misidentification of a medical device or drug device combination products in the absence of proper printing inks could result in errors in the treatment of the patient.

There are no currently available known alternatives, which are ready for evaluation through R&D. Once an alternative would be identified for the ink formulation, qualification of the alternative would be required for the mentioned applications. Alternatives will likely require extensive biocompatibility testing and may also require clinical trials, dependent on the application and location of the printing inks. Alternatives may trigger process changes at multiple sites across multiple locations and due to the variety of sophisticated high-volume manufacturing methods, significant process development is anticipated after the formulation is finalized and passes all the biocompatibility testing increasing the substitution timeline. A derogation of 12 years once an alternative is identified is needed to evaluate alternatives, validate, qualify and implement the most promising alternative.

Robotic arms

PFAS (FEP, ETFE, PFA) are used in main cable assembly of robotic arms of an angiography system. Combination of more than 20 individual cables, which are not in contact with patient or user as they are a fixed installation inside the instrument with different functions: high-Voltage cables, power supply cables,

control cables, signal cables etc. Most of the individual cables are multifilament cables. Parts of the cable assembly are heavily and quickly bended when the medical device is in operation.

PFAS are used for insulation action as the thickness of insulation is a key factor of cable assembly bending capability. PFAS substitutes will cause an increase of thickness of the whole cable assembly. Bending performance (bend radius, bend velocity) will decrease and lead to a downgrade of system performance. A thicker cable assembly will no longer fit into the robot construction.

They are also used for their sliding and non-sticking properties, as low friction sliding of the individual cables among each other is essential for the bending capability of the cable assembly. PFAS substitutes (i.e., use of fabric hoses) show poorer sliding properties. Bending performance (bend radius, bend velocity) will decrease and wear will increase. This will lead to a downgrade of system performance, reduced lifetime and reliability of the individual cables. Especially in angiography systems reliability is of maximum importance, as the systems are operating during emergency surgery, and a system failure can be fatal.

Finally, they are used for their flame retardant properties, because fire safety requirements are extremely high for medical systems in clinical environment. The unique characteristic of PFAS is the combination of insulation properties, non-stick properties, mechanical strength and flame retardant properties in one substance. There is no comparable material available to fulfil all these requirements in parallel.

100% substitution will be impossible due to the wide range of outstanding properties of PFAS. Substitution with downgraded system performance and significant change of system design will probably be possible with a 12 year derogation once an alternative has been identified. It is impossible to replace the part until mid-2025. Time for development is not sufficient, no matter how much resources are provided for this task: development of cable assembly with alternative materials, reliability-tests/EMV-tests /safety-test, several iterations to optimize results, approval of product change. Therefore, the product would have to be taken from the market, as only 50% of PFAS in the cable can possibly be replaced prior mid-2030 (in the case where a 5 year derogation is granted), limited to parts of the cable where installation space is not restricted and the movement stress during system operation is less challenging. Some construction redesigns have to be done.

At their end-of-life, the robotic arm is taken back, resold, or upgraded.

Magnetic resonance imaging systems (MRI systems)

PTFE is used in cables and sleeving in low temperatures due for its insulation action, as PTFE has a very low dielectric constant, which means that it does not absorb much energy from electromagnetic fields. This makes it an excellent insulator for use in low-temperature environments, where other materials may be prone to electrical breakdown. In addition, PTFE has a very high dielectric strength, which is the maximum electric field that a material can withstand before electrical breakdown occurs. This property makes PTFE an excellent insulator for use in high-voltage applications, which are common in many low-temperature environments.

PTFE has a very low thermal conductivity which means that it does not transfer heat very well. This is important in low-temperature environments where maintaining a stable temperature is critical. PTFE insulation can help to reduce unwanted heat transfer and maintain a stable operating temperature.

PTFE is highly resistant to chemicals, including most solvents and acids. This makes it an excellent choice for use during manufacturing when the cables may be in contact with other chemicals such as lubricants or adhesives where chemical reactions may be a concern.

PTFE maintains flexibility for cable bending and positioning without cracking during temperature transition from room temperature to extreme low temperature where other materials may become brittle and crack. Such cracks will compromise electrical insulation properties and result in irreparable damage to the magnet system.

At the moment, there is no technical alternatives known with similar properties as PTFE against extreme conditions (low temperature to 4K Celsius). It is impossible to identify suitable alternative materials for the specific working conditions of the applications and completion of all design changes, safety and reliability tests within 2 years. Therefore, the product would have to be taken from the market, and thus, it would reduce the accuracy of diagnosis (e.g., of cancer or neurological disorders), but also the quality of life (impact on monitoring the effectiveness of new drugs/therapies development in pharmaceutical industries).

At their end-of-life, MRI scanners are taken back, refurbished, resold, or they are upgraded, repaired or reused.

Blood Gas Systems

PFAS (PTFE) are used in main cable assembly of varying lengths and conductor count in Blood Gas systems, in special developed detector cable for extra durability in terms of dynamic movements.

Structural Polystyrene Foam is used in instrument housings.

PTFE insulators can be very thin and minimally impact thermal measurements while still providing the necessary electrical insulation around a thermistor or thermocouple component.

PTFE is used to satisfy UL 94 V-0 requirements to self-extinguish and open flame is essential to satisfy fire safety standards for medical equipment.

It is used in mold-release applications to allow molded part to be removed from the mold with fewer ejection pins. This is required to maintain flatness/smoothness specifications for fluidic seals.

Substitution materials do not meet all of the requirements of the current design. Any alternative will downgrade system reliability and endanger clinical availability. No alternative has yet been identified for each application. Given the time required to identify alternatives, approve new vendors, convert old vendors to new suppliers, qualify untested materials, complete engineering verification and clinical validation, there will not be an alternative ready by 2025. As of mid-2023, we continue to discover new places where PFAS is used in the manufacture of our products. Many products are made with vendor proprietary formulations that are found to include PFAS. Plastic molded parts that do not contain PFAS have trace amounts of PFAS found in mold release agents used by the vendor. Electronics production and components continue to identify PFAS in components previously believed to be PFAS-free.

There is no confidence that any of the above products can be certified 100% PFAS free within 2 years.

The main challenges are identifying all PFAS in the supply chain; coordinating with many vendors and design changes simultaneously across all affected products; legacy products on existing last time buy (LTB) inventory must either undergo extensive redesign, or premature end-of-life (EoL); and finding equivalent performance with PFAS-free materials.

When it comes to the end-of-life, instruments can be used for many thousands, or even millions of tests over their service life. Readers are refurbished when returned by customers to be re-sold, re-using the vast majority of parts within them (only swapping out damaged or non-functional parts). Electronics and Printed Circuit Board Assembly (PCBAs) can be recycled.

Multi-use cartridges and Single-use cards are biohazardous waste, which is typically incinerated depending on user laboratory disposal practices, possibility of autoclaving if not incinerated. Instruments not refurbished must be incinerated.

PFAS is in some wiring components, printed circuit board assemblies, moving mechanical assemblies (within hinges, sides, other bearing surfaces), and the structural foam of the enclosure.

Oxygen sensor is deep within the measurement cartridge in a location the user cannot access. Service personnel do not access the biohazardous components, which includes the oxygen sensor.

In-vitro diagnostics devices (IVDs): Laboratory Systems

IVDs are used to detect patient illnesses, infectious diseases and to determine the effectiveness of medical treatment.

PFAS are used for insulation and chemical resistance purposes, as chemical resistance in IVD tubing is of the utmost importance. The use of tubing in IVDs is extensive and varies from product-to-product. If PFAS is present in tubing, but PFAS-free tubing is required in the future, the impact of a change is highly significant. There is a potential presence of PFAS in tubing purchased from suppliers and/or use of PFAS in suppliers' tubing production processes to ensure that chemical resistance is ensured.

If tubing or electronic wire components made of or containing PFAS must be changed, potentially hundreds of IVD laboratory diagnostics devices are impacted, and 100% of the Laboratory Systems portfolio that include automated liquid handling would be affected.

Tubing: The use of tubing in IVDs is extensive, as it is used to transport patient samples through an IVD analyser and to combine the patient sample with chemical substances (reagents). A patient sample is combined with reagents via tubing, resulting in a chemical reaction that a sensor detects. The IVD devices' software is custom-programmed to report the clinical result of the IVD test, based upon the signal generated by the chemical reaction and detected by the sensor.

When tubing contacts patient samples and reagents, IVDs must be tested extensively to ensure that: 1) tubing materials do not cross-react with an individual's patient sample, 2) tubing materials do not cause contamination from one patient sample to another, 3) tubing materials do not cause contamination from one reagent to another, 4) tubing materials used to transport a sample from one device to another device do not result in cross-reactivity or contamination and 5) that software properly interprets and reports patient results. This process is called "validation". If various types of tubing in IVD instruments contain PFAS, but patient results meet product claims registered via medical regulatory authorities, hundreds of unique devices and patient tests must re-validated. The validation could require up to 15 years to complete due to the complexity of validation testing.

Electrical wire insulation: Insulation of electric wires on custom printed circuit boards, power cords and other internal wiring is necessary to: ensure that a specific current must be consistently maintained by the insulated wire component; to protect the wire from heat generated by other parts withing the IVD device; and to ensure that the wire component does not present a heat source that can damage other parts of the IVD device.

If PFAS are used in conjunction with electrical wire insulation, extensive testing will be required if substitute parts have a "like-to-like" performance to ensure the following: 1) expected patient results are maintained (e.g., that no change to insulated electric wires properties occurs), 2) no change to the longevity of parts occurs, 3) no software changes are required as a result of the part change and 4) conformance to

international standards related to electronic products is maintained. If a "like-for-like" replacement of an electronic part is not available, extensive validation of parts with different electronic properties would be required, with a potential timeline of 10-15 years.

Conclusion OR impact:

If the IVD products could not be placed on the market, healthcare institutions would be required to make capital investments for alternative devices. It is not likely that any institution would be able to maintain their current level of care due to costs to purchase new devices elsewhere. In addition, there are certain tests that are unique to the products, if those test were no longer available for devices, patient care would be compromised for certain disease states.

Over 650 million test assays per year in the EU are performed with affected devices. If hospitals and/or patient sample diagnostic laboratories are unable to purchase the IVD devices, alternative tests (assays) for the wide range disease states would not be commercially available and will not meet the high level of accuracy provided by the impacted devices. As a result, patient's conditions may be more difficult to diagnose and treat as other, less suitable methods would have to be used (if they exist). In addition, regulatory body approvals do not allow lower-level performance products to be placed on the market, as such approval would be withdrawn if the adopted parts that do not meet performance claims. As such, this would mean that products which would otherwise support patients from being diagnosed and/or treated, would no longer be able to be placed on the market.

Intensive care devices and systems

The following products have, for example, already been identified as being affected by the PFAS Restriction proposal:

- Intensive care ventilators,
- Anesthesia machines,
- Incubators,
- Patient Monitoring Systems,
- Medical media supply systems,
- Hospital Gas Management Systems.

In these products, fluoropolymers such as PTFE, PVDF, PFA, FKM are essential materials in the following components:

- Hoses, seals and other gas-carrying parts,
- Electrochemical sensors,
- Lubricants,
- Valve coatings.

The materials are indispensable mainly because of their resistance to aggressive media. More specifically:

- Hoses, seals and other gas-carrying parts in medical devices must be permanently resistant to pure oxygen and, for example, anesthetic gases,
- In electrochemical sensors fluoropolymers are used as membranes in strongly acidic electrolytes (e.g., sulfuric acid) or in the electrodes to control their wetting and prevent dissolution. In lead-free oxygen sensors, introduced due to the RoHS Directive, the materials must also withstand free oxygen radicals that would permeate all other plastics.

Furthermore, all electronic components contained in these products rely on semiconductors, the production of which is impossible without PFAS. Producing semiconductors in Europe is a declared goal of the EU Commission. This goal would be thwarted by a comprehensive PFAS ban. At the production plants, components made of fluoropolymers ensure durability, energy savings and safe operation. A broad PFAS ban would result in the unavailability of the necessary production equipment to manufacture the products, including their spare parts.

Emissions:

No emissions of PFAS into the environment are to be expected from these products and the materials they contain. The materials can be considered as harmless to health and as neither fulfilling the criteria of Article 68 of the REACH Regulation nor those of the justification of the present Restriction proposal. According to information from upstream suppliers, the production of the materials is possible without emissions of harmful PFAS chemicals into the environment. This can be ensured by appropriate regulatory measures.

The products are in use for a very long time, in some cases over 20 years. Proper disposal at the end of life is ensured, among other things, by the requirements of the WEEE Directive and other voluntary take-back and recycling offers that go beyond WEEE. In the interests of the circular economy, we would welcome an obligation to return waste to the manufacturer, but this has so far been prevented by European waste shipment regulations. In the pyrometallurgical recycling processes and any incineration of residual waste, the fluoropolymer components are usually thermally destroyed and converted into hydrogen fluoride, which is mineralized as fluoride in the flue gas cleaning process. We are not aware of any emissions of PFASs that are harmful to health from this pathway. Even in the case of deposition, the materials would behave chemically inert in the long term and would not cause emissions to the environment.

Substitution possibilities:

According to the current state of knowledge, there will never be alternative materials that meet all the necessary requirements due to chemical-physical laws. Manufacturers and the regulatory authorities are not prepared to accept any compromises in terms of the functional safety of the products, because human lives depend on it. Due to the high cost, fluoropolymer materials are only used where absolutely necessary.

Derogations:

Only a broad exemption for the use and manufacture of fluoropolymer materials in professional and industrial applications could ensure that all vital products remain available. A specific exemption for the manufacture and use of fluoropolymers (in each case including accessories and spare parts) represents a minimum requirement, but one that appears insufficient for the reasons stated above. Any time limit should at least be designed in such a way that the exemption is reviewed at the end of the time limit and does not lapse without replacement (analog to the RoHS Directive).

The limit values for non-polymeric PFAS in articles must be based on the possibilities of chemical analysis in order to make the Restriction proposal manageable and to avoid legal uncertainties. The limit value of 25 ppb mentioned in the Restriction proposal is far below the measurement limit of the available analytical methods.

Such intensive care equipments like ventilators, anaesthesia devices and neonatal care incubators will no longer be available because less reliable products would not get an approval by the authorities. Equipment already in use at the hospitals would not work anymore after a short period because spare parts could also not be placed on the market anymore. Thousands of patients would most likely die.

Annex 2: Non-exhaustive list of uses of PFAS in medical technologies

Below is a non-exhaustive table of different uses of PFAS in medical technologies (MDs and IVD reagents and instruments):

Uses of PFAS in MDs, and in the device part of integral drug-device combination	Uses of PFAS in IVD reagents and instruments
• Blood contact invasive devices such as e.g., endoscopes, grafts/covered stents, catheter component to improve the device deliverability, catheter tubings for infusion of medication and IV fluids and drug-eluting stent (DES) – blood flow within/between arteries and veins and for DES to control drug release to inhibit the vessel re-narrowing; • Medication contact components - minimise drug-device interactions; • Surgical sutures: pledgets made of PTFE serve as suture abutments when suturing soft tissue. They are essential in heart valve operations; • Fluoropolymers, like PTFE and PVDF, are used in several components for the treatment of serious acute and chronic diseases, and also components such as stents, guidewires, catheters, dilators; • Implantable and invasive medical devices, such as cardiac patches, felts and fabrics; • In hernia meshes for rapid healing of hernia; • Cleaning of medical devices as cleaning solvents in vapor degreasing applications; • Reprocessing devices of medical devices via cleaning, disinfection and sterilization; • Surgical drapes and gowns; • Ophthalmic products (endotamponades- in surgery to reposition a detached retina, eye drops, contact lenses); • Medical tapes and wound dressings; • Medical imaging devices, such as ultrasounds and minimal invasive endoscopes; • Not MD-specific uses in other materials and components such as electrical components and batteries of active medical devices; • Medical equipment for continuous patient monitoring; • Printing inks that are used to create markings for identification, scale, measurement, size, and other functional attributes on medical devices and on the device part of an integral drug-device combination; • Packaging.	• IVD testing kits for haemostasis products that detect blood coagulation; • Heat-transfer agent in IVD clinical chemistry diagnostic testing instruments, which is essential to the functioning of the instrument; • Surfactant properties in <i>in vitro</i> diagnostic assays, which allow measures of various parameters such as magnesium concentration in serum, plasma and urine; • Fluoropolymers like PTFE and PVDF are used in several components for analytical instruments; • Others: Coating on the dispense tip, tubing and tubing connectors, distributors, plugs, washers, seals and gaskets, syringe pump valves, O-rings and sealants, fittings, PTFE coated tank, dry lubrication of moving mechanical parts, manufacturing equipment, without which the assays cannot be manufactured, filtration media; • Packaging.

For a more exhaustive list of medical technology uses, please consider MedTech Europe's input to the [public consultation on the PFAS Restriction proposal](#), Part 33.

Annex 3: Non-exhaustive list of types of PFAS used in medical technologies

Below is a non-exhaustive table of different types of PFAS used in medical technologies (medical devices and IVD reagents and instruments):

Types of PFAS used in MDs, and in the device part of integral drug-device combination	Types of PFAS used in IVD reagents and instruments
• PTFE; • FEP; • Perfluoropolyether; • PVDF; • PVDF-HFP; • Perfluorinated acrylates (C6 – C14); Hydrophobic surface treatments – surface bound or reacted fluoropolymers of undisclosed composition; • PTFE coatings • Specialty fluorinated lubricants; • FKM/FPM fluoroelastomers; • FFKM/FFPM perfluoroelastomers; • PTFE and PVDF suture materials; • Semifluorinated alkanes (for example 1-(Perfluorhexyl)octane and 1-(Perfluorobutyl)pentane).	• PTFE; • FEP; • PVDF; • FKM/FPM fluoroelastomers; • FFKM/FFPM perfluoroelastomers; • PCTFE; • ETFE; • Hexafluoropropanol; • Trifluoroacetic acid; • Trifluoroacetic acid anhydride; • Trifluoromethane-sulfonic acid anhydride Trifluorotoluene; • Methyl trifluoromethanesulfonate.

For a more exhaustive list of medical technology uses, please consider MedTech Europe's input to the [public consultation on the PFAS Restriction proposal](#), Part 33

Note: As mentioned above, the medical technology sector is a downstream user of materials and components. Companies have been working with their suppliers to map the uses of PFAS in medical technologies and continue to find new uses over time. The EU REACH Restriction proposal for per- and polyfluoroalkyl substances (PFAS) includes over 10,000 PFAS substances, including polymers. Many of these substances are currently not regulated under existing hazardous substance legislation under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) or in European legislation. Due to the grouping approach and the long list of PFAS substances, this runs the risk that in the future, new uses of PFAS will be found, which are not covered by one of the derogations and then will not be permitted.

Annex 4: Overview of the design cycle steps required for a medical technology

High-level required steps:

Step 1: Generic testing

Finding an alternative, that performs as well as or better than the former substance/material/technology:

- Changing to an alternative material must follow medical device regulations
- Evaluate feasibility for alternate options, product development, verification/validation, aging testing, biocompatibility testing, pre-clinical studies, clinical trial, and regulatory submissions and approvals
- 10+ years to redesign per impacted product; multiple product changes will result in longer timelines from testing to selecting an alternative (see below for detailed steps)

Step 2: Specific device testing (indicative best-case timings)

- Material feasibility testing (incl. pre-clinical, animal safety testing and design verification) – at least 1 year
- Sample testing / making parts for testing, including industrialisation / Change of manufacturing processes and tools – at least 1 year
- Formal Verification & Validation (V&V) testing – at least 1 year
- Biocompatibility testing – at least 6 months up to 2 years dependent on the device type
- Clinical phase submissions/approvals – at least 6 months
- Clinical trial enrollment – at least 2.5 years
- Clinical trial follow-up – at least 1 year
- Clinical trial report – at least 3 months
- Quality Lab
- Regulatory submissions – at least 1 year
- CE regulatory approval – at least 18-24 months; 5-26 months if for the rest of the world (regulatory approval timing assumes regulatory bodies could support these product submissions *without delays*)
- Procurement time – at least 1-3+ years¹⁵

High-level required steps	Exemplary process steps required depending on scope of individual materials require replacement
Identify potential materials and supplier for alternatives	Evaluate new material(s) based on: - Material properties (e.g., electrical resistivity, tensile strength, durability, chemical resistance, temperature resistance, biocompatibility, etc.) - Intended use/function of material (one alternative may not be suitable for all application) Evaluate Suppliers: - Supplier capabilities & costs

¹⁵ This could be highly variable, depending on the Technology Readiness Level of the material, which is especially relevant if a new substance has to be invented to replace the given PFAS. For example, if the new substance has only been synthesized at lab-scale, then the upstream supplier may spend years on scale-up, to make the substance available at a commercial production scale. Ideally, an alternative could be identified which is already available commercially, but this cannot be ensured for PFAS, and all uses.

	- Suppliers Quality Management Systems (QMS) & Documentation to ensure traceability - System integration feasibility in Enterprise Resource Planning (ERP) system for data exchange
Define/Select potential alternative(s) material/supplier and frame project	- Select material or multiple alternatives by balancing risks on costs and timeline for testing - Establish project plan & test plan to define resources to introduce alternative material - Secure project funding & resources for material testing & implementation: - o Management buy in for decision (constraints depending on financial capabilities and availability of resources) - o Technical project lead - o Supplier (capability to provide sample for testing) - o R&D (evaluate risks for contamination and/or suitability of material used) - o Manufacturing for functional testing - o Regulatory for impact on global registrations - Initiate change control process and collect stakeholder inputs: - o Evaluate Regulatory constraints - o R&D ▪ Evaluate scope & documents required update due to material change (risk management) ▪ Define test lab ▪ Initiate risk assessment for new material Design Failure Mode and Effect Analysis (DFMEA)/ Process failure mode and effects analysis (PFMEA) - o Manufacturing ▪ Evaluate risks and establish conditions for functional testing to evaluate alternatives without impacting regular production (risk for contamination and other control measures required for test execution) - o Procurements & Software Quality Assurance (SQA) ▪ Setup new supplier
Test alternative(s)	- Produce parts for testing - Prepare test setup - Identify Quality lab and contract new lab if required (NDA where required) - Formal V&V process: Execute testing and evaluate manufacturing process capabilities

	- If required, return manufacturing condition to regular production after functional & V&V testing until test outcome (>3 month lead time if Biocomp and Packaging Tests are additionally required to simulate material stability and behavior on long term performance). - Biocompatibility tests including extractable and leachanle test
Select & Implement alternative	Execute Change Control Process - Approve alternative material - Approve and implement new supplier (agree on contract and condition) - Update technical documentation (drawing, DMFEA/PFMEA, technical summary files, IFU, labeling, material specification, etc.) - Update of manufacturing procedures & process (Design transfer), if needed update or source/setup production equipment - Update IFU & Labeling update or register new product - Regulatory product registration if required (510k, CE and others where required) - Initial sample testing - Market release (Customer training, Marketing campaign etc.) - Compliance assessment of new material and local requirements for substances

Annex 5: PFAS and Fluoropolymers Emissions Bibliography

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rest_pfas_annex_e_31106_en - Medicoindustrien.pdf;

Kære Jeppe,

Her kommer som aftalt en update omkring D4, D5 og D6, som er væsentlige i noget medicinsk udstyr, hvorfor det er vores vurdering, at et forbud vil have negative patientsikkerhedsmæssige konsekvenser. Ligeledes følger info omkring PFAS, som er et væsentligt opmærksomhedspunkt for os i øjeblikket.

D4, D5 og D6:

Kort om D4, D5 og D6:

- Inden for medicinsk teknologi bruges stofferne som silikoner i medicinsk udstyr, i IVD-tests samt i ar- og stomiprodukter.
- En fordel ved cyclosiloxaner er, at de er kemisk stabile og biokompatible, hvilket betyder, at de sandsynligvis ikke vil forårsage allergiske reaktioner eller medføre andre negative bivirkninger i kroppen.
- De er samtidig hydrofobe, hvilket betyder, at de ikke blander sig med vand og på den måde kan forhindre dannelse af biofilm.

Status omkring udfasning af D4, D5 og D6:

- Der er lagt op til, at begrænsningen skal gælde for fremstilling, markedsføring og brug af D4/D5/D6 på grund af deres PBT- og vPvB-egenskaber. Der er dog blevet foreslået en undtagelse for "Placing on the market of D5 and D6 for use as medical devices, as defined in Directive 93/42/EEC or in the Regulation (EU) 2017/745, for the (i) treatment/care of scars and wounds, (ii) prevention of wounds, and (iii) care of stoma." Har man ikke øje for disse undtagelser, vil det selvsagt kunne være problematisk i et patientsikkerhedsmæssigt perspektiv, ligesom det vil have en negativ effekt for producenter og leverandører af disse teknologier.

PFAS

Et andet – meget vigtigt - opmærksomhedspunkt er PFAS:

- Det er ikke nogen hemmelighed, at der er et stort fokus både nationalt og europæisk på udfasning af PFAS. Det kan få meget alvorlige konsekvenser for branchen, hvis ikke medicinsk udstyr undtages, da PFAS – ligesom i pharma – har stor betydning for produkternes funktionalitet og patientsikkerhed.
- I lovforslagets nuværende form er der tre mulige udfasningshorisonter for PFAS:
 - Den korte med 18 måneders overgangsperiode
 - Den mellemkorte med 12 år + 18 måneders overgangsperiode
 - Undtagelse fra udfasning
- Det er umiddelbart kun API'er (pharma), som er helt undtaget. Medicinsk udstyr opdeles i stedet efter udstyrskategori i den korte og mellemkorte udfasningshorisont (se tabel E.109 s. 327 i vedhæftede).
- Tilgangen, hvor der tages stilling til hver enkel udstyrskategori, er i vores øjne dybt uhensigtsmæssig, da listen for udstyr med mellemkort tidshorisont er ufuldkommen. Til trods for en høringsproces i samarbejde med vores kollegaer i MedTech Europe og deres netværk bliver vi løbende kontaktet af medlemmer, hvor deres udstyr ikke fremgår af listen for mellemkort sigt. Hvis lovforslaget stemmes igennem i sin nuværende form, har disse medlemmer kun 18 måneder til at udfase PFAS i udstyr og produktion, hvilket ikke vurderes til at være realistisk og derfor kan få dybt alvorlige konsekvenser for patienter og medicobranschen.
- Der er blandt vores medlemmer forståelse for, at industrien har et miljøansvar, herunder at bidrage til minimering af PFAS i naturen, men dette ansvar må ikke udvande patienthensynet. Ved en så simpel tilgang til PFAS-udfasning, som der lægges op til, risikerer udstyr at udgå af markedet inden for to år med de alvorlige konsekvenser til følge, som er skitseret ovenfor.
- I stedet mener vi, at man skal gå andre veje:
 - Alt medicinsk udstyr bør undtages – ligesom pharma - eller som minimum få mellemkort sigte ift. udfasning med undtagelse af enkelte specificerede udstyrskategorier.
 - I relation til ovenstående punkt skal det bemærkes, at det er vores vurdering, at en mellemkort frist er innovationshæmmende, da virksomheder kan være tilbageholdende med at bygge produktionsanlæg til eksisterende udstyr, såfremt PFAS indgår i udstyr og/eller i produktionen, og virksomhederne ikke

kender til PFAS-alternativer på nuværende tidspunkt.

- Grunden til, at branchen er afhængig af PFAS er, at stofferne har unikke kemiske egenskaber (herunder coating, ligesom det degenerer kun ved meget høje temperaturer), som er vanskelige at erstatte inden for få år – hvis overhovedet. Ifølge MDR skal substitutioner af materiale / stof i udstyr som minimum have tilsvarende (helst bedre for at det giver mening for virksomheden) risikoprofil, før en substitution i udstyret kan godkendes.
- Som du formentlig er orienteret om, er der i regi af Miljøstyrelsen nedsat en taskforce omkring PFAS: [Ekspertgruppen skal sætte retning for PFAS-indsats - Miljøstyrelsen \(mst.dk\)](#). Sammensætningen af denne task-force bestående udelukkende af forskere illustrerer meget godt, at fokuset rent politisk pt. ligger på det miljømæssige og knap så meget på det sundheds- og markedstilgængelighedsmæssige. Det bekymrer os.

Ser frem til at drøfte nærmere omkring ovenstående.

Med venlig hilsen,

Stellan Nørreskov Wulff

Chef for Politik og Kommunikation – Director of Public Affairs & Communications

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Denne mail er fra Medicoindustrien. Mailen og vedhæftede filer er fortrolige og kan indeholde juridiske informationer. Medicoindustrien kan ikke gøres ansvarlig for råd og vejledning.

Fra: Jeppe Kramer Jørgensen (EM-DEP) <[REDACTED]@em.dk>

Sendt: 22. august 2023 16:59

Til: Stellan Nørreskov Wulff <[REDACTED]@medicoindustrien.dk>

Emne: SV: Møde ml. EM/Medicoindustrien

Yes, sorry. D4, D5 og D6 ☺

Fra: Stellan Nørreskov Wulff <[REDACTED]@medicoindustrien.dk>

Sendt: 22. august 2023 16:56

Til: Jeppe Kramer Jørgensen (EM-DEP) <[REDACTED]@em.dk>

Emne: SV: Møde ml. EM/Medicoindustrien

Hej Jeppe,

Perfekt – vi ses d. 4. september ☺

Du hører fra os ang. REACH – det er D4, D5 og D6, right?

Mh.,
Stellan

Med venlig hilsen,

Stellan Nørreskov Wulff

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Sendt: 22. august 2023 16:53
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Kære Stellan

Ingen problemer. Vi kan desværre ikke kl. 9 - så lad os holde fast i kl. 10.

Vi kan tales ved, når det nærmer sig. Jeg hører som nævnt også meget gerne fra dig, hvis I skulle have bemærkninger til begrænsningen af D3, D4 og D5 i REACH-forordningen – tak.

Mvh.
Jeppe

Fra: Stellan Nørreskov Wulff <[REDACTED]@medicoindustrien.dk>
Sendt: 22. august 2023 16:32
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Kære Jeppe,

Beklager de interne uenigheder om tidspunkt. Vi holder fast i kl. 10-11 (medmindre I kan allerede kl. 9 eller 9:30) og kommer alle tre fysisk 😊

Mh.,
Stellan

Med venlig hilsen,

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Denne mail er fra Medicoindustrien. Mailen og vedhæftede filer er fortrolige og kan indeholde juridiske informationer. Medicoindustrien kan ikke gøres ansvarlig for råd og vejledning.

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Hej Stellan

Vil I vende internt, om mødet skal rykkes, eller om vi skal tage det over Teams eller uden Peter? 😊

Mvh.
Jeppe

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Hej Jeppe

Denne mandag er ikke god, da vi har bestyrelsesmøde, hvor jeg gerne skulle være lidt forberedt. Et TEAMS-møde er muligt, da vi kan spare transporten og dermed få tingene til at hænge sammen.

Mange hilsner,
Peter



Annex to the ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): Per- and polyfluoroalkyl substances (PFASs)

IUPAC NAME(S): n.a.

EC NUMBER(S): n.a.

CAS NUMBER(S): n.a.

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	E.2.3.5./E.2.8.5./E.2.9.5./E.2.10.5./E.2.11.5./E.2.12.5./E.2.14.5. – integration of conclusions from E.2.3.3. in summary table	
	E.2.9.1. – minor text changes and recalculation of projected yearly use	
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	E.4.1.4.6. – addition of paragraph on a planned project describing regulatory needs	
	Addition of Appendix E.2. - Overview on information available on alternatives	

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Annex E Impact Assessment

E.1. Risk Management Options

For details on risk management options, see section 2.2. of the main report.

E.2. Impact Assessment for specific uses

E.2.1. PFAS manufacturing

E.2.1.1. Baseline

For all PFASs, there is an expectation of market growth in the absence of regulatory action leading to an overall increase in EU- production or import, or both, of PFAS as a substance or in articles.

No specific data is available for production growth of PFAA and PFAA precursors produced in the EU-27 although there is an expectation of global growth in demand from downstream uses related to the textile industry, one of the most extensive users of non-polymeric PFASs. As default a steady growth of 2%/y is taken by the Dossier Submitters in absence of other information.

For fluorinated gases the picture is mixed. The market is increasing, and growing volumes of fluorinated gases are needed, however the EU-28 production of HFCs has decreased while HFO import increased (EEA, 2021). The alternative to HFCs, i.e. HFOs, are mainly produced in Asia and the United States of America and imported into Europe (Booten et al., 2020; Seidel and Ye, 2016). The Dossier Submitters are not aware of a production location of HFOs in the EU-27. Therefore, the annual growth of the EU-28 production during the last 10 years has been calculated based on reported tonnages by the EEA. These figures show an annual decline of 10% in the production of HFCs. This trend is taken by the Dossier Submitters as representative (negative) annual growth figure due to the regulatory phase down of HFC use.

For polymeric PFAS, only for fluoropolymers detailed information is available. In 2022 PTFE is the most applied fluoropolymer but PVDF and FEP will have a growing market share. For FEP this is largely because of the growing electronics market (FEP is used extensively in cables like LAN cables) as well as solar cell and fiber optic applications. PVDF is expected to grow enormously due to its increasing applications in lithium-ion batteries (i.e. used in electrified transport) and architectural coatings.

Expected EEA fluoropolymer consumption growth is for a large part driven by initiatives such as the Green Deal. Applications driving the anticipated growth include hydrogen fuel cells, coatings for photovoltaic and wind power, REDOX (reduction-oxidation) flow batteries and lithium-ion batteries, and water electrolysis for the hydrogen economy. For some of the uses non PFAS substances are available. A substantial growth in the fluoropolymer films market in Europe is anticipated due to the growing transportation sector across the region. Fluoropolymer films have a wide range of applications in construction, transportation, industrial processing, food and pharmaceuticals, packaging, and others.

The global leading producer of fluoroplastics, AGC chemicals¹, estimated a global annual increase of fluoroplastic consumption of 4-4.5% until 2023. More recent data suggest a global growth rate of 5.6% for PTFE alone between 2020 –2027 (InvestSaudi, 2021). The Dossier Submitters take a yearly growth rate of 5% as representative for the polymeric PFAS

¹ <https://www.agcce.com/fluoroplastics/>, date of access: 2023-01-11.

production in the EU-27.

E.2.1.2. Alternatives

In general, the manufacturing/production of PFAS has the sole purpose to produce PFASs, therefore analyses of alternatives for PFASs manufacture as such has no meaning. The availability, hazards and feasibility of PFAS-free alternatives to PFAS substances in many downstream applications and products is assessed for each of the sectors affected.

E.2.1.2.1. Polymerisation aids in manufacture of fluoropolymers

During the manufacturing of about 40-50% of all fluoropolymers other non-polymeric PFASs (such as PFOA, PFNA, PFHxA, 6:2 FTSA) are used as polymerisation aid to produce fluoropolymers (see also A.2.1.4.1.). In the section below we assess the state of play as regards the introduction of alternative non-PFAS polymerisation aids in fluoropolymer manufacture.

Technical feasibility

For decades, the ammonium salts of perfluorooctanoic acid (PFOA) and perfluorooctylsulfonic acid (PFOS) have been used in aqueous emulsion polymerization to produce fluoropolymers. With the recognition of the environmental and health concerns associated with long chain functional perfluoroalkyls, fluoropolymer manufacturers began the development of alternative emulsifiers and different polymerization techniques. The challenge was to ensure that fluoropolymers could still be safely manufactured while minimizing emulsifier emissions and use.

Currently, industry is in transition to use non-PFAS polymerisation aids, at least for the manufacturing of PTFE, PVDF and FKM. It is not clear whether all PTFE, PVDF and FKM can already be produced without PFAS polymerisation aids at industry level however four major PFAS producers announced they can produce their fluoropolymers PTFE and PVDF without PFAS polymerisation aids (see Annex A.2.1.).

Other types of fluoropolymers still require the use of fluorinated polymerisation aids for their manufacture. According to industry (Drohmann et al., 2021), fluorinated polymerisation aids are used to achieve ultra-high molecular weights which are needed to obtain the desired properties for the critical sectors of chemical industry, aerospace, automotive, medical devices, pharmacological applications, semiconductors, etc. Currently it is not possible to remove fluorinated polymerisation aids from these manufacturing processes that account for about 17% of the global production of fluoropolymers (Sales et al., 2022).

In the 2nd stakeholder consultation, it was stated that fluoropolymer resin manufacturing industry is working to develop non-fluorinated polymerisation aids as an alternative to fluorinated polymerisation aids, wherever possible. Different manufacturers are likely to be at different stages of development with various fluoropolymers and their respective grades. Their work on alternatives was based on information in recent patent applications. When commercialised, this will significantly further increase the percentage of fluoropolymers made without the use of fluorinated polymerisation technology. While it is difficult to anticipate a date when 100% of the fluoropolymer production will be possible without the use of fluorinated polymerisation aids, key industrial players expect that within 10 years (i.e. before 2032) they will be at or very close to that objective (Sales et al., 2022).

Human health and environmental hazards

For the non-PFAS alternative polymerisation aids relevant for fluoropolymer manufacture, information on classification, the octanol/water partition coefficient (Log K_{ow}) and bioconcentration factor (BCF) were assessed. Additionally, it was assessed whether the

alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHAs dissemination site.

In relation to the non-PFAS alternative polymerisation aids relevant for fluoropolymer manufacture, the list of alternatives contained 10 identified alternative substances or group of substances to long chain PFAS as processing aids. The data is however not sufficient for further evaluation. For one group of substances named “siloxane and silicone polymers”, it is indicated that it may contain residues of D4, D5 and D6 cyclic siloxanes. D4, D5 and D6 cyclic siloxanes are known PBT/vPvB substances and in addition D4 is considered an endocrine disruptor. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.1.3. Overall, the human and environmental hazards of alternatives to long chain PFASs polymerization aids are unknown. Environmental impacts

Production of fluorinated production aids itself can lead to emissions of many poly- and perfluorinated by-products, both highly volatile and water soluble (Hopkins et al., 2018). Secondly, the fluorinated polymers, such as PTFE, are themselves processed at high temperatures of 340–400 °C, using up to 0.5% w/w of perfluoro- and polyfluoro-emulsifiers and dispersing agents including ADONA, HPFO-DA and other PFOA replacements (Table A.6) (Gomis et al., 2015).

E.2.1.4. Economic and other impacts of RO1

The following section describes the economic and other impacts of RO1: Full restriction of production of all PFAS with entry into force after a transitional period of 18 months.

E.2.1.4.1. Economic impacts: Producer surplus losses

Loss of turnover of suppliers that are unable to import PFAS into the EEA due to the proposed restriction has not been estimated as it is expected that almost all of the relevant profits are incurred by companies located outside the EEA.

The number of main production sites of PFAS in the EU is estimated to be around 20 (A.2.1.3.1.) mainly producing PFAS monomer and polymer. There is a limited production of fluorinated gases for refrigerant use in the EU. Estimated annual production volumes for the EEA are presented in Annex A.2. Polymeric PFAS contain both fluoropolymers and perfluoropolyethers; however only for fluoropolymers detailed information is available.

A rough estimate of the sales value can be made by multiplying the produced volume of PFAS by the average market price. Market prices are highly dependent on the type of PFAS, the customer and level of competition. Therefore, only a rough indication can be provided by the Dossier Submitters as these details are not known.

A wide variety of prices per tonne of PFAAs and PFAA precursors has been reported by stakeholders during the Call for Evidence varying from €10 000 and €90 000 to several million euros for specialised applications. Due to the absence of any other reliable estimates, the midpoint of the €10 000 and €90 000 interval (i.e., €50 000) is taken by the Dossier Submitters as representative price per tonne. The price for PFAAs and PFAA precursors are used as a proxy for all non-polymeric PFAS and non-fluorinated gasses. Regarding the price of fluorinated gases, the price monitoring for HFC refrigerants and their alternatives carried by Kleinschmidt (2020), the average price of HFC blends (R404A; R410A; R407C and R134a) in Q3/2019 was between €18 000 and €40 500 per tonne. It is unknown to the Dossier Submitters which HFCs are produced in the EEA and some of the fluorinated gases in the abovementioned blends do not fall into the scope of the proposed restriction. However, in

absence of any other information, the midpoint of the €18 000 and €40 500 interval (i.e., €29 250) is taken by the Dossier Submitters as representative price per tonne HFC.

Prices for polymeric PFAS are based on information for fluoropolymers and vary widely. Ranges from €8 000 to five million euros have been reported by stakeholders in the CfE. However, some of the higher prices reported by companies most likely referred to the price of a product (article) manufactured using fluoropolymers. PlasticsEurope reports an overall price per tonne fluoropolymer produced in the EU28 of €21 000 for 2020 and is taken by the Dossier Submitters as representative price per tonne (Wood, 2022).

An indication of the profit margin for the fluoropolymers can be derived from public information. An EBITDA margin of 21% is reported for the sale of fluor products in a presentation by Chemours and similar figures were reported during the CfE by other companies (Chemours, 2020). In absence of other information, the Dossier Submitters take this profit margin as representative for all PFAS groups.

Table E.1 shows the estimated profit in the production of PFAS per PFAS group.

Table E.1. Annual production volume and associated profits in the EU. Numbers are in two significant figures and based on 2020 prices and volumes.

PFAS group	Production volume in EU (t/y)	Average market price (€/t)	Assumed profit margin (%)	Estimated profit (million €/y)
PFAA and PFAA precursors	86 000	50 000	21	900
Fluorinated gases	96 000	29 000	21	580
Polymeric PFAS	75 000	21 000	21	330

Source: Own calculations based on data collated by the Dossier Submitters.

In case of a full ban the Dossier Submitters expect most production facilities in the EU-27 to stop operating after entry into force of the proposed restriction. Some facilities might be able to continue at a reduced production capacity to produce PFAS for those uses that are derogated under RO1 (see A.3.17.). Continuation of EU manufacture under RO1 depends on the specifics of the required PFAS for derogated uses and the state of competitiveness of these EU production facilities compared to non-EU competitors. The total tonnage of PFAS used as active substance is estimated at ~6 000 t/y. It is not known to the Dossier Submitters to what degree PFAS substances are used as active ingredient in the derogated biocidal, plant protection and medicinal product uses are produced in the EU-27 or imported. Therefore, the closure of all production facilities in the EU-27 is taken by the Dossier Submitters to estimate an upper boundary of the potential producer surplus losses.

The total net present value (NPV) of the producer surplus losses is estimated in Table E.2 using a 3% discount rate, as proposed in the most recent version of the 'Better Regulation Guidelines and Toolbox' published by the European Commission for market goods (EC, 2021a; EC, 2021b). The NPV values (see Table E.2) are for 2020 and the analysed time period starts in the anticipated year of implementation of the proposed restriction (2025).

Table E.2. NPV (in 2020) of producer surplus losses of PFAS producers for different time periods after the anticipated implementation of the proposed restriction in 2025. A discount rate of 3% and PFAS group specific yearly growth rates are applied. Numbers are in two significant figures and based on 2020 prices and volumes.

PFAS group	NPV of producer surplus losses in million euros	
	30 years	50 years
PFAA and PFAA precursors	21 000	33 000
Fluorinated gases (HFCs only)	1 800	1 800
Polymeric PFAS	15 000	30 000
Total	38 000	65 000

Source: Own calculations based on data collated by the Dossier Submitters.

The Dossier Submitters have no reliable information to determine the value of the production facilities after closure. However, some of the losses from the premature retirement of assets are expected to be recouped through either resale of equipment or as scrap value. No information is available to estimate the magnitude of this recouperation, however the Dossier Submitters expect this magnitude to be insignificant compared to the producer surplus losses.

In addition to producer surplus losses in the manufacturing of PFAS, producer surplus losses can also occur in the supply chain supplying raw materials to PFAS manufacturers. Closure of all PFAS production facilities in the EU-27, which is taken by the Dossier Submitters to estimate an upper boundary of the potential producer surplus losses in PFAS manufacturing, is likely to affect raw material suppliers. The main feedstock for overall PFAS production is hydrofluoric acid (HF) together with chloroform used in the production of fluoropolymers. The main application of HF is in the production of fluorocarbons and almost 70% of the HF is used for fluorinated organic substances (see Annex A.2.1). In 2015, European HF production reached 232 000 t with a value estimated around 270 million EUR². Chloroform is mainly used as an industrial intermediate to manufacture fluoropolymers but it also has other uses as an industrial extraction solvent or laboratory agent³. Chloroform is registered under REACH with a total yearly volume (production and/or import) between ≥100 000 to <1 000 000 t by 14 active registrants in a joint registration. The EU Risk Assessment Report on chloroform indicates 84% of chloroform produced in Europe is used as feedstock in Europe to produce HCFC-22 (out of scope) and reports an estimated production volume of 302 800 t for 2002 in the European Community (EURAR, 2007). This HCFC-22 is subsequently used as feedstock in the production of fluoropolymers (now) or as refrigerant (R-22) and foam blowing agent (in the past). Production for the latter uses has been phased out. The share of HCFC-22 used for fluoropolymer production at the time of reporting the total production volume is estimated at around 50% based on Booten et al. (2020). This would indicate that about 42% of the chloroform produced in Europe would serve as feedstock in the production of fluoropolymers.

An indication of current market prices for HF and chloroform is taken from www.chemanalyst.com. As of June 2022, the European reported price per tonne for HF is \$2298 (~€2 300) and \$827 (€830) for chloroform.

An accurate estimate of producer surplus losses in the raw material supply chain cannot be made by the Dossier Submitters as the anticipated response by the EU producers of HF and chloroform (e.g. export; alternative EU market; closures or operating at reduced capacity) is not known. However, it is likely producer surplus losses will occur in the raw material supply chain as HF and chloroform are predominantly used for PFAS manufacturing.

As an indication of the magnitude of potential producer surplus losses in the raw material

² <https://www.eurofluor.org/what-is-hf/>, date of access: 2023-01-11.

³ <https://www.chlorinated-solvents.eu/products/chloroform-cfm/>, date of access: 2023-01-11.

supply chain the Dossier Submitters calculate the upper boundary of producer surplus losses after 30 and 50 years after implementation of the proposed restriction. As conservative approach the Dossier Submitters assume no alternative sales markets are available for the HF and chloroform volumes used in the PFAS manufacturing after closure of the PFAS manufacturing locations. Reported EU production volumes for HF and chloroform are extrapolated to 2022 volumes using a steady 2% annual growth. In absence of other information, the same profit margin is applied as for PFAS manufacturing (Table E.3).

Table E.3. Annual production volume and associated profits in the EU of the raw material supply chain. Numbers are in two significant figures and based on 2022 prices and estimated volumes.

Raw material	Production volume in EU(t/y)	% used for PFAS manufacturing	Average market price (€/t)	Assumed profit margin (%)	Estimated profit (million €/y)
HF	270 000	70	2 300	21	90
Chloroform	450 000	42	830	21	33

The estimated producer surplus losses are the upper boundary of expected costs due to the proposed restriction (Table E.4). Downstream users of the produced PFAS will to some extent switch to other chemical substances as alternative to PFAS. Therefore, some of the expected profit losses are offset by other actors, i.e. the producers of alternative chemical substances. The magnitude of the losses that can potentially be offset is dependent on whether the alternative chemical substances are produced in the EU and the associated profit margins.

Table E.4. NPV (in 2022) of producer surplus losses of the raw material supply chain for PFAS producers for different time periods after the anticipated implementation of proposed restriction in 2025. A discount rate of 3% and a generic 2% growth rate are applied. Numbers are in two significant figures and based on 2022 prices and volumes.

Raw material	NPV of producer surplus losses in million euros	
	30 years	50 years
HF	2 200	3 400
Chloroform	800	1 200
Total	3 000	4 600

E.2.1.4.2. Economic impacts on customers

Distributors and formulators of PFAS, e.g. drying, powder generation, mixing and/or bulking of PFAS substances, could incur producer surplus losses. The Dossier Submitters have no information on, e.g. number of sites in Europe, profit margin and/or volumes, to estimate potential producer surplus losses. Producer surplus losses of distributors and formulators may already be accounted for in the producer surplus estimation for PFAS manufacturers if formulation and distribution costs would be included in the reported average market prices (see Table E.1).

Economic impacts on the different sectors that use PFAS are described in the different use-specific sections below in Annex E.

E.2.1.4.3. Other impact on society

As a result of RO1, the Dossier Submitters anticipate closure of all the PFAS production facilities in the EU-27. This will most likely result in job losses and therefore costs to society. Direct employment in the production of 49 000 t/y fluoropolymers is estimated at 4 500 full-time jobs across the EU-28 (Wood, 2022). No data on the number of direct employees in the production of fluorinated gases or PFAA and PFAA precursors is available. In absence of

reliable data, the Dossier Submitters assume direct employment is linearly correlated with the production tonnages. In addition, the same output per worker is assumed in all PFAS manufacturing. This would imply a direct employment in the production of polymeric PFAS of 6 900 employees, for fluorinated gases 8 800 employees and for PFAA and PFAA precursors of 7 900 employees.

In addition to job losses due to closure of the PFAS production locations, job losses are likely in the raw materials supply chain if no alternative sales markets are available for HF and chloroform volumes used in the PFAS manufacturing. In the production of HF gas around 300 people are directly employed at nine HF production sites in four European countries². The number of people directly employed in the production of chloroform in Europe is unknown to the Dossier Submitters. In absence of reliable data, the Dossier Submitters assume the direct employment is linearly correlated with the production tonnages of both HF and chloroform. In addition, the same output per worker is assumed in HF and chloroform. This would imply a direct employment in the production of chloroform of 510 employees. In a simplified approach, the Dossier Submitters only assume job losses for the share of HF and chloroform tonnage used for PFAS manufacturing are relevant. Therefore, the number of people directly employed in the production HF and chloroform used in PFAS production is estimated at 210 for both sectors (Table E.5).

Table E.5. Overview of estimation of job loss based on direct employment in the manufacture of PFAS and in the raw material supply chain. Numbers are in two significant figures.

Category	Number of direct jobs
PFAA and PFAA precursors	7 900
Fluorinated gases (HFCs only)	8 800
Polymeric PFAS	6 900
HF production for PFAS manufacture	210
Chloroform production for PFAS manufacture	210
Total	24 000

The monetisation of the social costs due of unemployment follows the approach set out by ECHA 2016 (Dubourg, 2016). In this approach the loss of unemployment is estimated considering the following impacts:

- The value of output/wages lost during the period of unemployment
- The costs of job search, hiring and firing employees
- The scarring effect, i.e. the impact of being made unemployed of future employment and earnings
- The value of leisure time during the period of unemployment.

The discounted net present value (in 2014) of the social costs of losing one job in the EU-28 was estimated at €87 000, equal to 2.7 times the average annual gross wage. This ratio varies across different member states, mainly driven by the country specific average duration of unemployment. Production locations of PFAS and of the raw material supply chain are distributed across Europe, supporting the use of an EU-average ratio. The average duration of unemployment decreased from 18 to 16 months since the approach was published by ECHA. The Dossier Submitters consider this change in unemployment duration not substantial enough to redo ECHA's assessment and takes the ratio of 2.7 as representative for the calculation of the societal costs of unemployment.

The EU-27 average annual gross wage for the manufacturing of chemicals is estimated at ~ €47 000 in 2019/2020 prices based on Eurostat sector data (CfE). The NPV in 2020 of the social costs of losing one job in the manufacturing of chemicals sector is estimated at €130 000 by multiplying the average annual gross wage by 2.7. The Dossier Submitters expect the proposed restriction to be implemented in 2025 with an entry into force in 2027. Therefore, the expected job losses do not take place before 2027. A discount rate of 3% yields a total NPV (2020) for expected societal costs due to job losses of the proposed restriction of

€2.3 billion (see Table E.6).

Table E.6. Estimated social costs of unemployment in NPV (2020).

Category	Number of direct jobs lost	Social costs of unemployment in the chemical manufacture sector (euro)	Discount factor	NPV (2020 in million euro)
PFAA and PFAA precursors	7 900	130 000	0.81	810
Fluorinated gases (HFCs only)	8 800			910
Polymeric PFAS	6 900			710
HF production for PFAS manufacture	210			22
Chloroform production for PFAS manufacture	210			22
Total	24 000			2 500

E.2.1.5. Economic and other impacts of RO2

The following section describes the economic and other impacts of RO2: Proposed restriction of all production of PFAS, except for sector- and use-specific derogations with entry into force of 18 months. The proposed use-specific derogations are mainly time-limited to five or 12 years and are described in the main dossier .

E.2.1.5.1. Economic impacts: Producer surplus losses

In RO2, the proposed derogations allow the time-limited manufacture and placing on the market of PFAS for the specific uses described in the derogations. The Dossier Submitters have limited information on the volumes of PFAS used in the proposed derogations. In addition, it is unknown if the specific PFAS used in the derogations are manufactured in Europe or are imported. Some European facilities might be able to continue at a reduced production capacity depending on the specifics of the required PFAS and the competitiveness of the production facility compared to import. As this information is not available to the Dossier Submitters, no reliable estimate of producer surplus losses can be produced for RO2.

The upper bound of the producer surplus losses for RO2 assumes EU-production locations of PFAS are not capable to produce only PFAS for those uses proposed to be temporarily derogated from the restriction at competitive margins compared to import. This upper bound has the same producer surplus losses as estimated for RO1. Depending on the volumes; derogation duration and specifics of PFAS used in the proposed derogations the producer surplus losses for RO2 could be lower. However, the expected reduction in producer surplus losses is limited. As example, in case 50% of the PFAS production in Europe could continue for supply to derogated uses only, the estimated NPV of the total producer losses in RO2 would be ~€3 500 to €8 000 million lower for PFAS producers and ~€290 to €670 million lower in the raw material supply chain. This example does not account for lower profit margins that are likely when production volumes are lowered significantly.

E.2.1.5.2. Economic impacts on customers

In RO2, distributors and formulators of PFAS, e.g. drying, powder generation, mixing and/or bulking of PFAS substances, would be allowed to process PFAS for the specific uses and durations described in the derogations. The expected reduction in costs for distributors and formulators under RO2 compared to RO1 is limited for the same reasons as mentioned in the section above.

As with producer surplus losses for PFAS manufacturing, the expected reduction of producer

surplus losses in RO2 compared to RO1 for distributors and formulators limited.

E.2.1.5.3. Other impact on society

As indicated above, some European facilities might be able to continue at a reduced production capacity depending on the specifics of the required PFAS and the competitiveness of the production facility compared to import. As this information is not available to the Dossier Submitters, no reliable estimate of job losses, and the social cost of unemployment can be produced for RO2.

The upper bound of the social cost of unemployment for RO2 assumes EU-production locations of PFAS are not capable to produce only PFAS for the use in the proposed derogations at competitive margins compared to import. This upper bound has the same social cost of unemployment as estimated for RO1. Depending on the volumes; derogation duration and specifics of PFAS used in the proposed derogations the social cost of unemployment for RO2 could be lower. However, the expected reduction in social cost of unemployment is limited. As example, in case 50% of the PFAS production in Europe could continue for supply to derogated uses only, the estimated NPV of the total social cost of unemployment in RO2 would be ~€170 to €370 million lower.

E.2.1.6. Summary of cost and benefit assessment

Table E.7 summarises the outcomes of the assessment of costs and benefits for the manufacturing of PFAS. More detailed information can be found in the accompanying text following the table.

Table E.7. PFAS manufacturing - Summary table on assessment of costs and benefits , based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
RO1; Full restriction of all production of PFAS	Not applicable	Analyses of alternatives for PFAS is performed at the level of use in the various sectors. Use of PFAS as polymerisation aids in manufacture of fluoropolymers: Sufficiently strong evidence that technically and economically feasible alternatives exist for non-polymeric PFAS as polymerisation aids in the production of PTFE, PVDF and FKM. Sufficiently strong evidence that technically and economically feasible alternatives for non-polymeric PFAS as polymerisation aids in the production of all other types of polymeric PFAS will become available within 10 years.	Evidence for an evaluation of expected emissions is lacking.	High producer surplus losses (order of magnitude: ~42 bn EURO 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 chain [sufficiently strong evidence]. High employment losses (order of magnitude: ~€2.5 bn NPV) as a result of high share of business closures [sufficiently strong evidence].	
RO2; Restriction of all production of PFAS with use-specific derogations: derogation for the use of polymerisation aids in the production of polymeric PFAS (except for PTFE, PVDF and FKM)	5 years	Sufficiently strong evidence that technically and economically feasible alternatives for non-polymeric PFAS as polymerisation aids in the production of all other types of polymeric PFAS will become available within 10 years from 2022.	Evidence for an evaluation of expected emissions is lacking.	No information is available to quantify a difference in the producer surplus losses between RO1 and RO2. Weak evidence available that producer surplus losses from business closures are reduced compared to RO1	n/a
	12 years		Evidence for an evaluation of expected emissions is lacking.		n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Conclusion	If a restriction of all production of PFAS with use-specific derogations is considered, a restriction of the use of PFAS as polymerisation aid in the manufacturing of PTFE, PVDF and FKM is proposed. For the use of PFAS as polymerisation aid in the manufacturing of all other fluoropolymers, a restriction with a five year derogation after the transition period is proposed.				

The **assessment of alternatives** in relation to PFAS manufacturing **for a full restriction with a transition period of 18 months** is based on expert judgement, evidence from the CfE and 2nd stakeholder consultation supplemented with literature with regards to use of non-PFAS polymerisation aids.

The evidence is sufficiently strong that technically and economically feasible alternatives for PFAS production are unavailable for the quantities required and that the substitution potential is low under RO1 and RO2. This is since PFAS manufacturing has the sole purpose to produce PFAS substances.

The evidence is sufficiently strong that technically and economically feasible alternatives for non-polymeric PFAS as polymerisation aids are available for the quantities required in the production of PTFE, FKM and PVDF and that the substitution potential is high under RO2. This is since four major PFAS producers have recently indicated to substitute to non-PFAS polymerisation aids.

The evidence is sufficiently strong that technically and economically feasible alternatives for non-polymeric PFAS as polymerisation aids are currently not available for the quantities required in the production all types of fluoropolymers but will become available within 10 years from 2022. The substitution potential is high under RO2. This is since industry indicated that some types of fluoropolymers still require the use of fluorinated polymerisation aids while at the same time there is a trend towards developing non-fluorinated polymerisation aids with key industrial players expect that this transition within 10 years.

The **assessment of benefits** in relation to PFAS manufacturing **for a full restriction with a transition period of 18 months** is based on expert judgement, evidence from Annex A on manufacture, import and export, market growth projections.

The **assessment of costs** in relation to PFAS manufacturing **for a full restriction with a transition period of 18 months** is based on expert judgement, evidence from Annex A on manufacture, import and export, market growth projections and:

- Literature and public databases, e.g. production volumes; direct employment and sales prices of HF and Chloroform
- Principles relating to social costs of unemployment;
- The CfE, e.g direct employment, sales prices of fluorinated gases and fluoropolymers and profit margins;

For PFAS manufacturing the Dossier Submitters assessed (i) producer surplus losses resulting from company closures, as well as producer surplus losses in the supply chain and (ii) employment losses.

Producer surplus losses for PFAS manufacturing are determined based on an assessment of (i) the most likely reaction of affected companies, (ii) the production volumes of the different PFAS groups, (iii) the average market prices and profit margins of the different PFAS groups and (iv) the projected production growth rates for the different PFAS groups.

Producer surplus losses in the raw material supply chain are determined based on an assessment of (i) the production volumes of raw material used for PFAS manufacturing, (ii) the average market prices and profit margins of the raw materials and (iii) the projected production growth rates for the raw materials.

The Dossier Submitters consider that the evidence is sufficiently strong that the socio-economic costs to industry in the form of producer surplus losses from business closures are high under a full restriction (RO1). This is based on the assessment of alternatives pointing towards a high share of company closures, high producer surplus losses due to high margins, no information on the offset potential and high impacts on the wider supply chain.

The Dossier Submitters consider that the evidence is weak that the socio-economic costs to industry in the form of producer surplus losses from business closures are reduced under a full restriction with derogations (RO2).

The Dossier Submitters consider that the evidence is weak to exactly quantify the socio-economic costs to industry in RO1 due limited information and subsequent assumptions in production volumes, sales values and profit margins of the different PFAS groups. In addition, there is no information on the offset potential. The quantified socio-economic costs are an indication of the order of magnitude.

The Dossier Submitters consider that no suitable evidence is available to quantify a difference in the socio-economic costs to industry between RO1 and RO2 due lack of information on production volumes and profit margins for PFAS produced under RO2.

Employment losses for PFAS manufacturing and in the wider supply chain are determined based on an assessment of (i) number of direct jobs involved, (ii) the average gross wage and (iii) the ratio between the annual gross wage and the social cost of losing a job.

The Dossier Submitters consider based on the assessment of alternatives pointing towards a high share of business closures that the evidence is sufficiently strong that the socio-economic costs to society in the form of employment losses are high under a full restriction (RO1).

The Dossier Submitters consider that the evidence is weak that the socio-economic costs to society in the form of employment losses are reduced under a full restriction with derogations (RO2).

The Dossier Submitters consider that the evidence is weak to exactly quantify the socio-economic costs to society in RO1 due limited information and subsequent assumptions in direct job losses. The quantified socio-economic costs are an indication of the order of magnitude.

The Dossier Submitters consider that no suitable evidence is available to quantify a difference in the socio-economic costs to society between RO1 and RO2 due lack of information on production volumes under RO2 and associated jobs losses.

E.2.2. TULAC (Textiles, Upholstery, Leather, Apparel and Carpets)**E.2.2.1. Baseline**

The assessment of the time path of PFAS use (tonnage) and emissions under the baseline scenario considers expected growth rates for different PFAS groups as shown in Table E.8.

Table E.8. Assumptions for projecting tonnage volumes and emissions.

PFAS groups	Assumption (2020 – 2070)
Non-polymeric C2 - C3 substances	Under the baseline scenario, it is assumed that usage in all sectors grows at the standard steady 2% rate year on year. The physical properties and water/oil repellence of ultrashort-chain substances is likely to differ from longer ($\geq$ C5) chains based on industry responses, with a loss in oil repellence in particular. Therefore, it is assumed that the growth rates for C5 and above will be different to C2-C3 on the basis that the specific application is different, i.e., C2-C3 is unlikely to act as a true substitute for C5/C6 chemistries.
Non-polymeric C4 substances	Under the baseline scenario, it is assumed that use in technical textiles continues to grow at 2% annually in lieu of any market data. Based on the CfE, it is assumed that use in home textiles and consumer apparel remains broadly static. The stakeholder ⁴ interviews suggest that there may be more demand in home textiles than consumer apparel, which has now moved strongly towards fluoropolymers. Therefore, a 1% increase annually for home textiles and a 1% decline annually for consumer apparel, applied year on year from 2021 – 2050, is assumed.
Non-polymeric C5 substances	It is assumed that these substances follow the same trend as C4 chemistry.
Non-polymeric C6 substances	The CfE suggested that there was a strong market preference for C6 as the natural replacement for C8 due to its water and oil repellence capabilities. Where there are ongoing REACH restrictions on longer chain PFASs (C9 – C14), it could be expected that C6 would remain dominant. A steady 2% annual growth year on year from 2021 – 2050 is assumed for the baseline scenario.
Non-polymeric C9-C14 substances	In August 2021, a group restriction was included as Entry #68 in Annex XVII, REACH on perfluorinated carboxyl acids (C9-C14 PFCAs; see Regulation (EU) 2021/1297) and those substances that may degrade to them. This means that they are restricted from 25 February 2023 and from 4 July 2023 for the use in certain textiles.
Other non-polymeric substances	The “Other non-polymeric PFAS” category primarily includes longer chain PFASs $\geq$ C14, aromatic compounds and salts of reactions. This includes the use of some PFAS groups as process aids for the manufacture of non-fluorine-based textile polymers. In lieu of any additional supporting information, it is assumed that

⁴ TEGEVA, AGC, Daikin.

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PFAS groups	Assumption (2020 – 2070)
	there is a steady growth of 2% annually across all applications.
Fluoropolymers (all substances)	The fluoropolymer market is expected to grow very strongly in the short to medium term, but it is unclear how sustainable that is in the longer term. Therefore, for home textiles, consumer apparel, professional apparel and technical textiles 8% growth annually between 2020 and 2025 is assumed (based on market reports), thereafter it falls to 5% growth annually between 2026 and 2030. For medical textiles and other textiles 5% growth annually between 2020 and 2030 is assumed, where these applications may cover more niche markets. It is assumed that strong growth is unsustainable in the longer term with use across all sectors falling to a steady 2% continued growth between 2030 and 2040, and then 1% growth from 2040 to 2050, assuming market saturation may be reached at a future point.
Side-chain fluorinated polymers	Due to the growing awareness and concerns around side-chain fluorinated polymers as a source of non-polymeric PFAS emissions, it is assumed that growth becomes static in the consumer apparel market. For professional apparel and other textiles a steady growth of 2% annually is assumed.

Emission estimates are derived from use (tonnage) data by developing a basic source-flow model in order to make use of the data from the market analysis and substance identification. One key caveat of this approach is that on a more general level a very large number of PFAS substances have been identified as being in use or potentially in use (around 120 unique substances). Additionally, many of these unique substances appear in mixtures as combinations of substances, and furthermore in some mixtures it may be the case that specific substances are present as an impurity, rather than an intentional use (note that the data from stakeholders under the CfE does not always make clear what are impurities and what are intentional uses). The quality of market data also varies significantly from substance to substance. Therefore, the approach taken has not tried to develop estimates on a substance-by-substance basis but adopted a grouping approach (see Annex B.9.2.1 for further details). Where availability of data varies significantly on a substance-by-substance basis a key benefit of using grouping approaches is that impacts of varying specific data are lessened. Still, it means the estimates provided will have a higher uncertainty attached to them overall. However, this approach can still provide useful data to estimate the orders of magnitude for emissions when comparing PFAS groups and different sectors. For ease of presentation the PFAS groups were further aggregated into three main categories, i.e. short-chain non-polymeric PFAS, long-chain non-polymeric PFAS, and fluoropolymers, respectively.

Emission estimates presented in this section cover emissions during the use and production phase. The TULAC use phase covers a very wide set of applications with the specific emissions varying on an application-by-application basis. Broadly the current approach identified the following major application types:

- Home textiles
- Consumer apparel
- Professional apparel (including PPE)
- Technical textiles

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- Leather
- Other textile/textile-related applications.

To align continuity with an earlier study conducted by the European Commission in 2020 (Wood, 2020b), a holistic approach to how emissions may occur across all these application types, based on setting (indoor/outdoor use) and frequency of cleaning (including laundry)/wetting, was used. Furthermore, the ECHA R.16 Environmental exposure assessment guidance (ECHA, 2016), including Environmental Release Category (ERC) default emission factors to guide estimates, was used to derive emission estimates (see Annex B for further details).

The start year of the projection of tonnage and emission estimates is 2020 as presented in Table E.9 and Table E.10. Based on the assumptions set out in Table E.8 above, PFAS use and emissions in the TULAC sector are expected to grow under the baseline scenario. Moreover, by 2050 PFAS use and emissions will have broadly doubled. It should be noted that this is largely driven by continued demand for fluoropolymers in the TULAC sector.

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Table E.9. Projected yearly PFAS use in the TULAC sector of the EEA between 2020 and 2070 in tonnes (mean values based on market data).

PFAS substance group	2020	2025	2030	2035	2040	2045	2050	2060	2070
Non-poly C2-C3 substances	6 225	6 873	7 588	8 378	9 250	9 722	10 218	11 287	12 468
Non-poly ≥C4 substances ¹	14 268	15 773	17 414	19 227	21 228	22 311	23 449	25 902	28 612
All polymeric ²	71 723	100 595	128 382	141 750	72.207	156 504	172 877	190 964	210 943
Overall total use	92 216	123 241	153 597	169 355	102 685	188 537	206 544	228 153	252 023

¹ Includes also PFAA precursors.

² Includes also perfluoroalkyl ethers (PFPEs).

³ Total values can differ from the sum of estimates for PFAS group categories due to averaging of growth rates.

Source: Own calculations based on data collated by the Dossier Submitters.

Table E.10. Projected yearly PFAS emissions in the TULAC sector of the EEA between 2020 and 2070 in tonnes (mean values based on market data).

PFAS substance group	2020	2025	2030	2035	2040	2045	2050	2060	2070
Non-poly C2-C3 substances	1 471	1 624	1 793	1 980	2 186	2 298	2 415	2 668	2 947
Non-poly ≥C4 substances ¹	4 666	5 152	5 688	6 280	6 934	7 287	7 659	8460	9 345
All polymeric ²	16 643	23 342	29 791	32 892	36 315	38 167	40 114	44 311	48 974
Overall total use	22 780	30 118	37 272	41 152	41 358	47 752	50 188	55 439	61 266

¹ Includes also PFAA precursors.

² Includes also perfluoroalkyl ethers (PFPEs).

³ Total values can differ from the sum of estimates for PFAS group categories due to averaging of growth rates.

Source: Own calculations based on data collated by the Dossier Submitters.

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage). It is important to note that the assessment does not account for use volumes and emissions relating to textiles used for noise and vibration insulation in automobiles as this use only became known during the 2nd stakeholder consultation and no volume data is available to the Dossier Submitters. Figure E.1 shows expected PFAS use and emissions (all PFAS groups) for the TULAC sector as a whole, based on available market data and assumptions on growth rates shown in Table E.8. Growth rates adopted for PFAS use were also applied to emission projections.

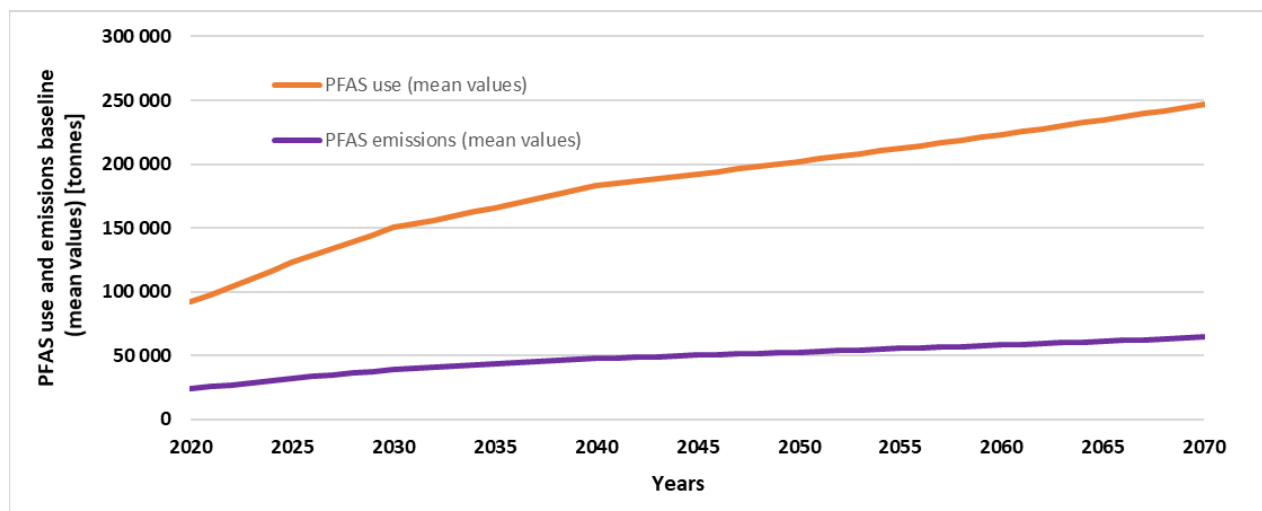


Figure E.1. Expected PFAS use and emissions in EEA under the baseline in the TULAC sector (mean values) [tonnes] ; Source: Own assessment based on TULAC market data collated by the Dossier Submitters.

E.2.2.2. Alternatives

E.2.2.2.1. Technical feasibility

The existence of technically feasible non-PFAS alternatives is one key factor determining the impact of the proposed restriction of PFASs on society as it determines the options available to companies to achieve compliance. Where technically feasible alternatives exist, substitution is a possible option for affected companies. Whether substitution is chosen as the preferred reaction to the proposed restriction depends – amongst other factors – on whether individual companies consider it economically viable for them to substitute. Where technically feasible alternatives do not exist, company closures will occur as a result of the proposed restriction. Given the importance of the most likely behavioural reaction of companies to understand the costs associated with the restriction proposal, the extent to which technically feasible alternatives are available for different sub-uses is described below.

TULAC-specific inputs to the CfE did not include information on specific alternative substances, the technical performance of possible alternatives or their availability. One respondent, however, reported **possible alternative substance groups** with an ability to provide water repellence, namely:

- Paraffin-based formulations;
- Polysiloxanes;
- Modified melamine resins;
- Polyurethanes; and
- Dendrimers.

Given the limited extent of information received during the CfE, desktop research⁵ was conducted as part of the dossier preparation to identify possible alternative substances. While no PFAS-free alternative provides a universal solution, alternatives could be identified for some of the sub-uses. An overview of the extent to which alternatives have been identified for different applications of PFASs based on this research is provided in Table E.11 below. Identified alternative substances can generally be grouped in the following (substance) groups:

- Hydrocarbons – including, for example, paraffin-based and melamine-based alternatives and waxes;
- Silicones;
- Polyurethane;
- Dendrimers; and
- Nanomaterials (EPA-DK, 2015)⁶.

Alternative technologies relying on spinning and weaving of the textile have also been identified as a chemical-free option for providing water repellence. Such techniques are based on control of the surface roughness and weaving density. One available technology, for example, provides water repellence as a result of fibre swelling when in contact with moisture. The size increase of fibres closes the weave and thereby prevents penetration of the fabric by water, while allowing body vapour to escape.

Table E.11. Overview of extent to which alternatives have been identified for different TULAC sub-uses (based on desktop research).

Sub-use		Number of identified alternative substances by chemical name and/or CAS number
TULAC	General, i.e. relevant for multiple sub-categories	49
Home textiles	Carpets and rugs	4
	Curtains and blinds	No use-specific substances identified
	Textile based coverings (e.g. fabrics for soft-furnishings, tablecloths, bedding)	5
Consumer apparel	Outdoor wear	5
	Indoor wear	No use-specific substances identified
	Sportswear	No use-specific substances identified
	Footwear	No use-specific substances identified
	Accessories	No use-specific substances identified
Professional apparel	Professional sportswear and footwear	No use-specific substances identified
	PPE for industrial and professional use (other than sportswear)	No use-specific substances identified
Technical textiles	Outdoor technical textiles	No use-specific substances identified
	Medical applications	No use-specific substances identified
	High performance membranes	No use-specific substances identified

⁵ This desktop research covered (i) safety data sheets (SDSs), (ii) other information sources of known producers/associations, (iii) scientific peer-reviewed literature identified through PubMed and Google Scholar, (iv) publications of national and regional environmental agencies, (v) publications of non-governmental organisations, (vi) documents prepared in relation to REACH, i.e. Risk Management Option Analyses (RMOAs), Annex XV restriction reports as well as RAC and SEAC documents relating to a sub-set of PFASs; and (vii) documents prepared in relation to the Stockholm Convention, e.g. risk management evaluations and 'Analysis of Alternatives' (AoA) reports.

⁶ According to EPA-DK (2015), substances with repellent properties containing nanomaterials are used as textile coatings for providing required properties while avoiding a significant increase in weight, thickness or stiffness. Functionalities like water repellence and stain resistance are achieved by embedding fabrics with tiny fibres (nano-whiskers) that form an air cushion around the fibre.

Sub-use		Number of identified alternative substances by chemical name and/or CAS number
Leather	e.g. indoor and outdoor wear, footwear, professional sportswear and footwear	3
Other	Home fabric treatments (sprays)	1
	Automotive use - Noise and vibration insulation ⁷	This use has been identified as part of the 2 nd stakeholder consultation. No information on alternatives was therefore collected as part of the desktop research.

The outcome of the research (summarised in Table E.11) suggests that alternatives for TULAC uses are available but that the existence of alternatives might be better in relation to uses in (or in relation to) home textiles and consumer apparel, including leather-based products. Issues in relation to the existence of technically feasible alternatives might exist in relation to professional apparel and technical textiles. While no use-specific alternatives were identified for these uses, as shown in Table E.11, some of the alternatives identified for TULAC in general (covered in the first row of the table) might however be relevant. This conclusion is generally in line with what has been revealed by the CfE. In fact, none of the 25 stakeholders completing the section on alternatives of the CfE indicated that technically feasible alternatives were available for professional apparel and technical textiles. The same applies to additional stakeholder interviews that were conducted at the time.

For many applications, responses to the CfE furthermore revealed that the biggest challenge with respect to the technical feasibility of alternatives is the replication of the multitude of functionalities simultaneously provided by PFASs. Suitable alternatives seem to be lacking especially in relation to uses for which functions beyond water repellence are required. A review of the broad categories of relevant chemical alternatives, i.e. dendrimer, hybrid (silicone/hydrocarbon), hydrocarbons, nanotechnologies, polyurethane and silicones with respect to functionality suggested that they are inferior to PFASs in relation to oil and dirt repellence. While silicone-, hydrocarbon and polyurethane-based products can according to information provided by one stakeholder in the 2nd stakeholder consultation – in principle – provide some oil repellence, this ability is limited to the use on hard surfaces (and not irregular surfaces like textiles). During consultations and the literature review, it became apparent that none of the PFAS-free finishing agents currently available on the market meet the same levels of performance with respect to repellence against blood, solvents, fuels and liquid chemicals as those containing PFAS.

Table E.12 links the different sub-uses of TULAC to the key groups of alternatives identified during the preparation of the dossier based on information from literature and information obtained during consultation with stakeholders, i.e. both the CfE and 2nd stakeholder consultation as well as stakeholder interviews.

⁷ Three stakeholders submitting TULAC-specific information to the 2nd stakeholder consultation reported the use of PFASs for insulation purposes in automobiles. Non-woven textiles are reported to be used for covering the surface of automobile sound absorption parts used in engine bays and other sound-generating components. One stakeholder also mentioned that such insulation serves the purpose of insulating against vibration in addition to noise. Water-and oil-repellence are described as essential functionalities provided by PFASs for this use.

Table E.12. Overview of key groups of alternatives deemed relevant for TULAC and their relevance in relation to the sub-uses of TULAC.

Sub-use		Dendrimer	Hybrid (Silicone/ hydrocarbon) ⁸	Hydro- carbons ⁹	Nano- technologies	Polyurethane	Silicones	Alternative technologies
Home textiles	Carpets and rugs	X ^{10 i}	X	X		X ^{11 i}	X	
	Curtains and blinds	X ^{9 iii}	X	X		X ^{10 iii}		
	Textile based coverings (e.g. fabrics for soft-furnishings, tablecloths, bedding)	X ^{9 iii}	X	X		X ^{10 iii}		
Consumer apparel	Outdoor wear	X ^{9 ii}	X	X		X ^{10 ii; 12}	X ¹¹	X ¹³
	Indoor wear	X ^{9 ii}	X	X		X ^{10 ii}	X ¹¹	
	Sportswear	X ^{9 ii}	X	X		X ^{10 ii; 11}	X ¹¹	X ¹²
	Footwear	X ^{9 ii}	X	X		X ^{10 ii; 11}	X ¹¹	X ¹²
	Accessories	X ^{9 iii}	X	X		X ^{10 iii}	X ¹¹	
Professional apparel	Professional sportswear and	X ^{9 ii}		X ¹⁴		X ^{10 ii; 13}	X ¹³	X ¹²

⁸ Information for this alternative is solely based on information from literature and/or the CfE.

⁹ Information for this alternative is, with the exception of information for leather applications and professional apparel, based on information from literature and/or the CfE.

¹⁰ Based on information from literature and/or the CfE, this alternative is reported to be used for (i) carpets, (ii) clothing made of cotton, polyester or blends and (iii) non-clothing textiles made of cotton, polyester or blends.

¹¹ Based on information from literature and/or the CfE, this alternative is reported to be used for (i) carpets, (ii) clothing and (iii) non-clothing textiles.

¹² Submissions to the 2nd stakeholder consultation reported the use of polyurethane membranes in outdoor textiles, sportswear and footwear. One submission also highlighted that polyurethane-based and silicone-based hydrophobic textile treatments have shown their potential in all relevant consumer apparel applications in recent years.

¹³ One alternative technology, for example, provides water repellence as a result of fibre swelling in contact with moisture – with the size increase of fibres closing the weave and thereby preventing penetration of the fabric by water. The use of this technology is reported to encompass application in jackets, coats, down jackets, ski wear, hats, shoes.

¹⁴ A submission to the 2nd stakeholder consultation reported the proven use of polyurethane membranes in most professional sportswear and footwear and PPE for industrial and professional use (other than sportswear) as a replacement for PTFE membranes. This stakeholder also reported that polyurethane-based as well as silicone-based and hydrocarbon-based hydrophobic textile treatments have shown their potential in some professional apparel applications.

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Sub-use		Dendrimer	Hybrid (Silicone/ hydrocarbon) ⁸	Hydro- carbons ⁹	Nano- technologies	Polyurethane	Silicones	Alternative technologies
	footwear							
	PPE for industrial and professional use (other than sportswear)			X ¹³		X ¹³	X ¹³	X ¹⁵
Technical textiles	Outdoor technical textiles					X ¹⁶		
	Medical applications					X ¹⁵		
	High performance membranes					X ¹⁵		
Leather	e.g. indoor and outdoor wear, footwear, professional sportswear and footwear		X	X ¹⁷		X ¹⁶	X	
Other	Home fabric treatments (sprays)						X	
	Automotive use - Noise and vibration insulation							

¹⁵ Information from one manufacturer of PPE suggested that an alternative weave construction could replace existing PFAS -based coatings in some PPE.

¹⁶ A submission to the 2nd stakeholder consultation reported the proven use of polyurethane membranes in all three categories of technical textiles.

¹⁷ A test and research institute submitting leather-specific information to the 2nd stakeholder consultation reported polyurethane and other polymer coatings as well as paraffins and waxes as possible alternative in relation to leather applications.

With respect to **home textiles**, dendrimers, silicone/hydrocarbon blends, hydrocarbons, polyurethane and silicones have been identified as relevant alternatives based on information from literature, stakeholder interviews and the CfE. In line with the conclusions based on the identification of alternatives in literature sources (presented in Table E.11), alternatives for use in home textiles seem to be generally available and substitution is thought to be a possible option for affected stakeholders.

An extensive scientific study, i.e. Glüge et al. (2022), comes to the same conclusion for carpets. An assessment of the availability of technically feasible alternatives in relation to curtains and textile based coverings was however not conducted. Based on an extensive literature review covering peer-reviewed journal articles, monographs, reports produced by industry, product descriptions and patents, and consultation with PFAS manufacturers and downstream users, the study concluded that substitution of PFASs in carpets is technically (and economically) feasible. Information on voluntary industry commitments for eliminating PFASs compiled by the Natural Resources Defense Council in a study supported by the United Nations Environment Programme points in the same direction. While voluntary commitments are reported to be dominated by apparel brands, the home textile sector is reported to be another sector making significant progress with phasing-out PFASs, especially in relation to carpets and rugs. In relation to carpets and rugs, commitments to completely eliminate PFASs from products by 2020 have been made by both manufacturers and retailers active in the sector. Actors having made commitments in relation to upholstery and home textiles more general have also been identified (SAICM, 2021).

The conclusion that alternatives for use in home textiles are generally available is further supported by TULAC-specific information gathered during the 2nd stakeholder consultation in response to the question whether the listed alternatives known to the Dossier Submitters are technically feasible in the product/process of the responding stakeholder. Only one answer specific to home textiles was received but this stakeholder indicated that the listed alternatives were deemed technically feasible.

With respect to **consumer apparel**, information from literature, stakeholder interviews and the CfE suggests that dendrimers, silicone/hydrocarbon blends, hydrocarbons, polyurethane and silicones are possible alternatives to PFASs. Alternative technologies have also been identified as relevant. The specific alternative technology described in the paragraph preceding Table E.11 has already been applied in products available on the market, with application areas being reported as (down) jackets, coats, ski wear, hats and shoes. In line with the conclusions reached as a result of the identification of alternatives in literature sources above, alternatives for consumer apparel applications can thus be considered to be generally available. A general trend of phasing out PFASs, in fact, appears to have developed in relation to this use based on recent restrictions on individual PFASs, especially as a result of increasing consumer pressure. Non-governmental organisation (NGO) initiatives have also promoted such developments. By 2018, Greenpeace's Detox campaign, which was launched in 2011, had, for example, resulted in significant substitution among the 80 companies, including fashion, sportswear, luxury, retail and outdoor brands as well suppliers, which had committed to stop using hazardous chemicals in clothing production by 2020. Of these 80 companies, which together account for 15% of global clothing production, 72% of companies had achieved complete elimination of per- and polyfluorinated chemicals from their products, while the remaining companies were making good progress¹⁸. Information on voluntary industry commitments for eliminating PFASs by 2020 compiled by the Natural Resources Defense Council in a study supported by the United Nations Environment Programme confirms this with commitments having been made by both high-end and low-end brands. Industry commitments for phasing out PFASs are reported to be dominated by fashion and apparel brands – with the successes of many fashion brands pointing to substantial phase-out opportunities according to the study. While sport and outdoor brands are reported to face

¹⁸ <https://www.greenpeace.org/international/press-release/17739/greenpeace-report-clothing-industry-shows-progress-in-cutting-hazardous-chemicals/>, date of access: 2023-01-11.

more challenges with respect to replicating required functionalities, the study stresses that a considerable number of outdoor brands have completely substituted away from PFASs. The study assumes that substitution should be equally feasible for sportswear given that required functionalities in sportswear and outdoor wear may likely be similar but the number of industry commitments are reported to be low in comparison (SAICM, 2021). More recent developments confirm the assumption that substitution is equally feasible for sportswear. Gribkoff¹⁹ mentions that two major sportswear companies reported that they have eliminated all PFASs from their products, with one having stopped using PFASs at the end of 2021. Another high-end sportswear brand reports to be phasing out PFASs, while others are reporting more concrete substitution plans with one company intending to stop the use of intentionally added PFASs by the end of 2022 and another company reporting to eliminate PFAS finishes by 2023.

Substitution is therefore thought to be a possible option for stakeholder affected by the proposed restriction. Further evidence supporting this conclusion was received during the 2nd stakeholder consultation.

In response to the question in the 2nd stakeholder consultation whether the listed alternatives known to the Dossier Submitters are technically feasible in the product/process of the responding stakeholder, three of five stakeholders providing information specific to consumer apparel indicated that the alternatives are feasible to their process/product. In addition, TULAC-specific information submitted to the 2nd stakeholder consultation provided additional evidence for the use of polyurethane in consumer apparel. One stakeholder reported that polyurethane (as well as polyester-based) membranes have been used in all relevant consumer apparel products for decades and are a proven alternative for PTFE membranes in consumer apparel – especially outdoor wear, sportswear and footwear. According to this stakeholder, polyurethane-based alternatives as well as silicone-based and paraffin-based (i.e. hydrocarbon-based) alternatives for the hydrophobic treatment of textiles, i.e. a treatment rendering the textile water repellent, have also demonstrated their potential in all consumer apparel applications in recent years - with substitution from PFAS-based treatments to alternative treatments having started in 2008. Another stakeholder reported that PTFE membranes in outdoor textiles have already been replaced by alternatives, such as polyurethane membranes, by several well-known industrial actors. A large fashion chain furthermore reported that they have completely substituted away from PFASs since 2013 and are satisfied with the performance of alternatives. According to this stakeholder, non-fluorinated water repellents are the standard in their industry. Similarly, another stakeholder supplying water repellent outdoor wear reported that they have been supplying PFAS-free products for many years.

For **professional apparel** applications, information from literature, stakeholder interviews and the CfE suggests that dendrimers and polyurethane might be possible alternative for some professional sportswear and footwear applications due to dendrimers having been reported as alternatives for the use of clothing made of cotton, polyester or blends; and polyurethane having been described as an alternative for clothing textiles in general. In addition, alternative technologies might also be relevant for both professional sportswear and footwear, given that the specific technology described in the paragraph preceding Table E.11 has already been applied in products available on the market, with application areas being reported as (down) jackets, coats, ski wear, hats and shoes.

Alternative technologies might also be relevant in relation to certain PPE applications. Information from one manufacturer of PPE suggests that an alternative weave construction could replace existing PFAS-based coatings in some PPE. For other PPE-related applications of PFASs, e.g. face masks, information submitted to the CfE suggests that alternatives might be available in the near future. In contrast, other stakeholders note that there are currently no suitable technically feasible alternatives for PPE – with one stakeholder, for example,

¹⁹ <https://www.ehn.org/pfas-clothing-2656587709.html>, date of access: 2023-01-11.

stating that they are focussing on reducing the amount of PFASs used and improving emission prevention given that alternatives are not deemed to be available in the next 10 to 12 years. With respect to footwear, one stakeholder submitting information to the 2nd stakeholder consultation notes that water repellence in combination with good water vapour permeability is crucial for PPE and that alternatives cannot replicate these functions/properties at a comparable level. A simultaneous reduction of tear strengths is also reported for the use of such alternatives. In line with the conclusions reached as a result of the identification of alternatives in literature sources, some alternatives might thus be available for use in professional apparel, but the availability of technically feasible alternatives seems to be more limited than for home textiles and consumer apparel applications – with alternatives not being suitable for all relevant applications.

Further evidence supporting the conclusion that alternatives are not known for all relevant applications is available from TULAC-specific answers to the question whether listed alternatives are technically feasible for the company's product/processes, which was asked in the 2nd stakeholder consultation. One stakeholder provided information specific to professional sportswear and footwear and indicated that the listed alternatives known to the Dossier Submitters are not technically feasible for the product/process of the company. Even stronger evidence is available in relation to PPE applications. Of 17 stakeholders providing PPE-specific information, only one stakeholder indicated that the mentioned alternatives are technically feasible for its product/process. The share of respondents indicating that alternatives are technically feasible is thus considerably lower than for consumer apparel – confirming the general conclusion that substitution is a less likely option in relation to PPE than for consumer apparel. One stakeholder submitting TULAC-specific information to the 2nd stakeholder consultation furthermore notes that no alternative for the processing aid used for producing a material qualified for the use in PPE Category III²⁰ is available.

Information provided in the 2nd stakeholder consultation however also provides additional evidence supporting the conclusion that technically feasible alternatives are available for some of the professional apparel applications. The stakeholder that also submitted information on the proven use of polyurethane (as well as polyester-based) membranes in all relevant consumer apparel over several decades, highlighted that polyurethane (as well as polyester-based) membranes are also a proven alternative to PTFE membranes in professional apparel – both professional sportswear and footwear as well as PPE. These alternatives are reported to have been used in most professional apparel applications for decades. Polyurethane-based, silicone-based and hydrocarbon-based hydrophobic textile treatments have also shown their potential in some professional apparel applications in recent years according to this stakeholder. According to the stakeholder, a switch to such water repellent treatments can happen instantly in many areas of application, including, for example, PPE for law enforcement.

While there is thus some evidence that technically feasible alternatives are available for at least some PPE applications, it is important to note that alternatives need to be chosen according to specific protection needs and standards that are required in different segments of the professional textile market. For example, in the medical sector, repellence to bodily fluids is necessary to avoid the transmission of diseases and in defence, firefighting, and the oil and gas industry repellence of non-polar stains is also part of the hazard management.

With a view of developing a more detailed understanding of the specific types of PPE for which

²⁰ Regulation (EU) 2016/425 distinguishes between three types of PPE, whereby Category I covers PPE protecting against minimal risks, more specifically superficial mechanical injury, contact with cleaning materials of weak action or prolonged contact with water, contact with hot surfaces not exceeding 50 °C, damage to the eyes due to exposure to sunlight, and atmospheric conditions that are not of an extreme nature (EC, 2016a). Category III covers PPE protecting against risks that may cause very serious consequences such as death or irreversible damage to health. Examples are PPE protecting users against substances and mixtures which are hazardous to health, harmful biological agents and bullet wounds or knife stabs. Category II covers PPE protecting users against risks not listed under Category I and III.

technically feasible alternatives are not deemed to be available, a further examination on professional textiles linked to PPE as specified in Regulation (EU) 2016/425 was undertaken by the Dossier Submitters. This examination aimed to determine whether their functionality and performance warrants the continued use of PFASs or whether alternatives are available. The results of this examination are set out in Table E.13.

PPE requires CE marking, by which the manufacturer indicates that PPE is in conformity with the applicable requirements set out in European Union (EU) legislation (EC, 2016a). This means that a set of European (EN) standards must be met for PPE that is placed on the EU market. Table E.13 contains a summary of critical properties and test standards relevant to PPE in which PFASs are commonly used. It also notes the PPE regulation risk category that the critical properties relate to and whether PFASs are required to fulfil this property or not. As indicated in Table E.13, the Dossier Submitters conclude that there are some Category III PPE applications, i.e.:

- Protection against (liquid and gaseous) chemicals, including aerosols and solid particles, and microorganisms;
- PPE applications for firefighting; and
- Use, care, and maintenance of some Category III PPE workwear (e.g. reimpregnation done by laundries);

Where PFASs are likely to be required to comply with the legal requirements according to Annex I of the PPE regulation (EU 2016/425). It is furthermore concluded that PFASs are not necessary to meet the technical requirements of Category I and II in Annex I of the PPE regulation, as technically feasible non-PFAS alternatives are available. With respect to PPE specifically designed for use by the armed forces or in the maintenance of law and order, to which the PPE regulation does not apply, the Dossier Submitters conclude that PFASs are likely to be required.

These conclusions are mirrored by information submitted during the 2nd stakeholder consultation. In line with the above conclusion that PFASs are required for protection against liquid chemicals, one stakeholder submitting TULAC-specific information to the 2nd stakeholder consultation, for example, notes that they are not aware of any alternatives to PFASs than can provide the required performance level for chemical repellence and penetration for washable EN13034 Type 6 fabrics.

Similarly, an industry stakeholder submitting information for PPE in relation to firefighting to the 2nd stakeholder consultation also stresses that PFASs are required for firefighting activities. In line with the Dossier Submitters' conclusion, the stakeholder reports that there is no alternative product or process known that provides the full spectrum of required protection in relation to firefighting.

With respect to PPE for military activities, information submitted to the 2nd stakeholder consultation by two national defence ministries is also in line with the conclusion reached by the Dossier Submitters that PFASs are required for PPE for military activities. Both ministries report protection against chemical, biological, radiological and nuclear (CBRN) agents and fire as the key protections provided by relevant PPE. The reduction of fire risks is also reported as crucial with respect to other textiles used in the military context, e.g. textiles in military vehicles. PFASs are reported as crucial for providing these functions. According to both ministries, water and oil repellence are reported as the key functionalities to be provided by alternatives to PFASs with a view of enabling protection against fire and chemical, biological, radiological and nuclear (CBRN) agents. While silicon waxes, dendrimers, nanomaterials as well as long-chain polymers were investigated as alternatives to PFASs, none of them are able to fulfill the minimum requirements according to one of the national ministries. In relation to CBRN protection, the second ministry submitting information to the 2nd stakeholder consultation highlights that the main technical challenge with reaching minimum rating levels for oil repellence (in accordance with standard EN ISO 14419) and water repellence (defined in accordance with the Bundesmann method, i.e. EN 39865) is reaching such levels

simultaneously. Compliance with oil repellence ratings is described as the major challenge in this respect. In addition, one of the ministries highlights that PFASs are used to provide water-repellent functionalities in a variety of clothing, e.g. different kinds of combat clothing in temperate areas, navy uniforms and flight jackets. With respect to water repellence, several alternatives exist according to this ministry but all of them provide a lower level of water repellence than PFASs.

Based on information available to the Dossier Submitters, technically feasible alternatives thus seem to be available to replace a potentially significant share of PFASs currently used in PPE. During stakeholder consultations following the 2nd stakeholder consultation, three companies in the PPE sector indicated that around 20% of PFASs used in PPE they put on the European Economic Area (EEA) market is used in relation to PPE protecting against Category III risks, i.e. the category for which PFASs continue to be necessary. The remaining 80% were used in PPE protecting against Category I or II risks. It is however important to note that the three aforementioned companies only account for a limited share of the market, with their total annual use volume of PFASs being approximately three tonnes. It is therefore uncertain whether the aforementioned information is representative for the entire market.

There is thus a potential for replacing PFASs in PPE, also due to indications from consultations that there may be an overuse of PFASs, with PPE with a higher level of protection being used than required. Overuse of PFASs could, for example, result from PPE customers' wish to equip their entire workforce at the facility with uniform clothing – with the tasks that require the highest level of protection setting the standard for the PPE used by all workers.

Table E.13. Summary of performance and test standards for PPE compiled based on stakeholders' answers and publicly available sources regarding the potential need for PFASs to get the required property.

Critical properties (performance)	Standards for protective clothing (Mostly from CEN/TC 162)	Risk categories²¹	Conclusion	Rationale for conclusion
Electrostatics	EN 1149 series	II	PFASs not required	Electrostatic properties are not reached by PFASs but with antistatic fibres.
Liquid chemicals	- EN 13034:2005+A1:2009 - EN 14605:2005+A1:2009 - EN 16523-1:2015+A1:2018	III(a) <i>Substances and mixtures which are hazardous to health</i>	PFASs required	Repelling liquids with low surface tension cannot be done with non-PFASs.
Protection against chemicals	- EN ISO 17491-3, -4:2008 - EN ISO 17491-4:2008 - EN ISO 19918:2017/A1:2021 - EN ISO 6530:2005 - EN ISO 374-1:2016/A1:2018	III(a) <i>Substances and mixtures which are hazardous to health</i>	PFASs required	Repelling liquids with low surface tension cannot be done with non-PFASs.
Protection against microorganisms	- EN ISO 17491-3, -4:2008 - EN ISO 17491-4:2008 - EN ISO 19918:2017/A1:2021 - EN ISO 6530:2005 - EN ISO 374-1:2016/A1:2018	III(c) <i>Harmful biological agents</i>	PFASs required	So-called barrier fabric to reinforce the knitted polyethylene terephthalate (PET) in the critical zones is common, whereby 70% of the barrier fabric is based on expanded polytetrafluorethylene (ePTFE) and the remaining 30% is based on breathable polyurethane barrier membranes (Karim et al., 2020).
Liquid and gaseous chemicals, including aerosols and solid particles	- EN 464:1994 product standard has been superseded by: EN 943-1:2015+A1:2019 - EN 943-2:2019	III(a) <i>Substances and mixtures which are hazardous to health</i>	PFASs required	Repelling liquids with low surface tension cannot be done with non-PFASs. For gaseous chemicals and aerosols, ePTFE membranes are required for protection (Feng et al., 2018). There may be some applications concerning solid particles where ePTFE membranes are not required (Oltmanns et al., 2016).

²¹ Risk categories according to Regulation (EU) 2016/425 (PPE), Annex I.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Critical properties (performance)	Standards for protective clothing (<i>Mostly from CEN/TC 162</i>)	Risk categories ²¹	Conclusion	Rationale for conclusion
Against rain	EN 343:2019	I(e) <i>atmospheric conditions that are not of an extreme nature</i>	PFASs will not necessarily be needed to fulfil EN 343. PFAS-free options can provide satisfactory protection against water.	PFAS-free durable water repellent (DWR) provides good protection and PFASs will not necessarily be needed to fulfil EN 343, if only water repellence is needed to fulfil the CE-certification. There is however a risk of not fulfilling highest Class 4 ²² without PFASs if the oil and fuel pre-treatment cannot be made optional in the certification, but that must be tested and evaluated. Likely ePTFE membranes may be used in combination with some sort of water repellent treatment that may be non-PFAS.
Splashes of molten metal²³	EN 348:1992	III(e) <i>High-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C</i>	PFASs not required	The protection of flammability and heat radiation is reached by using flame inherent fibres (such as aramid fibres) to prevent flammability and heat reflective fabrics to prevent heat radiation.
For firefighting activities	EN 469:2020	III <i>Subcategories (a) – (m)</i>	PFASs required	Required properties: - Heat and flame - High visibility - Protection against chemicals including aerosols, solid particles, and microorganisms - Others depending on the emergency situation
High visibility	EN ISO 20471:2013	II	PFASs not required	PFAS will not automatically be needed to achieve high visibility. Washing garments regularly to avoid getting the high visibility material permanently dirty is an alternative option.

²² Water penetration with 4 levels, where Class 4 is the most stringent requirement.

²³ See also "Heat and flame".

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Critical properties (performance)	Standards for protective clothing (<i>Mostly from CEN/TC 162</i>)	Risk categories ²¹	Conclusion	Rationale for conclusion
Heat and flame	EN ISO 11612:2015	III(e) <i>High-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C</i>	PFASs not required	Since PFASs are oil repellent there is additional protection with added PFAS, since oil and dirt can act as risk factors regarding flammability. However, to achieve the required protection against flammability, PFASs are not necessarily needed. The protection of flammability is reached by using inherent fibres which provide the protection.
Use, care, and maintenance (e.g reimpregnation done by laundries)	- CEN/TR 14560:2018 (guidance PPE heat and flame) - CEN/TR 15419:2017 (guidance PPE chemical protection) - CEN/TR 17330:2019 (guidance PPE heat and cold) - EN 24920 (spray test) - AATCC 118 (oil repellence grade) - EN 20811(waterproofness) - DIN 32763 (chemical resistance) - EN ISO 6530:2005 (penetration of chemicals mainly with low volatility)	III(a) <i>substances and mixtures which are hazardous to health</i> III(c) <i>harmful biological agents</i>	PFASs required	See: “Liquid and gaseous chemicals, including aerosols and solid particles”; and “Protection against microorganisms”
Cuts against handheld chainsaws	EN ISO 11393 series	III(l) <i>bullet wounds or knife stabs</i>	PFASs not required	Conventional fabric is not cut-resistant against a running chainsaw. Therefore, certain cut-resistant fabrics need to be used.
(National) ballistics standards/riot suits²⁴	National standards such as BS7971-10 & protection against Molotov cocktails²⁵ and other accidental risks.	III(l) <i>bullet wounds or knife stabs</i>	PFASs not required	If the bullet proof Kevlar (aramid) garment gets wet, it does not work. This means that an effective durable water repellent (DWR) treatment with non-PFAS should be sufficient.

²⁴ Regulation (EU) 2016/425 (PPE) does not apply to PPE specifically designed for use by the armed forces or in the maintenance of law and order.

²⁵ See “Heat and flame”.

With respect to **technical textiles**, information from literature, stakeholder interviews and the CfE suggests that technically feasible alternatives are generally not available – with stakeholder input suggesting that longer transition periods of up to 10 years are required for technical textiles. One stakeholder, for example, noted in the CfE that there are currently no alternatives available for use in medical textiles. This is in line with the conclusions reached as a result of the identification of alternatives in literature sources above, which suggests issues in relation to the existence of technically feasible alternatives for technical textiles.

Responses to the 2nd stakeholder consultation question of whether the listed alternatives known to the Dossier Submitters are technically feasible in the product/process of the responding stakeholder provide additional evidence in support of this conclusion. Of eight stakeholders providing information specific to technical textiles, only one stakeholder indicates that the alternatives known to the Dossier Submitters are technically feasible for their specific application.

In relation to PFAS applications in medical textiles, one stakeholder submitting information to the 2nd stakeholder consultation notes that there are currently no technically feasible alternatives to PFASs for medical gowns. While small quantities of PFASs allow for the delivery of the desired performance, while exhibiting additional required properties, such as chemical inertness and biocompatibility, that ensure the safe and effective use of the products, alternatives with the desired properties could not be identified yet.

Similarly, one stakeholder providing information in relation oil- and water-repellent PFAS-based finishes in industrial filter applications such as coalescing filters highlights that no alternative is known that is able to provide both water and oil repellence. With respect to PTFE-based membranes for filtration of very fine particles with high chemical and temperature resistance, the same stakeholder notes that the chemical and temperature resistance of potential alternatives is insufficient. A producer of filtration products for application in a wide variety of industries furthermore notes that PTFE's unique performance properties cannot be matched by any known non-PFAS alternative. The stakeholder is aware that some suppliers produce alternatives to PTFE membrane or PFAS-coated products but these suppliers use PFASs for processing fibres in a media slurry as part of the filter media process. Such alternatives are therefore no viable alternative in relation to the proposed restriction. While such filter media can also be produced without the use of PFASs, these alternatives still need to be trialled, tested and validated by downstream users – with doubts being expressed that these alternatives would work in all applications.

In addition, one stakeholder submitting TULAC-specific information to the 2nd stakeholder consultation provided information on the technical feasibility of alternatives for two different applications of PFASs in technical textiles for outdoor use. The use of fluoropolymers, specifically PVDF, as a top coat finish on polyvinylchloride-coated (PVC-coated) fabrics used for outdoor upholstery, marine applications and tents is reported to increase the durability of PVC-coated fabrics from three years to 10-15 years. This topcoat also provides resistance against ultraviolet (UV) radiation and protection against soiling. According to the stakeholder, no alternative is available that is as efficient as fluoropolymers for protecting coated fabrics in a durable manner. In addition to fluoropolymers, non-polymeric PFASs are used in the underlying solid coating layer consisting of PVC or acrylic for water repellence and oil repellence purposes or as yarn treatment. Such yarn treatments prevent the penetration of water along the yarn – thereby increasing its durability. According to the stakeholder, non-polymeric PFASs are the only option for jointly providing water and oil repellence. While research on alternatives for non-polymeric PFASs is ongoing, no suitable alternative has been identified for the moment due to constraints linked to the fabrication process, material compatibility issues and concerns on the performance in the final application with respect to fire and UV resistance. Alternatives known to the Dossier Submitters are described as potentially being suitable for providing water repellence.

Other information submitted to the 2nd stakeholder consultation, however, contradicts the conclusion that alternatives are not available for most technical textile applications to some

extent. The same stakeholder that provided information on the proven use of polyurethane (as well as polyester-based) membranes for consumer and professional apparel mentioned that such membranes are also a proven alternative for PTFE membranes used in outdoor technical textiles, medical applications and high-performance membranes.

As a result, the Dossier Submitters recognize that alternatives seem to be less generally available for technical textiles than for consumer applications for instance, but also notices that substitution might be a possible option for stakeholders in relation to - at least - some technical textile applications.

With respect to **leather**, information from literature, stakeholder interviews and the CfE suggests that silicone/hydrocarbon blends and silicone are possible alternatives to PFASs and that technically feasible alternatives are available. This is in line with conclusions reached based on the identification of alternatives in literature sources (presented in Table E.11) which revealed some use-specific alternative substances.

Further evidence supporting the conclusion that suitable alternatives exist is available from the 2nd stakeholder consultation. In relation to leather applications in automotives, one stakeholder reported that they have been able to identify an alternative whose oil and soil repellence properties are close enough to PFAS-based products and that they have as a result started to substitute away from PFASs. In addition, two other stakeholders reported that they are not using PFASs in relation to automotive upholstery and other textile uses in passenger compartments. Whether this refers to textile or leather coverings is however unclear. Contrasting information is however provided by other stakeholders. One stakeholder reported that a transition to alternatives is not possible within three years and that they would not be able to offer light coloured interiors to customers when PFASs are banned but it is again unclear whether this refers to textile or leather coverings. Another stakeholder providing information for automotive interiors also expresses concerns in relation to the feasibility of alternatives given that alternatives only offer water repellence, instead of a combination of water repellence, oil repellence and protection against soiling. A third stakeholder highlights that the use of PFASs is important for creating durable interior surfaces in automotives as PFASs provide a wear-resistant protective shell guarding the surfaces against common types of abrasion, e.g. scratching, marring and rubbing. According to this stakeholder, no alternatives showing an acceptable performance level could be identified despite extensive research.

Apart from the leather-specific submission relating to leather applications in automotives, only one other industry stakeholder provided leather-specific information to the 2nd stakeholder consultation. Submitted information relates to leather-based gloves for professional and sport applications. In contrast to the information provided for leather in automotives, this stakeholder reported that listed alternatives known to the Dossier Submitters are not technically feasible in their product/process. Particular concerns are related to the lower level of water repellence of alternatives leading to a requirement to change gloves more often during the day.

In addition to the information provided by industry stakeholders, a test and research institute reported polyurethane and other polymer coatings as well as paraffins and waxes as possible alternative in relation to leather applications.

In conclusion, some alternatives for leather applications seem to be available.

With respect to **home fabric treatments (sprays)**, one silicone-based alternative was identified as use-specific alternative based on the identification of alternatives in literature as shown in Table E.11. Some of the general alternatives identified in relation to TULAC might however also be relevant.

The use of **non-wovens used for insulation purposes in automotives has been identified as part of the 2nd stakeholder consultation**. No conclusion on the availability

of technically feasible alternatives has therefore been reached based on literature, stakeholder interviews and the CfE. The use was mentioned by three stakeholders submitting TULAC-specific information to the 2nd stakeholder consultation. Non-woven textiles treated with PFAS are reported to be used for covering the surface of automobile sound absorption parts used in engine bays and other sound-generating components for noise insulation purposes. One stakeholder also mentioned that such insulation serves the purpose of insulating against vibration in addition to noise. Water- and oil-repellence are described as essential functionalities provided by PFASs for this use as they help with maintaining performance levels of relevant parts. Stain-resistance and protection against soiling are also reported as a relevant functionalities provided by PFASs. According to information provided by one stakeholder, the use of PFASs is essential for achieving compliance with United Nations Regulation No 51 (UNR-51) and (EU) No 540/2014 noise regulations. Based on information from upstream actors in this stakeholder's supply chain, alternative substances or technologies are not available at this moment. Even if alternative technologies or substances were identified in due course, significant time would be required for the substitution away from PFASs. This is due to the significant amount of time – a minimum of 10 to 15 years – that is needed to develop and evaluate components and vehicles with a view to meeting type approval requirements.

In conclusion, technically feasible alternatives seem to be available for home textile and consumer apparel applications as well as leather applications as shown in Table E.14. With respect to professional apparel and technical textiles, alternatives for at least some applications seem to be available based on the information provided in TULAC-specific submissions to the 2nd stakeholder consultation. With respect to PPE, this is confirmed by the assessment on the necessity of PFASs for different types of PPE detailed in Table E.13. An alternative was also identified for home fabric treatments. No alternatives are known in relation to the use of non-wovens in automobiles for noise and vibration insulation purposes. With a view of illustrating how conclusions on the existence of technical feasible alternatives have changed based on additional information that was provided, the first stage of information collection, i.e. the CfE (which was complemented by stakeholder interviews and a literature review), and the second stage in the form of the 2nd stakeholder consultation are treated separately in Table E.14.

Table E.14. Broad assessment of technical feasibility of alternatives for TULAC sub-uses.

Sub-use	Conclusion based on CfE, stakeholder consultation interviews, consulted literature		Conclusion following 2 nd stakeholder consultation	
	Alternative-based products already available on the market	Technical feasibility of alternatives	Alternative-based products already available on the market	Technical feasibility of alternatives
Home textiles	Yes	Partial – depending on required functionality Alternatives available where only water repellence is required	No change to conclusion	No change to conclusion: One additional stakeholder confirmed the technical feasibility of alternatives
Consumer apparel	Yes	Yes Functions other than	No change to conclusion:	No change to conclusion

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Sub-use	Conclusion based on CfE, stakeholder consultation interviews, consulted literature		Conclusion following 2 nd stakeholder consultation	
	Alternative-based products already available on the market	Technical feasibility of alternatives	Alternative-based products already available on the market	Technical feasibility of alternatives
		water repellence are not deemed to be critical for this use	Several stakeholders report use of alternatives for products already placed on the market	
Professional apparel	No	No Alternatives cannot replicate certain required functionalities, e.g. oil repellence, stain resistance (ability to resist contamination with liquid soils) Some promising alternatives in the Research & Development (R&D) stage are mentioned	Yes E.g. polyurethane membranes are reported to be a proven alternative for both professional sportswear and PPE	Partial 2nd stakeholder consultation reveals information pointing towards proven use of alternatives, but many stakeholders also report that known alternatives are not feasible for their product PFAS use is identified as being necessary for some Category III PPE applications, while alternatives are deemed feasible for Category I and II
Technical textiles	No	No Alternatives cannot replicate certain required functionalities, e.g. oil repellence, stain resistance (ability to resist contamination with liquid soils)	Yes E.g. polyurethane membranes are reported to be a proven alternative for membranes used in outdoor technical textiles, medical applications and high performance membranes	Partial 2nd stakeholder consultation reveals information pointing towards proven use of alternatives, but many stakeholders also report that known alternatives are not feasible for their product

Sub-use	Conclusion based on CfE, stakeholder consultation interviews, consulted literature		Conclusion following 2 nd stakeholder consultation	
	Alternative-based products already available on the market	Technical feasibility of alternatives	Alternative-based products already available on the market	Technical feasibility of alternatives
Leather	?	Partial – depending on required functionality, e.g. water, oil, and stain repellence Alternatives available where only water repellence is required	?	Yes Stakeholder reports alternative whose oil and soil repellence properties are close enough to PFAS-based products
Other: Home fabric treatments (sprays)	?	Partial – depending on required functionality, e.g. water, oil, and stain repellence Alternatives available where only water repellence is required	No change to conclusion	No change to conclusion
Other: Automotive use – Noise and vibration insulation	Not assessed	Not assessed	No	No

E.2.2.2.2. Human health and environmental hazards

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log K_{ow}) and bioconcentration factor (BCF) was assessed. Additionally, it was assessed whether the alternatives fulfil PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative) criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHA's dissemination site. The ECHA webpage was last consulted on this data in January 2022.

In relation to TULAC, the list of alternatives contained 19 unique CAS numbers. Twelve (12) of the substances with unique CAS were classified according CLP (Classification, Labelling and Packaging of Chemicals; harmonised classification or self-classification). Ten (10) of the substances with unique CAS number did, according to their registration dossier, not fulfil the PBT or vPvB criteria and for the remaining substances, no data was found, meaning that none of these substances were known to fulfil the PBT or vPvB criteria. Two of the substances with unique CAS number may contain residues of D4, D5 and D6, cyclic siloxanes. D4, D5 and D6, and cyclic siloxanes are considered to be PBT/vPvB substances and D4 is considered to be an

endocrine disruptor. These substances were: alkyl polysiloxane solution and emulsion of polydimethylsiloxane, cationic. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

The list contained an additional 30 substances with unique substance names for which no CAS numbers were available. For these substances, no information on classification or PBT and vPvB assessments were available. The following substances in this selection, may contain residues of D4, D5 and D6, cyclic siloxanes (hazards mentioned above): aminofunctional polysiloxanes, organic silicon compound, polysiloxane and polyester, siloxane dispersion with modified polyamide, solvent-dilutable silicone solution, water-based silicone emulsion.

E.2.2.2.3. Availability

Information on whether alternatives identified as technically feasible are available to EEA companies in sufficient quantities is very limited. Information on the total volume of alternatives produced and supplied to the EEA is not available from the CfE and the 2nd stakeholder consultation. One interviewed stakeholder however reported that dendrimers are available on a large scale in the EEA, while hydrocarbons for use in industrial applications are also available and already used. Information on the amount of alternatives required following the entry-into-force of the restriction is also unavailable. As such, the Dossier Submitters cannot conclude on whether substitution will be prevented by supply shortages of relevant alternatives. Information in Wood (2020b), however suggests, that availability of alternatives in sufficient quantities is not the main challenge in relation to substitution. According to manufacturers and industry stakeholders, the main challenge would not be meeting industry demand for alternatives already on the market but the development of new alternatives for applications for which no technically feasible alternatives are known.

E.2.2.2.4. Substitution potential

As mentioned in section E.2.2.2.1, the existence of technically feasible alternatives determines the options available to affected companies to achieve compliance, e.g. substitution or closure of business (or business unit). Whether substitution takes place depends – amongst other factors such as the availability of alternatives (covered in section E.2.2.2.3) – on whether individual companies consider it economically viable to them to substitute. The substitution potential in relation to TULAC is thus dependent on the technical and economic feasibility of alternatives and their availability in sufficient quantities.

With a view of informing the assessment of the impacts of the restriction, which are heavily determined by the extent to which companies substitute, this section draws overall conclusions on the substitution potential in relation to different TULAC sub-uses, based on the evidence from:

- Literature, including documents developed by industry (e.g. safety data sheets (SDSs) and other documents of known producers/associations), academia (e.g. scientific peer-reviewed literature), non-governmental organisations as well as public actors (e.g. publications of national and environmental agencies and a variety of documents produced for regulatory processes under REACH²⁶ and the Stockholm Convention²⁷);
- The CfE, supplemented with information from stakeholder interviews; and
- The 2nd stakeholder consultation, more specifically answers (from a non-representative sample of stakeholders) to the question whether the listed alternatives known to the Dossier Submitters are technically feasible in the product/process of the responding stakeholder.

In relation to the sub-use **home textiles**, all sources of evidence described in section E.2.2.2.1 point to the conclusion that technically feasible alternatives exist, with five of seven

²⁶ RMOAs, Annex XV restriction reports, RAC and SEAC opinions.

²⁷ Risk management evaluations, Analysis of Alternative (AoA) reports.

alternative substance groups, i.e. dendrimers, hybrid blends, hydrocarbons, polyurethanes and silicones, being identified as relevant. The conclusion of the Dossier Submitters that technically feasible alternatives exist is confirmed by an extensive scientific study, i.e. Glüge et al. (2022), which assesses the availability of technically (and economically) feasible alternative for carpets only (and not curtains and textile based coverings) based on a review of a wide variety of documents²⁸, including industry documents and peer-reviewed academic literature, and consultation with PFAS manufacturers and downstream users. Another study, i.e. SAICM (2021), corroborates this conclusion through a compilation of real-life cases of substitution based on voluntary industry commitments. Commitments to eliminate PFASs from products by 2020 have been made by both manufacturers and retailers active in the sector according to SAICM (2021). These practical examples point to the economic feasibility of the identified alternatives.

Based on the above evidence, the Dossier Submitters consider that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives for home textiles. Information on whether the alternatives are available in the quantities required for use in home textiles is very limited. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that technically and economically feasible alternatives exist in sufficient quantities for use in home textiles. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high under a full ban with a transition period of 18 months.

As a result, no derogation is proposed and further assessed for home textiles.

In relation to the sub-use **consumer apparel**, all sources of evidence described in Section E.2.2.2.1 point to the conclusion that technically feasible alternatives for use in consumer apparel exist. Six of seven alternative substance groups, i.e. dendrimers, hybrid blends of silicones and hydrocarbons, hydrocarbons, polyurethanes, silicones and alternative technologies have been identified as relevant for consumer apparel based on literature, the CfE and stakeholder interviews. Information on real-life cases of substitution as a result of NGO initiatives and voluntary industry commitments corroborates the conclusion that technically and economically feasible alternatives exist. Greenpeace's Detox Campaign (launched in 2011), for example, had by 2018 resulted in substitution by fashion, sportswear, luxury, retail and outdoor brands – with 72% of the 80 involved companies having achieved complete elimination of per- and polyfluorinated chemicals from their products and the remaining companies having made good progress²⁹. The compilation of real-life cases of substitution based on voluntary industry commitments to eliminate PFASs by 2020 in SAICM (2021) revealed that commitments have been made by both high-end and low-end brands and include fashion, apparel, outdoor and sport brands (in relation to which the number of industry commitments is however reported to be low in comparison). More recent cases of completed or ongoing substitution intended to be completed in 2022 or 2023 in the sportswear industry are mentioned by Gribkoff³⁰. Submissions to the 2nd stakeholder consultation also point to the established use of alternatives in consumer apparel – both in relation to the use of membranes and hydrophobic textile treatments. In response to the question in the 2nd stakeholder consultation whether the listed alternatives known to the Dossier Submitters are technically feasible in the product/process of the responding stakeholder, three of five stakeholders providing information specific to consumer apparel indicated that the alternatives are feasible to their process/product.

Based on the above evidence, the Dossier Submitters consider that there is sufficiently strong

²⁸ The literature review covered peer-reviewed journal articles, monographs, reports produced by industry, product descriptions, patents, and consultation with PFAS manufacturers and downstream users.

²⁹ <https://www.greenpeace.org/international/press-release/17739/greenpeace-report-clothing-industry-shows-progress-in-cutting-hazardous-chemicals/>, date of access: 2023-01-11.

³⁰ <https://www.ehn.org/pfas-clothing-2656587709.html>, date of access: 2023-01-11.

evidence for the existence of technically and economically feasible alternatives for consumer apparel. Information on whether the alternatives are available in the quantities required for use in consumer apparel is very limited. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that technically and economically feasible alternatives exist in sufficient quantities for use in consumer apparel. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high under a full ban with a transition period of 18 months.

As a result, no derogation is proposed and further assessed for consumer apparel.

In relation to the sub-use **professional apparel**, evidence on alternatives is conflicting to some extent. The desktop research based on the literature sources mentioned above as well as information from the CfE point to the conclusion that technically feasible alternatives might not be available. No use-specific alternatives were identified for (i) professional sportswear & footwear and (ii) PPE as shown in Table E.11. (Some of the general alternatives identified for TULAC could however be relevant for these uses). Similarly, none of the stakeholders responding to the section on alternatives in the CfE (25 stakeholders) indicated that technically feasible alternatives are available. Some of the information from the 2nd stakeholder consultation also points in this direction. An analysis of answers from a non-representative sample to the question whether listed alternatives are technically feasible for the company's product/processes, for example, corroborates this conclusion. The vast majority of responding stakeholders, i.e. one (of one) stakeholder providing information specific to professional sportswear and footwear and 16 (of 17) stakeholders providing information for PPE, in fact, indicated that the mentioned alternatives are not technically feasible.

In relation to professional sportswear and footwear (a sub-category of professional apparel), two of the seven alternative groups, i.e. dendrimer and polyurethane, are however deemed to be applicable given that dendrimers are reported to be used for clothing made of polyester and blends of polyester and cotton and polyurethanes are reported as alternative for clothing in general. An alternative technology providing water repellence is furthermore reported to be applied in ski wear and shoes (amongst other applications), which suggests that it is relevant for professional sportswear and footwear. Information from the 2nd stakeholder consultation corroborates the conclusion that some alternatives are available. One stakeholder reports the proven use of polyurethane membranes in most professional sportswear and footwear as a replacement of PTFE membranes. The same stakeholder reports that polyurethane-based, silicone-based and hydrocarbon-based hydrophobic textile treatments have demonstrated their potential in some professional apparel applications. As a result, five of seven alternative groups, i.e. dendrimers, hydrocarbons, polyurethane, silicones and alternative technologies are deemed to be relevant to professional sportswear and footwear.

In relation to PPE (a sub-category of professional apparel), information from one stakeholder suggests that an alternative weave construction could replace existing coating in some PPE. Information from the 2nd stakeholder consultation further corroborates the conclusion that alternative are available for some applications with one stakeholder reporting the proven use of polyurethane membranes in PPE as a replacement of PTFE membranes. The same stakeholder reports that polyurethane-based, silicone-based and hydrocarbon-based hydrophobic textile treatments have demonstrated their potential in some professional apparel applications. As a result, four of seven alternative groups, i.e. hydrocarbons, polyurethane, silicones and alternative technologies are deemed to be relevant to some extent for PPE.

An additional analysis conducted by the Dossier Submitters to further strengthen the evidence base and resolve the problem of conflicting evidence focused on comparing stakeholder information on functionalities provided by PFASs and alternatives with performance

requirements set under EU legislation to determine whether the required performance can only be achieved using PFASs. For six of 13 categories, PFASs are found to be required – which explains the existence of conflicting evidence for PPE when assessing it as a category as a whole.

For professional sportswear and footwear, the Dossier Submitters consider based on the above evidence (and the evidence underlying the assessment of alternatives for other TULAC applications) that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives. The evidence is however considered to be somewhat weaker than for home textiles and consumer apparel due to the existence of some conflicting evidence, e.g. contradicting information from stakeholders providing information to the 2nd stakeholder consultation. Overall, sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives for professional sportswear and footwear, e.g. information from the 2nd stakeholder consultation pointing to the proven use of alternatives, strong evidence for consumer apparel applications (which are deemed to be comparable to some extent) and evidence for PPE for the protection against rain (which is deemed to be a good indicator for the existence of alternatives for professional sportswear and footwear), is however deemed to be available.

For PPE, the Dossier Submitters consider based on the above evidence that there is sufficiently strong evidence for the existence of technically feasible alternatives for seven of 13 applications, while alternatives are considered to do not exist for other applications, i.e.:

- PPE for protection against (i) liquid chemicals, (ii) chemicals, and (iii) liquid and gaseous chemicals, including aerosols and solid particles (Risk category III(a) relating to substances and mixtures which are hazardous to health);
- PPE for protection against microorganisms (Risk category III(c) relating to harmful biological agents);
- PPE applications for firefighting (Risk category III, subcategories (a) – (m)); and
- Use, care and maintenance of some Category III workwear.

Based on sufficiently strong evidence from other TULAC sub-sectors, e.g. consumer apparel, listed alternatives are also deemed to be economically feasible for PPE.

Both for professional sportswear and footwear as well as PPE, information on whether the alternatives are available in the quantities required is very limited. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that alternatives exist in sufficient quantities for relevant professional apparel applications. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high for professional sportswear and footwear and seven of 13 PPE applications under a full ban with a transition period of 18 months, while the substitution potential is low for the other PPE applications.

As a result, the following derogations are proposed and further assessed:

- Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c)
- Personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) – (m)
- Impregnation agents for re-impregnating of articles referred to above

In relation to the sub-use **technical textiles**, evidence on alternatives is conflicting to some extent. The desktop research based on the literature sources mentioned above as well as information from the CfE point to the conclusion that technically feasible alternatives might not be available. No use-specific alternatives were identified for (i) outdoor technical textiles,

(ii) medical textile applications and (iii) high performance membranes, as shown in Table E.11. (Some of the general alternatives identified for TULAC could however be relevant for these uses). Similarly, none of the stakeholders responding to the section on alternatives in the CfE (25 stakeholders) indicated that technically feasible alternatives are available. Some of the information from the 2nd stakeholder consultation also points in this direction. An analysis of answers from a non-representative sample to the question whether listed alternatives are technically feasible for the company's product/processes shows that the vast majority of responding stakeholders, i.e. seven (of eight) stakeholders providing information for technical textiles indicated that the mentioned alternatives are not technically feasible, with the dominant share of submissions relating to high performance membranes.

In relation to outdoor technical textiles, some application-specific stakeholder information submitted to the 2nd stakeholder consultation corroborates this conclusion, with one stakeholder reporting that no alternative is available that is comparable in terms of durable protection to fluoropolymer topcoat finishes on PVC-coated fabrics used for outdoor upholstery, marine applications and tents. Alternatives to non-polymeric PFASs used in the underlying coating layer for water and oil repellence purposes and as yarn treatments have not been identified despite ongoing research but alternatives listed by the Dossier Submitters are described as potentially suitable for providing water repellence. One of the seven alternative substance groups, i.e. polyurethane, is deemed to be applicable based on another submission to the 2nd stakeholder consultation reporting the proven use of polyurethane membranes as an alternative to PTFE membranes in outdoor technical textiles.

While application-specific submissions to both the CfE and the 2nd stakeholder consultation explicitly state that no alternatives are available for use in medical textiles, another submission to the 2nd stakeholder consultation reports the proven use of polyurethane membranes as an alternative to PTFE membranes in relation to this application. As for outdoor technical textiles, polyurethane is thus deemed to be applicable for medical textile applications.

With respect to high performance membranes, some individual submissions to the 2nd stakeholder consultation specifically state that alternatives are not available for coalescing filter as well as PTFE-based membranes for the filtration of very fine particles. Another stakeholder reports that some suppliers provide alternatives to PTFE membranes and PFAS-coated products, but that these suppliers use PFASs during the production process. While production without PFASs seems possible, such alternatives still need to be trialled and validated. As for outdoor technical textiles, one of the seven alternative substance groups, i.e. polyurethane, is furthermore deemed to be applicable for high performance membranes based on a submission to the 2nd stakeholder consultation reporting the proven use of polyurethane membranes as an alternative to PTFE membranes in relation to this application.

For outdoor technical textiles, the Dossier Submitters consider based on the above evidence (and the evidence underlying the assessment of alternatives for other TULAC applications) that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives. The evidence is somewhat weaker than for home textiles and consumer apparel due to the existence of some conflicting evidence, e.g. information from the CfE and 2nd stakeholder consultation pointing to the unavailability of alternatives for technical textiles as a whole as well as a lack of comparable alternatives for outdoor technical textiles. Overall, the Dossier Submitters consider, however, that sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives for outdoor technical textiles, for which water repellence is deemed of most importance, exists, e.g.:

- Information from the 2nd stakeholder consultation pointing to the proven use of alternatives for membranes used in outdoor technical textiles, which also highlights their economic feasibility;
- Stakeholder input from the 2nd stakeholder consultation suggesting that alternatives known to the Dossier Submitters could – with respect to water repellence - be suitable as an alternative for non-polymeric PFASs used in coating layers;

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- Sufficiently strong evidence for consumer apparel applications (which are deemed to be comparable to some extent); and
- Evidence for PPE for the protection against rain suggesting that PFASs will not be required to achieve relevant protection standards.

With respect to medical textile applications, the Dossier Submitters consider based on the above evidence that the evidence on the technical feasibility of alternatives for relevant applications is inconclusive. No conclusion on the substitution potential under a full ban with a transition period of 18 months can thus be drawn. As medical textile applications, by definition exclude uses within or on the patients such as bandages and refer to articles such as mattress protectors and curtains around beds, the Dossier Submitters consider that conclusions relating to the substitution potential of home textiles might be relevant to some extent.

With respect to high performance membranes, the Dossier Submitters consider based on the above evidence there is sufficiently strong evidence that technically feasible alternatives do not exist for all types of high performance membranes. The evidence is somewhat weaker than for home textiles and consumer apparel due to the existence of some conflicting evidence, e.g. information from the 2nd stakeholder consultation reporting the proven use of polyurethane membranes as an alternative to PTFE membranes.

Information on whether relevant alternatives are available in the quantities required for use in relevant technical textiles is very limited. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that relevant alternatives exist in sufficient quantities for relevant technical textile applications. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential for outdoor technical textiles is high under a full ban with a transition period of 18 months, while it is low for high performance membranes. The substitution potential for medical textile applications is unclear due to the inconclusive evidence base.

As a result, the following derogation is proposed and further assessed:

- Textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence.

In relation to the sub-use **leather applications**, evidence on alternatives is conflicting to some extent. The desktop research based on the literature sources mentioned above identified three use-specific alternatives for leather applications. (Some of the general alternatives identified for TULAC could also be relevant for these uses). Four of seven alternative substance groups, i.e. hybrid blends of silicones and hydrocarbons, hydrocarbons, polyurethane and silicones, are identified as technically feasible alternatives based on information from literature, the CfE and the 2nd stakeholder consultation. Two of them, i.e. hydrocarbons and polyurethanes, were identified solely based on stakeholder input from a test and research institute submitting information to the 2nd stakeholder consultation. Information from another stakeholder submitting information relating to leather applications in automobiles to the 2nd stakeholder consultation corroborates the conclusion that technically feasible alternatives exist. This stakeholder reports to have started to substitute away from PFASs after having identified an alternative whose oil and soil repellence properties are close enough to PFAS-based products. In relation to automotive upholstery, two further stakeholders report that they are not using PFASs, while three other stakeholders report that alternatives are not technically feasible due to preventing the supply of light-coloured interiors, their inability to provide oil and soil repellence and worse protection against common types of abrasion, such as scratching, marring and rubbing. To what extent these submissions refer to leather (instead of textile) coverings is however unclear. Another stakeholder submitting information in relation to leather-based gloves also reports that the listed alternatives known to the Dossier Submitters are not technically feasible, with particular

concerns being expressed in relation to the lower level of water repellence leading to a requirement to change gloves more often.

The Dossier Submitters consider based on the aforementioned evidence for leather applications and the evidence for consumer apparel pointing to the economic feasibility of named alternatives that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives for leather applications. The evidence is, however, considered to be somewhat weaker than for home textiles and consumer apparel due the existence of some conflicting evidence. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that technically and economically feasible alternatives exist in sufficient quantities for use in leather applications. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high under a full ban with a transition period of 18 months.

As a result, no derogation is proposed and further assessed for leather applications.

In relation to the sub-use **home fabric treatments (sprays)**, the conclusion on the substitution potential is only based on evidence from:

- Literature, including documents developed by industry (e.g. safety data sheets (SDSs) and other documents of known producers/associations), academia (e.g. scientific peer-reviewed literature), non-governmental organisations as well as public actors (e.g. publications of national and environmental agencies and a variety of documents produced for regulatory processes under REACH³¹ and the Stockholm Convention³²).

The desktop research based on the literature sources mentioned above identified one use-specific alternative for home fabric treatments. (Some of the general alternatives identified for TULAC could however also be relevant for these uses). Only silicone-based alternatives are identified as technically feasible alternatives. No information specific to this application was provided during the CfE and 2nd stakeholder consultation.

The Dossier Submitters consider based on the above evidence resulting from an extensive literature review taking into account information from a variety of actors, no contradictory evidence from consultation with stakeholders (and evidence relating to home textiles and consumer apparel) that there is sufficiently strong evidence for the existence of technically feasible alternatives for home fabric treatments. No information on the economic feasibility of alternatives for this specific application is available. Based on evidence for home textiles and consumer apparel pointing to the economic feasibility of the named alternative group, the Dossier Submitters however consider that alternatives are also economically feasible.

Information on whether the alternatives are available in the quantities required for use in home fabric treatments is very limited. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that technically and economically feasible alternatives exist in sufficient quantities for use in home fabric treatments. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high under a full ban with a transition period of 18 months.

As a result, no derogation is proposed and further assessed for home fabric treatments.

In relation to **textiles for the use in automotives, more specifically engine bays, for noise and vibration insulation**, the conclusion on the substitution potential is in contrast

³¹ RMOAs, Annex XV restriction reports, RAC and SEAC opinions.

³² Risk management evaluations, Analysis of Alternative (AoA) reports.

to other sub-uses only based on evidence from:

- The 2nd stakeholder consultation, during which three stakeholders reported the use of PFASs in relation to textiles used in engine bays for insulation purposes. Information on alternatives was only provided by one of these stakeholders.

The literature sources mentioned for other sub-uses³³ were not part of the assessment of alternatives for this use. As this use was identified as part of the 2nd stakeholder consultation, which took place after the desktop research assessing these documents, information on alternatives for this use was not collected from literature. For the same reason, the question in the 2nd stakeholder consultation asking whether the listed alternatives known to the Dossier Submitters are technically feasible in the product/process of the responding stakeholder was not of use for this application.

Information from one stakeholder submitting information to the 2nd stakeholder consultation suggests that the use of PFASs is essential for achieving compliance with noise regulations. Based on information from upstream actors in this stakeholder's supply chain, alternative substances or technologies are not available at the time of preparing this restriction proposal.

The Dossier Submitters consider based on the above evidence that the evidence is weak that technically feasible alternatives do not exist for textiles for the use in engine bays and that the substitution potential is low under a full ban with a transition period of 18 months. The evidence is considered to be weak due to only being based on one source type, i.e. the 2nd stakeholder consultation, and due to being based on information from one stakeholder only.

As a result, the following derogation is marked for reconsideration after the Annex XV report consultation and further assessed:

- [Textiles for the use in engine bays for noise and vibration insulation used in the automotive industry]

E.2.2.3. Environmental impacts

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.2.1, assuming business-as-usual and, consequently, on-going PFAS use and emissions. The analysis of environmental impacts focuses on two restriction options (ROs):

- **RO1**, adopting a ban of all PFAS used in TULAC;
- **RO2**, adopting a ban on PFASs in combination with use-specific derogations. Regarding the duration of the derogations two variants are distinguished, i.e. a 5-year derogation and a 12-year derogation.

Environmental impacts of RO1 are analysed quantitatively. In contrast, for the use-specific derogations emission data were largely lacking. Still, there is information to which PFAS group emissions will belong. Therefore, environmental impacts of RO2 are evaluated qualitatively in relation to maximum additional emission scenarios, i.e. a full derogation of the relevant PFAS groups. Note that these maximum additional emission scenarios do not represent restriction options but are used for comparative purposes only. Table E.15 below summarizes the characteristics of the restriction options, and the maximum additional emission scenarios.

³³ I.e.: Documents developed by industry (e.g. safety data sheets (SDSs) and other documents of known producers/associations), academia (e.g. scientific peer-reviewed literature), non-governmental organisations as well as public actors (e.g. publications of national and environmental agencies and a variety of documents produced for regulatory processes under REACH and the Stockholm Convention).

Table E.15. Characteristics of restriction options and of maximum additional emissions scenarios.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---
RO2 (5 years)	Ban with use-specific derogations	Derogations for defined uses of PFAS in the textile sector, causing additional emissions of PFAAs (C6) incl. PFAA precursors (side-chain polymers), and of fluoropolymers (incl. PFPEs)	18 months	5 years
RO2 (12 years)	Ban with use-specific derogations		18 months	12 years
Maximum additional emission scenario	Ban with full derogation of entire PFAS groups	PFAAs (incl. side-chain polymers); fluoropolymers (incl. PFPEs)	18 months	5 years
Maximum additional emission scenario	Ban with full derogation of entire PFAS groups	PFAAs (incl. side-chain polymers); fluoropolymers (incl. PFPEs)	18 months	12 years

*Maximum additional emission scenarios denote worst-case emission scenarios (assuming a full derogation of a particular PFAS group) against which emissions of proposed use-specific derogations are evaluated qualitatively. They do not represent restriction options.

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, restriction options are expected to be implemented in 2027. All emission estimates represent mean values. Table E.16 shows mean emissions and the expected mean emission reduction for a time path of 30 and 45 years (starting in 2025).

Table E.16. Total mean emissions and emission reduction of RO1 and maximum additional emission scenarios (TULAC sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	1 431 511	---	---
RO1	65 871	1 365 640	95
Maximum additional emission scenario '5-year derogation of all PFAAs incl. PFAA precursors ^{r*}	98 975	1 332 536	93
Maximum additional emission scenario '12-year derogation of all PFAAs incl. PFAA precursors ^{r*}	152 372	1 279 139	89
Maximum additional emission scenario '5-year derogation of all fluoropolymers incl. PFPEs ^{r*}	158 330	1 273 181	89
Maximum additional emission scenario '12-year derogation of all fluoropolymers incl. PFPEs ^{r*}	300 435	1 131 076	79
2025-2070			
Baseline	2 335 403	---	---
RO1	65 871	2 269 532	97
Maximum additional emission scenario '5-year derogation of all PFAAs incl. PFAA precursors ^{r*}	98 975	2 236 429	93
Maximum additional emission scenario '12-year derogation of all PFAAs incl. PFAA precursors ^{r*}	152 372	2 183 031	94
Maximum additional emission scenario '5-year derogation of all fluoropolymers incl. PFPEs ^{r*}	158 330	2 177 073	93
Maximum additional emission scenario '12-year derogation of all fluoropolymers incl. PFPEs ^{r*}	300 435	2 034 968	87

RO1 achieves a total PFAS emission reduction of about 95% of baseline emissions. Environmental impacts of RO2 are discussed qualitatively below for each proposed derogation.

- *Proposed derogation: Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c):*

During stakeholder consultations, three companies in the PPE sector indicated that about 20% of the PFASs used in PPE in the EEA were used in PPEs protecting against Category III risks. The remaining 80% were used in PPE protecting against Category I or II risks. Since these companies account for a small fraction of the market volume (their total annual quantity of PFAS use in PPE articles for the EEA market is approximately three tonnes), these estimates cannot be extrapolated to the entire EEA market for PPE. As a consequence, a precise

quantification of the amount of non-polymeric and polymeric PFASs used in relevant PPE was not possible. Based on existing evidence, an estimation of expected additional emissions assuming a full derogation of the PFAS covered by the proposed derogation (i.e. PFAAs, including PFAA precursors (side-chain fluorinated polymers) and fluoropolymers (in particular PTFEs)) can be provided. A 5-year derogation of PFAAs and PFAA precursors would cause additional emissions of about 1 260 t, and of about 2 700 t assuming a 12-year derogation. Total maximum additional emissions of a 5-year derogation of fluoropolymers including PFPEs would account of about 3 860 t, and of about 5 370 t assuming a 12-year derogation, respectively. While the fraction of PPE use for risk category III in the EEA is small (about 20%, see above), PFAS releases from textile treatment can be assumed to be high (ERC 5, 50% total release). There is **sufficiently strong evidence** that a derogation of PFAS use in PPE (either for 5 or 12 years) will cause substantial additional emissions which are below additional emissions under (worst-case) scenarios.

- *Proposed derogation: Personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m)*

The proposed derogation comprises PFAAs including PFAA precursors (side-chain fluorinated polymers) and fluoropolymers (in particular PTFEs). The evaluation of the quality of available evidence, and of expected environmental impacts, is equivalent to the aforementioned derogation.

- *Proposed derogation: Impregnation agents for re-impregnating of articles referred to above*

The proposed derogation comprises PFAAs including PFAA precursors (side-chain fluorinated polymers). The derogation is proposed corresponding to the potentially exempted uses of PPE (see the aforementioned derogations). The evaluation of the quality of available evidence, and of expected environmental impacts, is equivalent to the evaluation of the first listed derogation.

- *Proposed derogation: Textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence*

The proposed derogation comprises PFAAs including PFAA precursors (side-chain fluorinated polymers) and fluoropolymers (in particular PTFEs). Filters/membranes are likely to cause emissions under the baseline to a lesser extent compared to the first listed derogation, for example due to an assumed lower release factor (ERC 12a, low release), and provided that wear of these filters/membranes occurs under low mechanical impact. If, however, wear occurs under high mechanical impact (ERC12b), emissions from filter/membrane use can be expected to be higher (ERC 20% instead of 2.5%), and may then not be considered negligible. The evaluation of the quality of available evidence and expected environmental impacts of this derogation are nevertheless equivalent to the first listed derogation.

- *Potential derogation marked for reconsideration: Textiles for the use in engine bays for noise and vibration insulation used in the automotive industry*

As mentioned in section E.2.2.1 the assessment does not account for use volumes and emissions relating to textiles used for noise and vibration insulation in automobiles as this use only became known during the 2nd stakeholder consultation and no volume data is available to the Dossier Submitters. The environmental impacts of this derogation could therefore also not be assessed.

Overall, it can be concluded that the reduction of expected environmental impacts is highest under RO1 (full ban of all PFASs after the transition period). Additional emissions resulting from the use-specific derogations proposed can be expected to be significantly smaller

compared additional emissions under maximum additional emission scenarios. It is generally more effective to derogate PFAS groups for a shorter time period (5 years). The reason is obvious – derogations which stretch over 12 years will cause higher additional emissions. Moreover, as illustrated in Figure E.2, the expected market growth in the TULAC sector (see section E.2.2.1 for further details), will cause emissions to increase over time, leading to an increasing PFAS pollution burden in the environment. Furthermore, considering the strong evidence regarding additional emissions from the individual derogations, total emissions of all derogations are likely to be significant, though still much lower compared to the maximum additional emission scenarios.

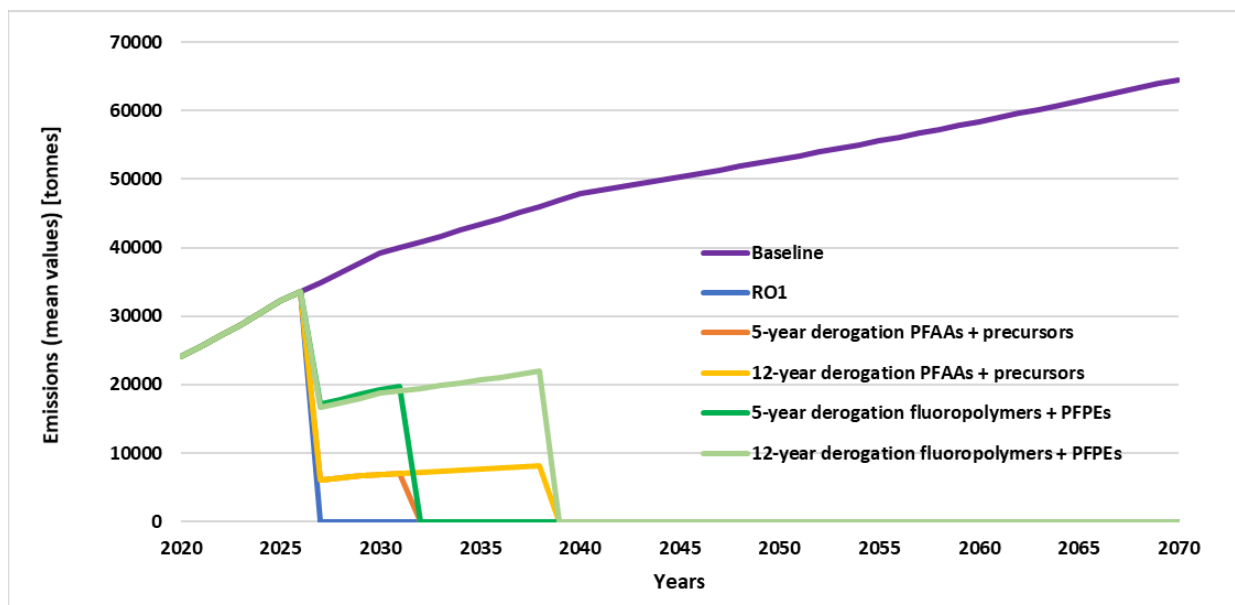


Figure E.2. Time path of mean emissions under the baseline, RO1 and maximum additional emission scenarios (TULAC sector, in tonnes); Source: Own calculations based on data collated by the Dossier Submitters.

E.2.2.4. Economic and other impacts

E.2.2.4.1. Economic impacts: Producer surplus losses

As mentioned in Section E.2.2.2, the availability of technically feasible alternatives is one key factor determining the economic impacts associated with a restriction as it determines the options available to affected companies to achieve compliance, e.g. substitution or complete closure of business (or business unit).

Depending on the reaction chosen by affected companies, different types of costs are faced. A company that substitutes, for example, faces Research & Development (R&D) 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 PFAS 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. If the ability to pass on costs to customers is limited, e.g. due to high competition, companies will face profit losses. A company that stops production in response to the restriction also faces profit losses – although at a higher magnitude. In addition, it might face costs in relation to dismantling plants.

Given the difference in the type of costs incurred by companies depending on their reaction, the total economic impacts on affected companies in each sub-sector depend on four factors, i.e.:

- The number of companies in each sub-sector that is affected by the restriction;
- The most likely reaction of affected companies in each sub-sector, i.e. the share of companies that substitute or stop production;
- The cost that a company faces as a result of substitution or a stop of production; and
- The ability of companies that substitute to pass on higher costs to their customers.

Limited information on the **number of affected companies in relevant TULAC sub-sectors** is available. Based on information from a briefing of the European Environment Agency, published in 2019, around 171 000 companies are active in the textile industry, including the apparel industry (EEA, 2019). According to EURATEX (2022), the number of active companies has decreased since, with around 143 000 companies estimated to have been active in the textile and clothing industry in the EU-27 as of 2021, with a turnover of €147 billion. This includes fabric producers, producers of man-made fibres and yarns as well as producers of home textiles, knitwear producers, producers of clothing and accessories, underwear, workwear as well as industrial and technical textiles. Around 67% of those companies are reported to be active in the clothing industry with a turnover of €65.3 billion, while the remaining approximately 48 000 companies are active in the textile industry, which, amongst others, includes the production of man-made fibres. While a more precise split on the number of companies per sub-sector is not provided, EURATEX (2022) reports that the leading contributors to total EU-27 production are the clothing and accessories industry (accounting for 31%) as well as the industrial and technical textile industry (accounting for 17% of total EU-27 production), as shown in Table E.17, which also provides information for the other industry branches.

Assuming that the share of total EU-27 production is a representative indicator of the number of companies in each industry sector, the Dossier Submitters estimated the number of companies active in each TULAC sub-sector. The number of companies associated with each of the industry branches mentioned by Euratex is presented in Table E.17, while Table E.18 provides an overview of the number of companies per TULAC sub-sector.

Table E.17. Estimated number of companies in different Euratex industry branches based on EU-27 production shares for 2021.

	Share of EU-27 production (according to EURATEX (2022))	Estimated number of companies (rounded to the nearest 100)	Relevant TULAC sub-sector
Clothing & accessories	31%	44 800	Consumer apparel
Industrial & technical textiles	17%	24 500	Technical textiles
Fabrics	15%	21 700	---
Home textiles	14%	20 200	Home textiles
Knitwear	6%	8 700	Consumer apparel
Man-made fibers	5%	7 200	---
Yarns	5%	7 200	---
Underwear	4%	5 800	Consumer apparel
Workwear	2%	2 900	Professional apparel

Linking industry branches reported by Euratex with TULAC sub-sectors in the way described in the right-hand column of Table E.17, the Dossier Submitters estimate that around 59 300 companies are active in the consumer apparel sector, as shown in Table E.18. The lowest

number of affected companies is estimated for the professional apparel industry. As the underlying data from Euratex is related to workwear, the estimated number of companies for professional apparel is deemed to cover PPE only, while companies producing professional sportswear and footwear are deemed to be covered by the estimate for consumer apparel.

Table E.18. Estimated number of companies in different TULAC sub-sectors.

Sub-use	Estimated number of companies (rounded to the nearest 100)
Home textiles	20 200
Consumer apparel	59 300
Professional apparel	2 900
Technical textiles	24 500
Leather	No information available
Other	No information available

While the estimated numbers of companies per sub-sector need to be treated with caution given the lack of specific information on the extent to which specific sub-sectors are dominated by a small number of key market players instead of being constituted by a number of companies with a comparable production volume, the general picture of more companies being active in sectors with less specialisation requirements, e.g. consumer apparel, is in line with general expectations of the Dossier Submitters. This is due to the fact that barriers to entry such as time- and cost-intensive certification requirements are generally lower in such sectors encouraging market entry of new actors. In addition, industrial/institutional downstream users purchasing highly-specialised TULAC products for their applications, e.g. high performance membranes and PPE, might be more inclined to continue purchasing products from well-known and renowned suppliers than new suppliers entering the market in comparison to households purchasing products like home textiles and consumer apparel. In light of these considerations, the number of companies estimated to be active in the technical textile industry based on Euratex data might be deemed rather high given the expected significant barriers to market entry in relation to some types of technical textiles, e.g. high performance membranes. As the technical textile sector, however, incorporates several specialised sub-sectors, including sectors with likely less barriers to entry such as the market for outdoor technical textiles, the existence of a high number of companies cannot be ruled out.

According to EURATEX (2022), nearly 89% of companies active in the textile and clothing industry in the EU-27 are micro companies with up to nine employees, while 11% are small and medium-sized enterprises with up to 250 employees. Only 0.2% of companies are large companies with more than 250 employees.

The number of companies producing articles containing PFAS could not be identified by the Dossier Submitters. According to information received in the CfE, the major users of PFASs are companies producing consumer apparel followed by the home textile sector and technical textile sector. Neither information received during the CfE, nor information collected during the 2nd stakeholder consultation allowed for an estimation of the affected number of companies per sub-sector.

While no information on the number of affected companies is available, information on the share of production and the associated estimation of the number of companies in each sector (presented in Table E.17 and Table E.18) and information from the CfE (described above) indicating that the major users of PFASs are companies producing consumer apparel followed by home textiles and technical textiles suggests that the total number of affected companies might be highest in these industry sectors.

Quantitative information on the **most likely reaction of affected companies in each sub-sector**, i.e. the share of companies that substitute or stop production, is limited. While

industry was asked in the 2nd stakeholder consultation to indicate what the economic and social impact in terms of changes in employment numbers would be for their organisation if a restriction would take effect in three years, the Dossier Submitters deemed the number of companies providing information too low for developing representative quantitative estimates on the share of affected companies that would substitute rather than cease operation. The information received during the 2nd stakeholder consultation was however used to develop an overview of potential differences between sub-sectors with a view of supplementing conclusions that can be drawn based on information on the availability of technically feasible alternatives and the substitution potential (presented in section E.2.2.2). For this purpose, companies were allocated to relevant TULAC sub-sectors based on the provided description of their specific use, or where this was not provided, additional online research on the company. The most likely reaction of each company was then either directly determined based on a clear indication on the reaction provided through the description of economic impacts or, where this was not available, deduced from the information that the stakeholder provided in response to the questions on:

- Whether the listed non-PFAS alternatives are technically feasible in the process/product of the stakeholder;
- Whether the listed non-PFAS alternatives are economically feasible in the process/product of the stakeholder; and
- Whether the stakeholder company is actively working on finding alternatives.

With respect to home textiles, only one stakeholder provided information, which precludes a meaningful conclusion on the extent of companies that would substitute rather than stop production. Similarly, no meaningful conclusion can be drawn for leather applications in relation to clothes and accessories, while information provided in relation to textile and/or leather uses for automotive interiors in the passenger compartment reveals a trend towards business closures. Information provided by five stakeholders active in the consumer apparel industry suggests a mix of reactions in response to a proposed restriction of PFASs, with a rather equal split between companies indicating that they do not need to take any action, as they have already completed the transition, and companies implementing an alternative or closing their business (or business unit). Information provided in relation to the production of professional apparel and technical textiles (which is dominated by information relating to high performance membranes) suggests a clear tendency towards closure of business as reaction to a complete ban of PFASs with very few or no respondents already using alternatives or being expected to substitute in response to the restriction proposal based on the information provided. While this information provides some useful additional evidence, the conclusions should be treated with caution given the aforementioned small sample size and likely response bias – with companies facing business closures being thought to disproportionately respond to the 2nd stakeholder consultation (in comparison to companies that substitute) in an attempt to provide evidence for derogations and companies that face no major changes being more likely to not respond to the 2nd stakeholder consultation.

Information on the most likely reactions of stakeholders active in different sub-sectors derived from the 2nd stakeholder consultation should thus be used in conjunction with conclusions that can be drawn based on the technical feasibility of alternatives. Table E.19 therefore provides an overview of conclusions that can be reached based on the stakeholder consultation on the economic impacts and information on the availability of technically feasible alternatives.

Table E.19. Broad assessment of most likely reaction of affected companies in different TULAC sub-sectors to the restriction of PFAS.

Sub-use	Conclusion on most likely reactions based on information on technical feasibility of alternatives and substitution potential (Source: CfE and 2 nd stakeholder consultation, stakeholder consultation interviews, consulted literature)	Conclusion on most likely reactions based on information on economic impacts at company level (Source: 2 nd stakeholder consultation)
Home textiles	Mainly substitution, due to: • Five of seven alternative substance groups being identified as relevant; • Products based on alternatives already being available on the market, which points to the economic feasibility of identified alternatives as well as customer acceptance (despite potential difference in functionality)	No conclusion on trend possible
Consumer apparel	Mix of substitution and closure of business assumed, due to: • Six of seven alternative substance groups being identified as relevant; • Products based on alternatives already being available on the market, which points to the economic feasibility of identified alternatives as well as customer acceptance; • The consumer apparel sector being the sector with the most pronounced trend to substitution as a result of voluntary industry commitments and consumer pressure; • Successful substitution by both high-end and low-end brands; and • A good technical feasibility of alternatives as functions other than water repellence are not deemed to be critical for this use. Given the high market penetration of alternatives, substitution is however deemed to be a less promising endeavour for companies that still use PFASs. Such companies face potentially significant competition of stakeholders that have already successfully substituted and might be able to offer products at lower prices, e.g. due to having completed the amortization of R&D and capital costs. As a result, some business closures might occur.	Rather equal split between companies indicating that they do not need to take any action, as they have already completed the transition, and companies implementing an alternative or closing their business This information supports the conclusion that a high share of companies affected by the restriction might stop operating despite the availability of technically feasible alternatives.
Professional apparel	Mix of substitution and closure of business, with some tendency towards business closures (especially in relation to PPE) assumed due to: • Five of seven alternative (substance) groups having been identified as relevant for professional sportswear and footwear and four of seven groups having been identified as relevant for PPE; and • The conclusion of the Dossier Submitters that technically feasible alternatives do not seem to exist for several Category III PPE applications.	Information provided in relation to the professional apparel industry suggests a clear tendency towards business closures as reaction to a ban of PFASs with very few or no stakeholders submitting information already using

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Sub-use	Conclusion on most likely reactions based on information on technical feasibility of alternatives and substitution potential (Source: CfE and 2 nd stakeholder consultation, stakeholder consultation interviews, consulted literature)	Conclusion on most likely reactions based on information on economic impacts at company level (Source: 2 nd stakeholder consultation)
		alternatives or being expected to substitute in response to the restriction.
Technical textiles	Mix of substitution and closure of business, with tendency towards business closures assumed for some applications, e.g. high performance membranes, due to: • Limited implementation of alternatives on the market; • Information pointing to challenges with the replication of the multitude of functionalities simultaneously provided by PFASs; but • Stakeholder information pointing to the proven use of an alternative in relation to all types of technical textiles; and • A good substitution potential for outdoor technical textiles (despite differences in functionality) as described in Section E.2.2.2.4.	Information provided in relation to the technical textile industry (which is dominated by information relating to high performance membranes) suggests a clear tendency towards business closures as reaction to a ban of PFASs with very few or no respondents already using alternatives or being expected to substitute in response to the restriction.
Leather	Mainly substitution, due to: • Four of seven alternative substance groups being identified as technically feasible; • Products based on alternatives being implemented on the market, e.g. for automotive interiors; and • Alternatives being identified that allow for the provision of functionalities beyond water repellence at a comparable level, which was initially thought to be a concern. The identification of relevant alternatives by some stakeholders is thought to encourage other stakeholders to invest in R&D efforts as the perceived chance of success increases. The seemingly more limited market penetration of alternatives facilitates winning market shares, which might be a further encouraging factor for affected companies.	No conclusion on trend possible
Other: Home fabric treatments (sprays)	Mainly substitution, due to: • Silicone-based alternatives having been identified as relevant; and	No relevant information provided

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Sub-use	Conclusion on most likely reactions based on information on technical feasibility of alternatives and substitution potential (Source: CfE and 2 nd stakeholder consultation, stakeholder consultation interviews, consulted literature)	Conclusion on most likely reactions based on information on economic impacts at company level (Source: 2 nd stakeholder consultation)
	• Home textiles based on alternatives already being available on the market, which points to the economic feasibility of identified alternatives as well as customer acceptance of potential differences in performance (in relation to functions other than water repellence)	
Other: Automotive use - Noise and vibration insulation	Mainly business closures assumed, due to: • No alternatives being known; and • Implementation of alternatives, if/once identified, being described as a time-consuming process.	No relevant information provided

In addition to the above considerations, the extent of affected companies that opts for substitution rather than ceasing their operations in response to a proposed restriction of PFASs is affected by the **time that is required for completing substitution and implementing the product on the market**. If the required timeframe conflicts with the expected entry-into-force of the restriction proposal, business closures are imminent even if technically feasible alternatives exist. Based on the expected entry-into-force of the proposed restriction in 2025 and a standard transition period of 18 months for all sectors, substitution processes requiring a timeframe significantly exceeding 3.5 years are therefore deemed to trigger business closures.

With respect to home textiles, one stakeholder submitting information in relation to PFAS-based processing aids for carpet production to the 2nd stakeholder consultation reports that three to five years are needed for completing the transition once a suitable alternative is identified. Given that the minimum timeframe reported in the 2nd stakeholder consultation is in line with the timeframe available until the expected entry-into-force date of the proposed restriction and that substitutions in this sector have already been undertaken or are in progress, e.g. as a result of voluntary industry commitments described in Section E.2.2.2, business closures are expected to be triggered by the perceived market potential rather than concerns in relation to the timeframe available for substitution.

With respect to consumer apparel, one stakeholder submitting information for footwear applications to the 2nd stakeholder consultation notes that two to three years are required for completing the substitution process once an alternative has been identified as suitable. Due to many successful examples of completed transitions away from PFAS and the reported timeframe being in line with the timeframe available until the expected entry-into-force date of the proposed restriction, business closures are expected to be triggered by the perceived market potential rather than concerns in relation to the timeframe available for substitution.

The timeframe of two to three years for completing the substitution process in footwear applications is also reported to be applicable for footwear application in regulated areas, i.e. in PPE.

Another stakeholder submitting information to the 2nd stakeholder consultation in relation to PPE indicates that the development of a new product based on an alternative is not the most time-consuming aspect in the substitution process. Problems with respect to time rather arise in relation to the certification of products and products that are already on the market. According to the stakeholder, the normal life cycle of PPE consists of many years, with PPE that is already on the market relying on re-impregnation. If re-impregnation is not possible as a result of the restriction, the protective performance of products is lost and products need to be replaced. As a result, complete substitution to PPE that does not rely on the use of PFAS is reported to take several years. Another stakeholder submitting information to the 2nd stakeholder consultation specifies that one to two years are required for certification, including dossier preparation and testing, once a product has been designed that meets the requirements of relevant EU regulation for PPE. With respect to PPE providing protection against splashes of liquid chemicals in line with EN 13034 Type 6, the certification process is reported to take around four months on average by a stakeholder submitting information to the 2nd stakeholder consultation. While this is a category of PPE for which PFASs are deemed to be required to achieve certification levels according to the Dossier Submitters' analysis presented in Table E.13, it provides a good indication of the approval time required for other PPE categories for which substitution is deemed feasible. A manufacturer of PPE for industrial applications and fire-fighters furthermore suggests that three years are required for achieving approval of PPE using alternatives to PFAS.

Further information on the overall timeframe required for substitution, not only for certification, is also available from the 2nd stakeholder consultation. One stakeholder estimates that 12 to 18 months are needed once a suitable alternative has been identified – with relevant steps including wash tests and certification for fabrics as well as garments. Another stakeholder submitting information in relation to PPE to the 2nd stakeholder

consultation also mentions that fabrics must be approved for application in garments before these can be placed on the market. All intermediary producers along the supply chain are reported to require time to conduct relevant tests and carry out approvals. This process is estimated to take between 18 and 36 months. Additional time is reported to be required afterwards for scaling-up processes. In line with this estimate, one stakeholder providing information on face masks in consultation prior to the 2nd stakeholder consultation suggests that at least three years are needed to adopt alternatives once the feasibility of alternatives is demonstrated.

As timeframes for completing substitution processes reported by different stakeholders all refer to timeframes of less or around three years, business closures are not expected to be triggered by concerns in relation to the timeframe required for substitution alone.

With respect to technical textiles for medical applications, such as surgical gowns, any changes to products made must be properly assessed under the Medical Device Regulation (EU Regulation 2017/745) with a view of determining potential implication on the safety and efficacy of the product. Regulatory requirements range from internal documentation to complete re-approval. According to a stakeholder submission to the 2nd stakeholder consultation, the average approval time for surgical gowns varies from days up to several years depending on the significance of the change. More specific information is provided by two other stakeholders submitting information for medical textile applications to the 2nd stakeholder consultation. According to one stakeholder, who also refers to legal re-qualification requirements when new substances are employed in the medical sector, approval of products under legal approval schemes takes between three and ten years on average. The other stakeholder notes that fabrics used in such applications must pass tests before being placed on the market. As for PPE, all intermediary producers along the supply chain are reported to require time to conduct relevant tests and carry out approvals – with between 18 and 36 months being required for this process based on the stakeholder's best knowledge. Additional time is reported to be needed for scaling-up processes afterwards. Based on the large variation in required timeframes reported for medical textiles, with estimates ranging from days to ten years for approval alone, no clear conclusion on the required timeframe for substitution can be drawn by the Dossier Submitters.

The timeframe of 18 to 36 months for tests and approval along the supply chain reported for medical textiles is also reported to be relevant for filtration applications. Another stakeholder submitting information to the 2nd stakeholder consultation reports a much shorter time frame for approval. Approval of filtration media in line with the VDI 3926 test³⁴ is reported to take three months on average. Information on the total timeframe required for substitution is also available from both stakeholder consultation efforts preceding the 2nd stakeholder consultation and the 2nd stakeholder consultation itself. A stakeholder providing information based on its past experience with substitution from C8 to C6 substances in filtration applications reports that substitution took eight to ten years. A supplier of filters for mist and dust removal in a variety of industrial applications submitting information to the 2nd stakeholder consultation reports a shorter timeframe of at least three years for commercializing the alternative technology and receiving customer validation and approval. Substitution might thus be feasible in the timeframe available until the restriction takes full effect but some uncertainty prevails – especially based on practical experiences from the past.

Textile- or leather-based coverings in automotive interiors are also subject to validation and certification requirements prolonging the required timeframe for substitution and implementation of new alternative-based products on the market. A stakeholder submitting information to the 2nd stakeholder consultation notes that re-design of products needs to be complemented with re-validation of all products according to the technical specifications of original equipment manufacturers (OEMs) as well as re-certification according to International

³⁴ The VDI 3926 test is a standard test for the evaluation of cleanable filter media. It is a standard developed by the "Verein Deutscher Ingenieure e.V" which translates as association of German engineers.

Automotive Task Force (IATF) standards. The average approval time in this sector is described as two to four years, with complete transition to the alternative requiring up to five years. In contrast, another stakeholder submitting information to the 2nd stakeholder consultation, reports that more than one year would be required for completing the transition to the alternative once a suitable alternative is identified. For other leather applications, e.g. gloves, a stakeholder submitting information to the 2nd stakeholder consultation reports a timeframe of two to three years for completing substitution once a suitable alternative is known. In conclusion, substitution is deemed to be feasible for the majority of relevant application in the timeframe until the restriction takes full effect as several stakeholders report timeframes of less than or around three years. While information for automotive applications also refers to longer timeframes, such timeframes are deemed to represent an indication of the maximum time required given the complexity and high certification needs associated with automotive applications. Such timeframes are thus not deemed to be relevant for the entire leather industry. Business closures are thus expected to be triggered by the perceived market potential rather than concerns in relation to the timeframe available for substitution.

As mentioned above, the **cost that a company faces as a result of substitution or a stop of production** is an additional key determinant of the total economic impacts on affected companies resulting from the proposed restriction.

With respect to **business closures**, the extent of producer surplus/profit losses faced by TULAC-producing companies depends on both the typical annual sales volume of companies in each industry sector as well as the margin in the sectors, i.e. the difference between production costs faced by a company and the revenue resulting from the typical annual sales volume.

Information on sales losses at company level has been received during the 2nd stakeholder consultation in which stakeholders were asked to provide information on the economic impact on their company if the use of PFASs is prohibited in three years. While the sample of quantitative estimates is limited and has been further reduced by unclarities with respect to the nature of the numbers reported by stakeholders, e.g. unclarity on whether reported numbers refer to annual sales values or sales values over several years, they provide some insights into sales values in different sub-sectors. For all relevant TULAC sub-sectors, Table E.20 presents the number of company-specific estimates for sales losses provided as well as the relevant range.

Table E.20. Range of sales losses resulting from business closures based on information provided in the 2nd stakeholder consultation.

Sub-use	Sample size, i.e. number of companies providing useable quantitative information on sales losses	Reported annual sales losses in million euro	Reported annual sales losses in million euro
		Minimum	Maximum
Home textiles	n/a	n/a	n/a
Consumer apparel	n/a	n/a	n/a
Professional apparel	6	1.2	200
Technical textiles	5	10	50
Leather	n/a	n/a	n/a
Other: Home fabric treatments (sprays)	n/a	n/a	n/a
Other: Automotive use - Noise and vibration insulation	n/a	n/a	n/a

Based on the information submitted to the 2nd stakeholder consultation, it thus seems reasonable to assume that sales losses as a result of business closures range from a few million to several hundred million euros per company. No information on significant differences in annual sales values between different sub-sectors is available to the Dossier Submitters.

Producer surplus/profit losses to companies active in the TULAC industry resulting from business closures are dependent on the margin in the sector, i.e. the difference between production costs and revenue, which might differ between sub-sectors. If margins are low, the impacts from foregone sales on companies active in the sector will be less pronounced. Regardless of the margin, business closures could furthermore have wider impacts on industry through indirect impacts on companies active in the supply chain whose sales revenues could also be negatively affected. Such indirect impacts on industry will be most pronounced for sub-sectors, where the market penetration of alternatives is low and business closures are the dominant reaction of affected companies as the extent to which market shares of companies ceasing operation will be taken over by other EU companies active in the TULAC industry, i.e. early adopters of alternatives, is more limited. As a result, the impacts on the wider industry will not only include impacts on producers of PFASs but also suppliers of other production inputs, e.g. synthetic fibres. An assessment of the expected extent of indirect impacts on industry in relation to different sub-sectors is provided in Table E.24.

While no quantitative information on typical margins is available to the Dossier Submitters, some indications can be provided based on a general understanding of the level of competition in different sub-sectors - with highly competitive industries with a high number of active companies usually having lower margins than industry sectors with a very limited number of active companies. Mass markets producing goods for the general public, i.e. the home textile industry, consumer apparel industry as well as the leather industry are deemed to be industries with generally low margins given the high number of relevant companies and the price-sensitive nature of the market, in which price is thought to be a key factor considered by the customer in its purchasing decision. Variations in margins can however be expected in these sub-sectors due to the existence of high-end and low-end brands. Overall, margins in relation to textiles for use in engine bays of automobiles and the professional apparel and technical textile industry are deemed to be higher than in the aforementioned industry sectors given the smaller target market for many product types, e.g. professional sportswear and footwear and PPE, and/or higher up-front costs for suppliers, e.g. in relation to R&D costs for more complex products and certification costs, which suppliers will likely aim to recoup through higher margins. Higher up-front costs are deemed to be especially relevant in relation to PPE, high performance membranes as well as textiles for the use in engine bays. Given the higher barriers to entry into the market, e.g. due to certification needs for several product types, competition in these market segments is also deemed to be lower than, for example, in the home textile and consumer apparel industry, enabling higher price margins. As a result, company closures in the professional apparel and technical textile industry (especially in relation to high performance membranes) as well as in relation to textiles for the use in engine bays are deemed to be associated with higher producer surplus losses per company than company closures in the home textile, consumer apparel and leather industry. Margins for outdoor technical textiles are deemed to be lower than for other technical textiles due to the larger target market, with products being of relevance for the general public and the more price-sensitive nature of the market.

Information on potential costs associated with dismantling plants as well as potential difference across sub-sectors is not available. It is also unknown to what extent companies stopping production in response to the restriction can recoup losses from premature retirement of their production assets through sale³⁵, scrappage³⁶ or deployment.

³⁵ A production asset has resale (or salvage) value if it can be sold to a new user in its existing form.

³⁶ A production asset can be considered to have scrap value if it cannot be sold in its current form, and

Information on the margins in different industry sectors is also beneficial for understanding the magnitude of producer surplus losses resulting from **substitution** given that they are one factor determining the extent to which companies internalize substitution costs instead of passing them on to their customers. High margins providing opportunities to internalize costs without endangering profitability might encourage affected companies to opt for substitution rather than business closure even if high up-front investments, e.g. for R&D activities, are required. The decision on whether costs will be internalized or passed on to customers will however also be dependent on an understanding of the extent to which customers in each sector and their demand for the product is sensitive to price changes. Confidence about the possibility of charging higher prices to customers, without undue sales reductions, might also encourage affected companies to opt for substitution rather than business closure. Margins as well as the price elasticity of demand³⁷ in different sub-sectors thus play a crucial role in determining whether affected companies opt for substitution and whether they would bear the costs associated with substitution in the form of producer surplus losses or whether these costs would rather be borne by customers through increased product prices.

Given these interlinkages, Table E.21 provides an overview of the Dossier Submitters' conclusions on margins and the price elasticity of demand in different sub-sectors and the associated implications in relation to the share of affected companies opting for substitution and the relevant actors in society that will likely face the costs of the restriction. A low margin might negatively impact the share of substitution by discouraging affected companies from opting for substitution given that it is more likely that substitution endangers the profitability of their business. A high price elasticity of demand might also negatively impact the share of substitution as companies know that they will not be able to easily recoup the costs incurred for R&D activities, whose outcome is uncertain, as well as potential investments in new machinery by increasing prices charged to their customers. Companies would instead have to accept a negative impact on their margins. A low price elasticity of demand, in turn, might encourage affected companies to make the necessary investments and opt for substitution - especially if positive examples of substitution exist - as they are aware that there is likely a good opportunity for recouping the costs at a later stage. A low price elasticity of demand also makes it more likely that costs will be fully passed on to customers, especially if the profit margin is already low. If the price elasticity of demand is high, while profit margins are low, companies might, in contrast, try to limit cost increases for customers as much as possible and pass on only a share of the costs.

instead can only be sold for parts (in particular, chemical process equipment is often made of high-grade steel that may have a robust scrap value).

³⁷ The price elasticity of demand indicates the extent to which the quantity demanded changes due to a price change, assuming that other factors that influence demand are unchanged.

Table E.21. Margins in different TULAC sub-sectors, possible implications on the share of affected companies opting for substitution and actors facing the costs resulting from substitution.

Sub-use	Size of profit margin	Price elasticity of demand *	Possible implications on share of affected companies opting for substitution	Expected extent to which companies pass on costs to customers *
Home textiles	Low	High	Negative	Partial
Consumer apparel	Low	High	Negative	Partial
Professional apparel	High	Low	Positive	High
Technical textiles	High, for high performance membranes	Low, for high performance membranes	Positive, for high performance membranes	High, for high performance membranes
	Low, for other outdoor technical textiles and medical applications	High, for outdoor technical textiles and medical applications	Negative, for outdoor technical textiles and medical applications	Partial, for outdoor technical textiles and medical applications
Leather	Low	High	Negative	Partial
Other: Home fabric treatments (sprays)	Low	High	Negative	Partial
Other: Automotive use - Noise and vibration insulation	High	Low	Positive	High

* The price elasticity of demand is deemed to be the crucial determinant of the ability of companies to pass on costs. Together with the margin, it determines the extent to which companies are expected to pass on costs in each sub-sector. The conclusions of the Dossier Submitters on this aspect differ from the conclusions drawn in a consultancy report titled "The use of PFAS and fluorine-free alternatives in textiles, upholstery, carpets, leather and apparel", that was produced for the European Commission (Directorate General for Environment) and published in October 2020. The report concludes in the table titled "Evaluation of potential alternatives by TULAC use category" that the ability for passing on costs is high for the home textile and consumer apparel industries, medium for the leather industry and low for the professional apparel and technical textile industries. The main argument for the low and medium ability are differences in the level of competition faced from outside the EU, with "significant competition" being reported for sectors for which a low ability to pass on costs is reported and "some competition" being reported for sectors for which a medium ability to pass on costs is reported (Wood, 2020b). In contrast, the Dossier Submitters conclude that the ability to pass on costs is:

Low (not high, as reported in Wood (2020b)) for home textiles and consumer apparel as a result of the high price elasticity of demand;

High (not low, as reported in Wood (2020b)) for professional apparel and technical textiles as a result of the low price elasticity of demand; and

Low (not medium, as reported in Wood (2020b)) for leather due to the high price elasticity of demand.

The Dossier Submitters do not consider competition to be a key determinant of the price elasticity of demand (and consequently the ability to pass on costs) and rather considers it to be a key determinant of the profit margin. Sectors with high levels of competition usually have lower margins than sectors of an oligopolistic or monopolistic nature. The Dossier Submitters also deem the level of non-EU competition for the home textile and consumer apparel to be comparable if not higher than for other sectors and therefore does not agree with the assessment of competition levels in Wood (2020b). As the proposed restriction would also apply to imported articles, the Dossier Submitters also consider it more relevant to assess the level of competition with EU actors that already produce PFAS-free products than with non-EU actors. Many companies in the consumer apparel industry have, for example, already substituted and offer PFAS-free products, which is deemed to increase pressures on price (for reasons further described below) and limit the ability of actors that will substitute in response to the restriction to pass on costs.

Especially in the consumer apparel industry, the ability to pass on costs to customers is also deemed to be limited by competition with companies that have already substituted. Many companies, including well-known brands, already have substituted away from PFASs. Such companies will likely be able to offer their products at increasingly lower prices over time following upscaling of their processes, e.g. as a result of increasing demand for their products, and the associated decreasing marginal costs, and as a result of having completed the amortization of R&D and capital costs. Companies substituting to alternatives in response to the restriction are thus expected to face high pressures in relation to price, which limits their ability to pass on costs. This limited ability to pass on costs as a result of (i) the expected high price elasticity of demand, (ii) generally low margins, and (iii) price pressures resulting from competition with EU companies that have already adopted alternatives increases the producer surplus losses that a company opting to substitute might face. In addition to the loss in producer surplus from internalizing investment costs, such companies might also face producer surplus losses from losing (parts of) their market share to EU companies which already adopted alternatives prior to the announcement and implementation of the restriction, e.g. due to a more renowned brand profile for their products.

Total costs incurred by a company in relation to substitution comprise:

- Costs associated with research on alternatives and re-development of products;
- One-off costs for new equipment; and/or
- Changes in operating costs, e.g. higher raw material costs resulting, for example, from differences in the unit cost of the alternative in comparison to the cost of PFASs or a higher volume of the substance being required.

With respect to the **costs associated with Research & Development (R&D)**³⁸, very limited information on the costs incurred by an affected company is available. While one stakeholder submitting information to the CfE reported that the company invests an estimated 5% to 6% of their annual sales value into R&D activities each year to develop new and innovative solutions, it is not clear to what extent such a budget would be sufficient for research on alternatives to PFASs and product re-development. The Dossier Submitters also assume that such costs might vary significantly between sectors, with R&D activities in relation to applications with more complex functionality requirements being deemed more time-intensive and costly than R&D activities in relation to products that, for example, only require water repellence. R&D costs incurred by companies in the home textile, consumer apparel and leather industry are therefore deemed to be lower than costs incurred by companies supplying professional apparel (especially PPE), technical textiles (especially high performance membranes) and textiles for use in engine bays of automobiles.

In relation to **capital costs**, i.e. costs for new equipment, manufacturers of alternatives

³⁸ It is important to note that R&D costs also constitute an investment in an intangible asset that may have value to the company.

indicated that alternative textile finishes are applied in the same way as PFAS-based textile treatments. Minimal costs in relation to the purchase of new equipment are therefore anticipated by the Dossier Submitters. Additional information on this aspect was not received during the CfE and 2nd stakeholder consultation. No information is available on whether different types of equipment are required for using alternatives in relation to other relevant applications, e.g. membranes. The use of alternatives is however reported to be associated with longer processing times. This increase in processing times could affect production capacities and result in the need for additional machinery. The extent to which production capacities are affected and the costs associated with equipment used by companies in the sector is, however, unknown.

While some information on **changes in operating costs** resulting from differences in unit costs of alternatives in comparison to PFASs and differences in required volumes is available, quantitative information on cost differences between PFAS- and alternative-based textile treatments is a key data gap.

For fluoropolymers, information provided by one stakeholder during the CfE suggests that fluoropolymer applications are not motivated by price but solely functionality considerations. The use of polymers is reported to be limited to special applications - with fluoropolymers being replaced by cheaper alternatives wherever possible given that their use has no economic advantages. As a result, increases in operating cost due to higher unit costs of alternatives are deemed unlikely by the Dossier Submitters in relation to uses of fluoropolymers. Information from the 2nd stakeholder consultation that the production costs of polyester- or polyurethane-based membranes are lower than that of PTFE-based membranes supports this conclusion.

In addition, some information on differences in unit prices and volumes required in comparison to PFAS is available for five of the seven substance groups identified as suitable alternatives, as shown in Table E.22.

Table E.22. Information on differences in unit prices and loading of alternative substance groups in comparison to PFAS.

Chemical group	Loading (in comparison to PFAS)	Absolute price of alternative (€/kg)	Unit purchasing price (in comparison to PFAS)
Dendrimer	Much higher Application volume is two to four times higher, according to information from manufacturer	~€10/kg (for Ruco-Dry Eco) Cost depends on application, country, purchase quantity and customer, according to information provided by manufacturer	n/a
Hybrid (Silicone/ Hydrocarbon)	Higher UNIPERL dosage is higher than average fluorocarbon dosage, according to information provided by manufacturer	~ €10/kg (for UNIPERL HDS)	n/a
Hydrocarbons	Higher	€15-20/kg (for Zelan™), according to stakeholder interview	n/a

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Chemical group	Loading (in comparison to PFAS)	Absolute price of alternative (€/kg)	Unit purchasing price (in comparison to PFAS)
Nanotechnologies	n/a	n/a	<15% higher, according to information provided by manufacturer for Plasmaguard Part 3 product But no increase in cost per unit on finished goods
Polyurethane	n/a	n/a	Lower (in comparison to fluoropolymers)
Silicones	n/a	n/a	n/a
Alternative technologies	n/a	n/a	n/a

With respect to applications of PFASs for the purpose of water repellence, consultation with manufacturers of alternatives indicates that the overall raw material cost associated with using an alternative is more or less the same as the raw material cost associated with PFAS. While unit prices of alternatives providing water repellency is lower in some cases, the amount of the substance that is required can be up to 50% higher in comparison to C6 technologies leading to broadly comparable costs. This is in line with conclusions drawn by EPA-DK (2015) which concludes that alternatives provide acceptable functionality at comparable costs in applications where oil and alcohol repellence as well as repellence of oil-based dirt is not required.

In relation to textile treatments, increases in operating costs are however expected. In interviews conducted in support of the preparation of the dossier, it was indicated that the use of alternatives could lead to textile maintenance requirements which could impact the processing cost.

Information specific to textile and non-woven treatment auxiliaries for textile finishes that are based on side-chain fluorinated polymers was also provided in the 2nd stakeholder consultation. In line with the information provided above in relation to water repellence, alternatives to side-chain fluorinated polymers providing water and oil repellence are reported to be cheaper. The stakeholder, however, reports that the use of alternatives leads to higher raw material costs overall due to higher dosage requirements, with required volumes being around twice as high as for side-chain fluorinated polymers. Increases in other operating costs are also described. As a result of a higher sensitivity of alternatives in comparison to side-chain fluorinated polymers, companies are reported to incur higher production costs due to the need for additional production steps (including additional washing steps), and additional chemical additives.

While information on whether the use of alternatives leads to higher raw material costs for the chemical itself is mixed and seems to depend on the required functionality, the Dossier Submitters conclude that some increases in operating costs are likely as a result of the additional production steps.

In addition to increases in operating costs, additional **costs in relation to re-certification** and approval of their products will also be incurred by some companies. Such costs are deemed to be especially relevant for companies producing PPE and technical textiles, more specifically medical applications and high-performance membranes, as well as companies producing non-wovens or textiles for use in automobiles. No information on the magnitude of costs is available to the Dossier Submitters.

Quantitative information on the **total costs per company associated with substitution** is also limited. One company submitting TULAC-specific information to the 2nd stakeholder consultation in relation to the use of a PFAS-based processing aid in relation to a material qualified for the use in PPE Category III reports that total costs of at least €100 million are expected – including costs associated with research on alternatives, subsequent process developments, asset retrofits and qualification requirements. In relation to filtration applications, one company providing information during the 2nd stakeholder consultation reported that past substitution efforts from one PFAS to another PFAS were associated with costs of €5 million. Given the limited sample of and wide variation in cost estimates, no conclusions on the typical cost incurred by a company in relation to substitution in response to a restriction proposal of PFASs can be drawn by the Dossier Submitters.

Table E.23 summarises the information on the key components determining the total economic impacts on affected companies resulting from a full ban of PFASs. It also provides some overarching conclusions on the total producer surplus losses incurred by affected companies in each sub-sector.

Table E.23. Conclusions on total economic impacts on directly affected companies resulting from a full ban of PFASs.

	Home textiles	Consumer apparel	Professional apparel	Technical textiles	Leather	Other: Home fabric treatments (sprays)	Other: Automotive use – Noise and vibration insulation
Number of affected companies							
Number of companies estimated to be active in the sub-sector	20 200	59 300 (including companies producing professional sportswear and footwear)	2 900 ³⁹ (which only covers companies producing PPE, not professional sportswear and footwear)	24 500	Unknown	Unknown	Unknown
Share of companies affected by the restriction proposal due to using PFASs	Unknown, but not all companies are deemed to use PFASs based on information from voluntary industry commitments The share of companies using PFASs is deemed to be higher than for consumer	Unknown, but the share of companies using PFASs is deemed to be comparatively low given existing substitution trends	Unknown, but the share of companies using PFASs is deemed to be comparatively high	Unknown, but the share of companies using PFASs is deemed to be comparatively high	Unknown, but the share of companies using PFASs is deemed to be comparatively high as substitution does not seem to be as widespread as for home	Unknown	Unknown

³⁹ Companies producing professional sportswear and footwear are not included in this estimate, which is based on Euratex data relating to workwear. Given the comparatively small customer base for professional sportswear, the number of companies active in this industry branch is however considered to be low. As such, the Dossier Submitter is confident that the number of companies active in the professional apparel industry is smaller than the number of companies in other sub-sectors even when considering professional sportswear and footwear.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

	Home textiles	Consumer apparel	Professional apparel	Technical textiles	Leather	Other: Home fabric treatments (sprays)	Other: Automotive use – Noise and vibration insulation
	apparel.				textiles		
Conclusion: Number of companies affected by the proposed restriction (in comparison to other TULAC sub-sectors)	Medium ⁴⁰	High	Low ⁴¹	High ⁴²	Unknown	Unknown	Unknown
Most likely reaction of affected companies							
Most likely reaction	Based on information on impacts at company level from 2nd stakeholder consultation	No conclusion possible	Rather equal split between closure of business & substitution	Clear tendency towards business closures	Clear tendency towards business closures (especially in relation to high performance membranes as submitted information is dominated by information relating to this	No conclusion possible	No relevant information provided

⁴⁰ A considerable share of companies in the home textile industry is deemed to already use alternatives. A percentage share is not known. It is noted that the share of companies that still uses PFASs in the home textiles industry is higher than in the consumer apparel industry, however the number of companies active in the consumer apparel sector is significantly higher compared to the home textiles sector. As a result, the number of affected companies has been classified as 'medium' for home textiles and 'high' for consumer apparel.

⁴¹ The share of companies in the professional apparel industry that use PFASs is deemed to be comparatively high. Given the small number of companies estimated to be active in the sector, even a high share of companies using PFASs implies that the number of affected companies is 'low' in comparison to other sectors.

⁴² The share of companies in the technical textile industry that use PFASs is deemed to be comparatively high. A percentage share is not known. The share is however deemed higher than in the home textile industry, where significant progress with phasing-out PFASs has been made – also as a result of voluntary industry commitments (see Section E.2.2.2). Substitution in the technical textile sector appears more limited, with information from the 2nd stakeholder consultation pointing towards proven use of alternatives, while many stakeholder however report that known alternatives are not feasible for their product. Due to the slightly higher number of companies active in the sector and the higher share of companies that are deemed to still use PFASs, the number of affected companies in the technical textile industry is classified as 'high', while it is classified as 'medium' for the home textile industry.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

		Home textiles	Consumer apparel	Professional apparel	Technical textiles	Leather	Other: Home fabric treatments (sprays)	Other: Automotive use – Noise and vibration insulation
					application)			
	Based on information on technical feasibility of alternatives	Mainly substitution	Mix of reactions – with some business closures given the high market penetration of PFAS-free products	Mix of reactions with tendency towards business closures (especially in relation to PPE)	Mix of reactions with tendency towards business closures for some applications, e.g. high performance membranes, while substitution is more likely for outdoor technical textiles	Mainly substitution	Mainly substitution	Mainly business closures
Conclusion: Expected share of business closures (in comparison to other TULAC sub-sectors)		Low	Medium	High ⁴³	High (for high performance membranes) Low (for outdoor technical textiles) Unclear for medical applications, but potentially lower than for high performance membranes	Low	Low	High

⁴³ In relation to the professional apparel, information received during the 2nd stakeholder consultation reveals a clearer tendency towards business closures, which is higher than for the consumer apparel industry (classified as 'medium'). The expected share of business closures is therefore reported as 'high'. This is deemed to hold despite the availability of alternatives for some applications, e.g. professional sportswear, as the sector for professional sportswear is deemed to be a niche sector with a limited number of competitors. A high share of substitution for producers of professional sportswear would thus not affect the conclusion for professional apparel as a whole.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

		Home textiles	Consumer apparel	Professional apparel	Technical textiles	Leather	Other: Home fabric treatments (sprays)	Other: Automotive use – Noise and vibration insulation
Costs at company level								
Business closure: Cost per company active in the sector (in comparison to other TULAC sub-sectors)	Sales value per company	- Sales losses are deemed to range from a few million to several million euros per company - No sector-specific information is available						
	Producer surplus losses⁴⁴	Low	Low	High	High (for high performance membranes) Low (for outdoor technical textiles and medical applications)	Low	Low	High
	Costs for dismantling plants	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Substitution: Cost per company active in the sector	Research & Development (R&D) costs	Medium	Medium	High (especially in relation to PPE)	High (for high performance membranes) Low (for outdoor technical textiles and medical applications)	Medium	Medium	High
	Capital costs	Low	Low	Low	Low	Low	Unknown	Low
	Operating costs	Some	Some	Some	Some	Some	Unknown	Some

⁴⁴ This row refers to the magnitude of the producer surplus loss at company level, which is dependent on the margin. As such, the categorization mirrors the categorization of the size of profit margins provided in Table E.21.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

		Home textiles	Consumer apparel	Professional apparel	Technical textiles	Leather	Other: Home fabric treatments (sprays)	Other: Automotive use – Noise and vibration insulation
	Certification costs			Some (for PPE)	Some (for medical applications and high performance membranes)			Some
	Total cost⁴⁵	Medium	Medium	Medium (in relation to professional sportswear) High (in relation to PPE)	Medium (in relation to outdoor technical textiles and medical applications) High (in relation to high performance membranes)	Medium	Unknown ⁴⁶	High
Ability to pass on costs to customers								
Expected extent to which companies pass on costs to customers		Partial	Partial	High	High (for high performance membranes) Partial (for outdoor technical textiles and medical applications)	Partial	Partial	High

⁴⁵ Given the limited sample of and wide variation in cost estimates provided by stakeholders, no conclusions on the typical cost incurred by a company in relation to substitution in response to a restriction of PFASs can be drawn by the Dossier Submitters. The indication provided here represents a conclusion based on the information provided for different cost components (shown in the preceding rows).

⁴⁶ Information pointing to some additional capital costs as a result of changes in processing times which might result in the need of additional machinery relate to textile finishes. Similarly, information pointing to increases in operating costs is related to the application of textile finishes. This information is not of relevance for the production of home fabric treatments, which is why the level of substitution costs for home fabric treatments is unknown.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

		Home textiles	Consumer apparel	Professional apparel	Technical textiles	Leather	Other: Home fabric treatments (sprays)	Other: Automotive use – Noise and vibration insulation
Total economic impacts on affected companies at sector level								
Conclusions on total economic impacts on affected companies	Total producer surplus loss: Company closures	Total producer surplus losses are limited by (i) the expected low number of company closures and (ii) the low level of margins, which limit the producer surplus losses at company level.	A high level of total producer surplus losses is expected, despite low margins, due to (i) the high absolute number of company closures (in light of the big size of the sector and the medium share of company closures).	Total producer surplus losses are exacerbated by (i) the considerable share of company closures, and (ii) the high level of margins.	Total producer surplus losses are exacerbated by (i) the comparatively high number of companies, (ii) the possibly considerable share of company closures (especially in relation to high performance membranes), and (iii) the high level of margins for high performance membranes	Total producer surplus losses are limited by (i) the expected low share of company closures and (ii) the low level of margins.	Total producer surplus losses are limited by (i) the expected low share of company closures and (ii) the low level of margins.	Total producer surplus losses are likely significant given (i) the expected high share of business closures, and (ii) the high level of margins.
	Total producer surplus loss: Substitution	Producer surplus losses are significant, despite comparatively low costs at company level due to (i) a medium number of companies being affected,	Producer surplus losses are significant, despite comparatively low costs at company level due to (i) a high number of companies being affected, (ii) the	Producer surplus losses are limited by (i) the low number of companies deemed to be active in the sector, (ii) the low share of substitution, and especially	Producer surplus losses are significant, especially due to the (i) the high share of substitution in relation to outdoor technical textiles, (ii) the likely considerable number of	Producer surplus losses are exacerbated by (i) substitution being deemed the dominant reaction to the proposed	Producer surplus losses are exacerbated by (i) substitution being deemed the dominant reaction to the proposed restriction, and (ii) partial internalization	Producer surplus losses are limited due to the low share of substitution.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

		Home textiles	Consumer apparel	Professional apparel	Technical textiles	Leather	Other: Home fabric treatments (sprays)	Other: Automotive use – Noise and vibration insulation
		(ii) substitution being the reaction of the majority of affected companies, and (iii) partial internalization of costs.	medium extent of substitution, and (iii) partial internalization of costs.	(iii) a good ability to pass on costs to customers, which outweighs comparatively high substitution costs (especially in relation to PPE) at company level.	companies being active in this mass market industry (due to the low barriers to entry) and (iii) partial internalization of costs in this industry, which outweighs the comparably low costs at company level to some extent.	restriction, and (ii) partial internalization of costs, which outweighs the comparatively low costs at company level to some extent.	of costs.	

The **total impact on EU industry** in the form of changes in producer surplus is not solely determined by total economic impacts on affected companies, i.e. the producer surplus losses resulting from substitution and business closures, assessed in Table E.23. Further relevant determinants of the total impact on the respective EU industry sectors are:

- The extent to which producer surplus losses resulting from business closures of affected companies are offset by gains in producer surplus of EU companies that already provide alternative-based products; and
- The extent of indirect impacts on companies, other than suppliers of PFASs, in the supply chain.

The capability of companies already supplying alternative-based products to offset impacts without incurring high costs themselves, which would limit the extent of offsetting, depends on a variety of factors including the market share of affected firms, the degree of specialisation and the extent of spare capacity. A high-level assessment of the extent of offsetting in each sub-sector is provided in Table E.24. Possibilities for offsetting producer surplus losses are deemed to be highest in the consumer apparel sector where many companies have already transitioned and the degree of specialization is comparatively low.

The extent of indirect impacts on EU upstream actors, other than suppliers of PFASs, is mainly influenced by the extent of business closures in a sub-sector. While substitution will impact the sales of EU companies producing PFASs (which, at EU level, will be balanced out – at least to some extent – by increased sales of other chemicals), major impacts on other suppliers, e.g. producers of synthetic fibres, are not expected as a result of substitution. Business closures of EU companies might, in contrast, lead to a reduction in the sales volumes of such EU suppliers – unless those are balanced out through increased sales to competitors of the business that closed down, i.e. companies that substitute in response to the restriction as well as existing suppliers of alternative-based products. The extent of supply-chain impacts in each sub-sector are assessed in Table E.24 – taking into account (i) the expected share of business closures in each sub-sector as well as (ii) the offsetting potential. The impacts on the supply chain are deemed to be highest for the professional apparel and technical textile industries and in relation to textiles for use in engine bays.

Table E.24. Assessment of offsetting potential in different TULAC sub-sectors in the EU as well as producer surplus losses in the upstream supply chain.

	Home textiles	Consumer apparel	Professional apparel	Technical textiles	Leather	Other: Home fabric treatments (sprays)	Other: Automotive use – Noise and vibration insulation
Potential for producer surplus gains of EU companies that already provide alternative-based products (Offsetting potential)⁴⁷							
Extent of competition	High	High	Low	Low ('High' in relation to outdoor technical textiles)	High	High	Low
Market share of affected companies	Medium	Low	High	High	High	Unknown	High
Degree of specialization	Low	Low	High	High ('Low' in relation to outdoor technical textiles)	Low	Low	High
Other barriers to entry e.g. extensive investment requirements, long-standing customer relationships	Low	Low	High	High ('Low' in relation to outdoor technical textiles)	Low	Low	High

⁴⁷ The criteria employed for assessing the potential for offsetting producer surplus losses of companies directly affected by the restriction are based on the SEAC guidance on assessing changes in producer surplus published in September 2021 (ECHA, 2021b). According to ECHA (2021b), the five criteria and the offset potential are related as follows: The offsetting potential is high if (i) the sector is associated with a high level of competition; (ii) the market share of affected companies is low (as this renders it more likely that other companies can supply additional volumes without the need for making investments themselves), (iii) the extent of specializations is low (as this increases the possibility of other companies to take over market shares), (iv) the sector is associated with low barriers to entry (as this increases the contestability of the market); and (v) a high share of competitors is located in the EU (as producer surplus gains of non-EU companies are not considered as part of socio-economic assessments related to EU legislation, and therefore do not constitute an offset).

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Share of EU competitors out of all competitors providing non-PFAS products	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Conclusion: Offsetting potential	Medium	High	Low	Low	Low	Unknown	Low
Producer surplus losses in upstream supply chain							
Expected share of business closures	Low	Medium	High	High (for high performance membranes); Low (for outdoor technical textiles) Unclear for medical applications, but potentially lower than for high performance membranes	Low	Low	High
Conclusion: Extent of producer surplus losses in upstream supply chain	Low – due to the small extent of business closures	Low – while the extent of business closures is higher than in the home textile industry, the offsetting potential is also higher	High – due to the high extent of business closures and low offsetting potential	High – due to the high extent of business closures (for some technical textile applications) and low offsetting potential	Low – due to the small extent of business closures	Low – due to the small extent of business closures	High – due to the high extent of business closures and low offsetting potential

E.2.2.4.2. Economic impacts on customers

In addition to the changes in producer surplus described in section E.2.2.4.1, a restriction of PFASs might also impact the customers of companies that use PFASs for the production of goods in the textile, upholstery, leather, apparel and carpet (TULAC) industry, i.e. industrial or professional downstream users and households. Negative impacts on customers might include:

- Consumer surplus losses, resulting from an increase in the price of the good at which it is offered to the customer;
- Welfare losses and/or costs resulting from changes in the characteristics of the good, i.e. its quality and lifetime, or the absence of the product (in case substitution is not feasible); and
- Additional costs – e.g. increased energy costs – incurred when using the good.

The extent of consumer surplus losses associated with price changes resulting from substitution is determined by (i) the change in the market price of the good which reduces the difference between the price that the customer has to pay and the maximum price the customer would be willing to pay, and (ii) the change in the quantity that is purchased in consequence of the price change. Changes in the quantity purchased in comparison to the baseline thus exacerbate consumer surplus losses. The extent to which the quantity purchased by customers changes depends on the price elasticity of demand for the good. For some goods, demand is very sensitive to price changes and a price increase will lead to a reduction in the quantity that is purchased. For other goods, the quantity of the good that is purchased does not change (much) as a result of the price change as customers deem it necessary to have access to the good and assign less importance to the price in their purchasing decision.

The extent of consumer surplus losses in different sub-sectors is therefore assessed based on (i) the magnitude of additional costs associated with substitution in each sub-sector and the extent, analysed in section E.2.2.4.1, to which companies are expected to pass on such costs to customers, (ii) the extent to which the demand for goods produced in each sub-sector is deemed to vary with price and (iii) the total volume of goods (containing PFASs) sold to EU customers per year, also taking into account the extent to which this volume will be replaced by alternative-based products (based on a consideration of the substitution share).

As mentioned in section E.2.2.4.1, the textile and clothing industry in the EU-27 had a turnover of €147 billion in 2021 (EURATEX, 2022)⁴⁸. Exports accounted for €58 billion in the same year (EURATEX, 2022), which implies that sales to EU customers equalled approximately €89 billion. In the same year, goods of a value of €106 billion were imported (EURATEX, 2022). A large share of textiles and clothing available to customers in the EU-27 was thus imported. Imports played an even bigger role in the clothing industry, where imports (at a value of €72 billion) exceeded the overall turnover of EU companies of €65.3 billion as well as the turnover based on sales to EU customers of around €32.3 billion (EURATEX, 2022).

Some information on the volumes of goods that are sold in different sub-sectors is also available. These are used as a basis for concluding on the magnitude of the volume of goods containing PFASs in each sub-sector. Table E.25 provides estimates of the sold production volume in 2019 at sub-sector level based on PRODCOM⁴⁹ data. Sold production volumes thereby refer to the volume of goods sold by producers located in the EU, Norway and

⁴⁸ This includes fabric producers, producers of man-made fibres and yarns as well as producers of home textiles, knitwear producers, producers of clothing and accessories, underwear, workwear as well as industrial and technical textiles.

⁴⁹ PRODCOM (abbreviated from the French term "Production Communautaire") is an annual survey producing data on the production of industrial goods in the EU.

Iceland⁵⁰. Estimates at sub-sector level have been derived by linking PRODCOM codes to relevant TULAC sub-sectors. For ease of comparison, PRODCOM data, which is presented in a variety of units, e.g. kilogram, cubic metres, pairs, items, has furthermore been converted to tonnes. Assumptions used to derive these estimates are provided below the table.

Table E.25. Sold production volumes for EEA countries in 2019; calculated based on PRODCOM data.

Sub-use		Sold volume (2019)	Units
Home textiles	Carpets and rugs	1 568 818 *	tonnes
	Curtains and blinds	161 662 *	tonnes
	Upholstery	940 400 **	tonnes
Consumer apparel	Indoor and outdoor wear	1 347 547 ***	tonnes
	Sportswear	45 412 ***	tonnes
	Footwear	-	-
	Accessories	-	-
Professional apparel	Professional sportswear and footwear	-	-
	PPE for industrial and professional use (other than sportswear)	101 187 **	tonnes
Technical textiles	Outdoor technical textiles	582 152 ****	tonnes
		1 265 ****	number of items
	Medical applications	-	-
	High performance membranes	-	-
Leather	Leather based goods	173 973 **	tonnes
	Indoor and outdoor wear	10 150 ***	tonnes
	Footwear	711 548 *****	tonnes
	Professional sportswear and footwear	-	-
Other	Home fabric treatments (sprays)	-	-
	Automotive use - Noise and vibration insulation	-	-

* Cubic metres (m³) converted to (thousands of) kilogram (kg) based on a conversion rate of (i) 2 kg/m² for carpets and rugs and (ii) 1 kg/m² for curtains.

** Number of items converted to (thousands of) kilogram (kg) based on a conversion rate of (i) 20 kg/item for upholstered furniture, (ii) 1 kg/item for professional apparel and (iii) 1 kg/item for leather products.

*** Mix of number of items and number of pairs converted to (thousands of) kilogram (kg) based on conversion rate of (i) 0.25 kg/item for consumer clothing, (ii) 0.5 kg/item for sportswear and (iii) 1 kg/pair for footwear.

**** Two separate values are presented for this sub-category as no conversion factor was identified.

***** Number of pairs converted to (thousands of) kilogram (kg) based on a conversion

⁵⁰ According to the 2021 edition of "European business statistics user's manual for PRODCOM", PRODCOM data includes information from two countries that are not an EU Member State, i.e. Norway and Iceland, while no data from three EU Member States (Cyprus, Luxembourg and Malta) is included based on the small economic size of the country, which exempts these countries from the duty to provide data (Eurostat, 2022). As the third EEA country that is not part of the EU, i.e. Liechtenstein, is also a country with a small economic size, PRODCOM data is deemed representative for the EEA.

rate of 1 kg/pair.

The volumes provided in Table E.25 refer to the entire volume of goods sold in 2019, regardless of whether they were sold to EU or non-EU customers. Reported values thus also include exports. While potential changes to the market price of relevant goods will also affect non-EU customers, associated consumer surplus losses faced by non-EU customers are not further considered as assessments of the socio-economic impacts under REACH typically focus on impacts on the EU/EEA. Consumer surplus losses associated with imports (for which volume data is provided in Table E.26) are, however, relevant. As the proposed restriction applies to both locally produced as well as imported articles, non-EU producers of PFAS-containing goods might also decide to substitute in order to be able to continue supplying products to the European market. Price changes of a similar magnitude as for locally produced goods can thus be expected for imported goods.

Table E.26. Summary of import and export data (2018) provided by Euratex.

Sub-use		Imported into EU-28 (t)	Exported from EU-28 (t)
Home textiles	Carpets and rugs	450 657	251 333
	Curtains and blinds	123 082	9 339
	Upholstery	88 028	8 356
Consumer apparel	Indoor and outdoor wear	2 862 574	167 971
	Sportswear	79 046	427 154
	Footwear	-	-
	Accessories	-	-
Professional apparel	Professional sportswear and footwear	-	-
	PPE for industrial and professional use (other than sportswear)	-	-
Technical textiles	Outdoor technical textiles	859 662	270 127
	Medical applications	124 639	66 519
	High performance membranes	-	-
Leather	Leather based goods	-	-
	Indoor and outdoor wear	-	-
	Footwear	-	-
	Professional sportswear and footwear	-	-
Other	Home fabric treatments (sprays)	-	-
	Automotive use - Noise and vibration insulation	-	-

Given that it is the total volume of goods sold to EU customers that is of relevance for consumer surplus losses resulting from the proposed restriction, Table E.27 provides an estimate of the order of magnitude of the volume of goods supplied to EU customers, taking into account the sold production volumes in Table E.25 as well as information on EU-28 import and export volumes for 2018 placed at disposal by Euratex, which are displayed in Table E.26. While this import and export data does not refer to the same year as the sold production volumes in Table E.25, which represent 2019 data, they constitute the best basis for providing an indication of the volume of goods supplied to EU customers in different sub-sectors as no other information of a comparable level of granularity is available to the Dossier Submitters. As the market situation is deemed to not have changed much between 2018 and 2019 given that both years fall before the start of the Covid-19 pandemic, the Dossier Submitters consider it appropriate to use 2018 data as a proxy for import and export volumes in 2019 in the absence of other data. As the main purpose consists of creating an understanding of the order of magnitude of consumer surplus losses in different sectors (instead of an exact monetary

estimation), the available datasets are also deemed to be an appropriate basis for the estimation despite the differences in the geographical scope (whereby data on sold production refers to the EU-28 plus Norway and Iceland, while import and export data covers the EU-28).

Combining information on the volume of goods supplied to European customers in relation to each sub-use with information on, firstly, the magnitude of additional costs associated with substitution in each sub-sector together with the extent to which companies are expected to pass on costs to customers and, secondly, the price elasticity of demand, Table E.27 provides information on the expected magnitude of consumer surplus losses in relation to each sub-use. Of the sub-sectors for which the magnitude of substitution costs could be determined, price changes are deemed to be lowest in relation to home textiles, consumer apparel, leather and outdoor technical textiles given that companies in these industries are expected to face lower substitution costs than other sub-sectors and are expected to only partially pass on increased costs resulting from substitution to their customers. For all of these sub-uses, consumer surplus losses are however deemed to be exacerbated by more significant changes in the quantity purchased as a result of the high price elasticity of demand. While price changes in the professional apparel industry (especially in relation to PPE), the technical textile industry (especially in relation to high performance membranes) and the automotive industry are expected to be higher than in the aforementioned sectors, consumer surplus losses are deemed to be limited by the smaller impact on purchased quantities given the lower price elasticity of demand. As such, the Dossier Submitters consider the annual volume of goods (containing PFASs) sold to EU customers to be the main determinant of differences in the magnitude of consumer surplus losses for different sub-uses.

As shown in Table E.27, the annual volume of goods (i.e. PFAS-containing and PFAS-free goods) sold to European customers is estimated to be highest with respect to consumer apparel and home textiles. The difference in sales volumes between home textiles and consumer apparel is likely underestimated as the estimation for consumer apparel is only based on one of the four relevant product types, i.e. indoor and outdoor wear, as no data was available for footwear and accessories, and the sold production, and import and export data for sportswear was found to be contradictory, as described in more detail in the table note. While the estimated volume is lowest for professional apparel, this estimate needs to be treated with caution, as it is solely based on sold production data for PPE and does not account for professional sportswear and footwear due to a lack of data. Similarly, the volume for technical textiles is deemed to be underestimated as the volume for outdoor technical textiles is not accounting for information on sold production volumes provided as number of items in Table E.25, and does not include medical textiles sold by EU companies as well as locally produced and imported high performance membranes due to a lack of data. The volume of leather-based products purchased annually is also deemed to be underestimated as it is based on data on only three of four relevant product categories (as no data was available for professional sportswear and footwear). The estimate also does not account for imports due to a lack of data. Given that the volumes are deemed to be underestimated for all uses except home textile, the Dossier Submitters, nevertheless, consider the conclusions on the comparative magnitude of sales volumes to be robust.

While the exact share of products produced in as well as imported into Europe that contain PFASs is unknown, information presented in Section E.2.2.2 indicates an existing trend to substitution predominantly in relation to consumer apparel but also home textiles, where various voluntary industry commitments have been made. As such, the market penetration of alternatives is deemed to be highest in the consumer apparel sector followed by the home textile sector. With respect to products containing PFAS, the Dossier Submitters therefore consider the difference in sales volumes between the home textiles and consumer apparel, on the one hand, and professional apparel, technical textiles and leather-based goods to be smaller than for the whole market. Information submitted to the CfE (already mentioned in Section E.2.2.4.1) revealing that the major users of PFASs are companies producing consumer apparel followed by the home textile sector and technical textile sector is not deemed to

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contradict this conclusion as the high use volumes are deemed to be a result of the sheer size of these sectors. As a result of the size of the sector, the Dossier Submitters conclude that the volume of goods in relation to which consumer surplus losses could occur, i.e. the share that is containing PFAS, is still higher in the home industry and consumer apparel sectors than in the other assessed sectors despite the higher market penetration of alternatives.

As a result, total consumer surplus losses triggered by changes to price resulting from substitution are expected to be highest in relation to consumer apparel and home textiles, followed by technical textiles and leather-based goods.

Table E.27. Conclusion on magnitude of consumer surplus losses resulting from price changes associated with substitution in relation to different TULAC sub-uses under a full ban of PFASs.

Sub-use	Magnitude of costs associated with substitution per company according to Table E.23	Expected extent to which companies pass on costs to customers	Price elasticity of demand	Annual volume of goods (with and without PFAS) sold to EU customers		Annual volume of goods (containing PFAS) sold to EU customers	Expected magnitude of consumer surplus losses from price changes (compared to other TULAC sub-sectors)
				Estimated volume (t, based on 2018/2019 data)	Magnitude (in comparison to other sectors)		
Home textiles	Medium	Partial	High	3 063 619	High	High (and the entire volume will likely be replaced by PFAS-free products given the high share of substitution)	High
Consumer apparel	Medium	Partial	High	4 042 150 *	High	High (and the entire volume will likely be replaced by PFAS-free products given the medium share of substitution and the potential of substituting companies to take over market share from companies ceasing production)	High
Professional apparel	Medium/High	High	Low	101 187 (which only covers PPE) **	Low	Low (and given that substitution is only an option for some types of PPE, consumer surplus losses from price changes will likely only be incurred in relation to a share of the volume reported here, but substitution and associated consumer surplus losses will also be incurred in relation professional sportswear and footwear)	Low
Technical textiles	Medium/High	Partial (for outdoor technical textiles and	High (with the exception of high	1 296 326 (mainly covering outdoor	Medium	Medium (and the majority of the volume will likely be replaced by PFAS-free products given the high share of substitution for outdoor	Medium

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Sub-use	Magnitude of costs associated with substitution per company according to Table E.23	Expected extent to which companies pass on costs to customers	Price elasticity of demand	Annual volume of goods (with and without PFAS) sold to EU customers		Annual volume of goods (containing PFAS) sold to EU customers	Expected magnitude of consumer surplus losses from price changes (compared to other TULAC sub-sectors)
				Estimated volume (t, based on 2018/2019 data)	Magnitude (in comparison to other sectors)		
		medical applications) High (for high performance membranes)	performance membranes)	technical textiles) ***		technical textiles)	
Leather	Medium	Partial	High	895 671 **	Medium	Medium (and the entire volume will likely be replaced by PFAS-free products given the high share of substitution)	Medium
Other: Home fabric treatments (sprays)	Unknown	Partial	High	n/a	n/a	n/a	Unknown
Other: Automotive use - Noise and vibration insulation	High	High	Low	n/a	n/a	n/a	Low, due to the low substitution share

* This estimate is based on information for indoor and outdoor wear only. Data on sportswear has not be used as the reported volume for sold production of 45 412 t is much lower than the export volume of 427 154 t. As such, at least one of the available volumes must be incorrect, which is why data for this use has not be taken forward.

** This estimate is only based on estimate of the sold production volume as no data on import and export volumes are available.

*** This estimate is based on (i) information for outdoor technical textiles, whereby information on sold production volumes provided as number of items in Table E.25 is not taken into consideration, and (ii) import data for medical applications. (No information on sold production volumes is available for medical applications).

In addition to the consumer surplus losses resulting from price changes, socio-economic impacts on customers under a full ban might also occur in the form of changes in quality or – in the worst case – the complete absence of products based on the non-existence of technically feasible alternatives.

Products, for which a full ban of PFASs is likely to lead to **products not being available to EU customers** as a result of technical feasibility considerations include, for example, Category III PPE for the protection against liquid and gaseous chemicals, including aerosols and solid particles, and microorganisms, and PPE for firefighting activities. A full ban of PFAS would also prevent maintenance, i.e. re-impregnation, of Category III workwear already in use. For these products, alternatives to PFASs are not able to provide the required functionalities at the level that is necessary to reach the requirements set out in EU legislation according to the assessment of the Dossier Submitters presented in Section E.2.2.2. As the provision of products of lower quality (below the set standard) is not acceptable for such products, a complete restriction of PFASs would actually result in the complete unavailability of suitable PPE for these types instead of changes to the quality of PPE on the market. The same applies for non-wovens used for insulation purposes in automobiles. According to stakeholder information (presented in Section E.2.2.2), alternatives do not allow to meet relevant standards, e.g. those set in noise regulations. The absence of such products is associated with wider impacts, e.g. impacts on industrial production processes in other sectors in Europe due to the non-availability of PPE. In relation to PPE, some room for using products with lower performance levels might however exist according to information provided by stakeholders (presented in Section E.2.2.2). Stakeholders reported that PPE with higher protection levels might be overused as a result of companies providing workers with PPE with higher protection than legally necessary for their activities – for example, due to the wish to equip the entire workforce with uniform clothing. As a result, some customers might be able to switch to different types of PPE available on the market for some applications without a negative impact on the protection of PPE users.

A lower performance level of alternatives with respect to the key functionalities provided by PFASs does however not preclude the adoptions of such alternatives in all sub-sectors. In relation to leather applications in automobiles one stakeholder responding to the 2nd stakeholder consultation, for example, noted (as reported in Section E.2.2.2) that they have been able to identify an alternative whose oil and soil repellence properties are *close enough* to PFAS-based products and that they have as a result started to substitute away from PFAS. Customers would thus face some changes in the characteristics of goods.

Where companies decide to substitute despite knowledge of differences in the performance level of alternatives in comparison to PFASs, consumer surplus losses as result of a change in product prices will be complemented by welfare losses and/or costs resulting from changes in the characteristics of the goods, i.e. its quality and lifetime. **Changes in the quality of the good** thereby refer to changes in functionality, e.g. the level of oil and soil repellence of leather-based seat coverings and furniture. A negative change in the quality of the good will either result in welfare losses, if the user takes the change as given, or result in higher costs, if the user attempts to counteract the change in quality through compensation measures, e.g. the use of a seat/furniture cover. Negative **changes in lifetime** also typically result in higher costs as downstream users will replace the good in shorter intervals. As stated in Wood (2020b), longer durability of products can thereby be the result of either the functionality itself being more long-lasting (e.g. the product being water repellent for longer) or of the provision of additional functionalities (in comparison to alternatives) that are beneficial for preventing staining of the product and might thus prevent early disposal of products.

As noted in Section E.2.2.2, information submitted to the CfE revealed that the biggest difference between PFASs and alternatives is their capacity to provide several functionalities simultaneously. While reaching broadly comparable levels of water repellence tends not to be a concern, identified alternatives reach lower levels of performance for other functionalities. A review of relevant chemical alternatives, i.e. dendrimer, silicone/hydrocarbon blends, hydrocarbons, nanotechnologies, polyurethane and silicones, suggested, for example, that

they provide inferior oil and dirt repellence. More specifically, a stakeholder submitting information to the 2nd stakeholder consultation stressed in relation to hydrocarbons, polyurethanes, and silicones that these alternatives are – in principle – able to provide some oil repellence but only when used on hard surfaces and not on irregular surfaces like textiles. According to the stakeholder, PFASs and these alternatives also differ in their durability resulting in negative impacts on the length of the service life of goods treated with alternatives. If used by producers of textile goods, the use of these alternatives would thus lead to changes in the quality and lifetime of the good. In the case of hydrocarbons, for example, quality losses (in relation to oil repellence) and negative impacts on lifetime of the good are likely in relation to home textiles, consumer apparel as well as leather applications as hydrocarbons were identified as relevant alternatives for these applications in Table E.12. In section A.3.3.1, oil repellence (in addition to water repellence) was however only identified as a key functionality provided by PFASs in relation to home textiles, sportswear and footwear and leather applications, while for other types of consumer apparel, i.e. outdoor wear, indoor wear and accessories, only water repellence was identified as a key functionality provided by PFASs. Quality losses in relation to oil repellence are thus of less importance for outdoor and indoor wear as well as accessories.

The Dossier Submitters therefore acknowledge that some welfare losses and/or additional costs as a result of changes in the quality or the lifetime of the good are likely to occur as a result of a restriction. Quantification of such impacts is not possible due to (i) uncertainties with respect to the annual volume of PFAS-based products sold in each sub-sector, (ii) uncertainty about the extent of companies that substitute, (iii) a lack of detailed information on the extent to which different alternatives will be chosen by affected companies and (iv) detailed (quantitative) information on the extent to which alternatives differ in functionality and the associated consequences. The choice of alternatives by companies is of particular relevance in this respect and the Dossier Submitters note that even the existence of a technically feasible alternatives with closely comparable functionality to PFASs does not necessarily prevent the occurrence of quality losses completely as knowledge about this alternative might not be available to all industry actors. The stakeholder providing information for leather applications in automobiles in the 2nd stakeholder consultation (previously referred to in Section E.2.2.2 as well as this section), for example, reported that they found an alternative whose oil and soil repellence properties is close enough to PFASs and that they have as a result started to substitute. In relation to the use of fluoropolymers (for anti-soiling purposes) in the manufacture of leather products, silicone-based products are furthermore reported by Drohmann et al. (2021) to be an alternative that could provide a comparable performance with respect to soil repellence with resistance to coffee being the sole exception. In contrast, another company stated in the 2nd stakeholder consultation in relation to the use of PFASs for textiles in automobiles that alternatives cannot replicate the oil and soil repellence level of PFASs. As such, conclusion of different stakeholders on the technical feasibility of alternatives with respect to oil and soil repellence varies. This might be due to differing requirements of companies but could also be due to knowledge differences with respect to alternatives – with some of the alternatives potentially being the result of recent successful R&D processes. Especially in relation to the first stakeholder, it can – given the unspecific information on the identity of the alternative – not be ruled that the substance used constitutes a substance currently unknown to the Dossier Submitters. For some applications, the extent of unavoidable quality losses could thus be smaller than anticipated based on the most widely known alternatives. While newly developed alternatives would not be implemented widely in the short term given the confidential nature of R&D results, the Dossier Submitters consider it likely that companies producing goods of higher quality (based on these alternatives) would take over market share from producers of goods of lower quality over time – if the lower quality is deemed unacceptable by customers, and that these alternatives would become more widely known over time.

Overall, quality losses are deemed to be most limited in relation to consumer apparel applications, more specifically indoor and outdoor wear as well as accessories, as these applications only require water repellence, according to the key functionalities provided by PFASs identified in Section A.3.3.1. Consumer sportswear and footwear as well as other textile

applications require the simultaneous provision of several functionalities rendering quality losses more likely and extensive than in relation to the aforementioned consumer apparel applications. While water repellence can be obtained with alternatives (as mentioned above), their performance is slightly lower than that of PFASs according to stakeholder information received in the CfE. Small changes in product quality could thus occur, e.g. there could be challenges concerning their technical performance under severe conditions. In general, such quality losses, as well as changes in durability, seem however acceptable to customers according to information submitted to the CfE by another stakeholder. In the 2nd stakeholder consultation, a big fashion chain, that has completely substituted away from PFAS, furthermore, reported that they are satisfied with the performance of alternatives and that non-fluorinated water repellents are the standard in their industry. As such, changes in the quality of indoor and outdoor wear and accessories as result of a full ban of PFASs are deemed to be negligible by the Dossier Submitters. Impacts on customers from a shorter lifetime of such products in the form of additional costs are deemed more significant in relation to consumer apparel. One stakeholder reported in the CfE that use of alternatives results in a higher replacement frequency or more frequent re-impregnation as alternatives withstand household laundering much less. Another factor that could – according to the Background Document to the opinion on the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances (ECHA, 2021a) – generally lead to a reduced lifetime of consumer apparel and/or additional cleaning costs is the lower performance of alternatives with respect to functions like oil and stain repellence. Referring to a study on PFAS coatings of school uniforms in the United Kingdom concluding that the use of stain-resistant textile finishes is not associated with a lower washing or replacement frequency, the Dossier Submitter for the restriction of PFHxA however stated that these functionalities might not be as important to customers as claimed by industry (ECHA, 2021a). As a result, the Dossier Submitters conclude that changes in the lifetime of consumer apparel due to a restriction of PFASs are probably mostly resulting from the lower capability of alternatives to withstand household laundering. The extent to which the lifetime of consumer apparel might be reduced as a result as well as the magnitude of costs for re-impregnating goods to counteract this deficiency to avoid disposal are unknown to the Dossier Submitters.

A reduction in the lifetime of the good is also possible in relation to home textile applications and textiles used for automotive interiors. As noted in the Background Document to the opinion on the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances, the use of alternatives providing a lower level of oil repellence and other functionalities like soil repellence might result in a reduced lifetime of home textiles as well as increased cleaning efforts. Such impacts were repeatedly mentioned by stakeholders in the Annex XV report consultation conducted in relation to the restriction on PFHxA (ECHA, 2021a). Customers might thus face increased costs for cleaning home textiles and automotive interiors or purchasing washable and replaceable covers, or – in the worst case – replacing home textiles more often. If such actions for counteracting the changes in functionality are not taken, customers might face welfare losses due to the inferior aesthetic appearance of their home and automotive interiors.

Stakeholder information also points to possible negative impacts on the lifetime of outdoor technical textiles. As mentioned in Section E.2.2.2.4, the substitution potential for outdoor technical textiles is high. A relevant alternative with respect to PTFE membranes used in outdoor technical textiles, for example, was reported by one stakeholder in the 2nd stakeholder consultation (as previously noted in Section E.2.2.2). This stakeholder reported that polyurethane- and polyester-based membranes are a proven alternative. Information on differences in the quality and lifetime of PFAS-based and alternative-based products is however not available. With respect to PFAS-based top coat finishes for, amongst other applications, outdoor upholstery and tents, stakeholder information from the 2nd stakeholder consultation however points towards a potentially significant loss in the lifetime of products as a result of a proposed restriction on PFASs. The lifetime of outdoor upholstery and tents is reported to be around three to five times shorter if PVDF is not applied as top coat finish on PVC-coated fabrics, with PVDF-coated fabrics lasting 10 to 15 years in comparison to three years without the top coat. Drohmann et al. (2021) furthermore states that PVDF coatings in

itself last between two and five decades and are thus significantly more durable than other coating technologies available for construction textiles. While requiring fewer re-coatings, PVDF coatings also have the benefit that the associated recoating process does – in contrast to other technologies – not create volatile organic compounds. A reduced lifetime of outdoor technical textiles, such as outdoor cushions and seating, was also mentioned in stakeholder responses to the Annex XV report consultation conducted in relation to the restriction on PFHxA. Stakeholders claimed that the reduced dirt, oil and soil repellence of alternatives would lead to visual impairments and reduced lifetime of goods (ECHA, 2021a).

For other products, e.g. some types of PPE, a full ban of PFASs is deemed to lead to their unavailability – as mentioned above – as alternatives to PFASs are deemed to not provide the required functionalities at the level that is necessary to reach the requirements set out in EU legislation. According to the assessment of the Dossier Submitters summarised in Table E.13, some types of PPE do, however, not require the use of PFASs to reach legally prescribed standards. One example is PPE for Risk Category I(e), i.e. atmospheric conditions that are not of an extreme nature, as alternatives are deemed to provide a satisfactory level of water repellence. Substitution to alternatives might however lead to some quality losses for such types of PPE. With respect to footwear, for example, one stakeholder reported in the 2nd stakeholder consultation that it is crucial that water repellence is combined with good water vapour permeability. According to the stakeholder, this combination cannot be replicated at a comparable level by alternatives, whose use would also read to a reduction of tear strengths. Downstream users of PPE, both those types for which substitution to alternatives is deemed feasible as well as those for which PFASs are deemed to be required to reach required performance standards, are furthermore expected to incur additional costs for replacing PPE earlier than planned. As mentioned in section E.2.2.4.1, PPE that is already on the market relies on re-impregnation to provide its protective performance. If relevant PFAS-based products are not available anymore as a result of the proposed restriction, relevant PPE would need to be replaced before reaching the end of its lifetime.

With respect to high performance membranes, information on whether suitable alternatives are available is mixed. While some stakeholders mentioned in the 2nd stakeholder consultation – as described in more detail in section E.2.2.2 – that no alternatives with an adequate performance level are currently known for PFAS-based finishes in industrial filter applications such as coalescing filters as well as PTFE-based membranes for filtration of very fine particles, another stakeholder points to the proven use of polyurethane (as well as polyester-based) membranes in relation to high performance membranes. Overall, the Dossier Submitters recognized in section E.2.2.2 that alternatives seem to be less generally available for high performance membranes than for consumer applications for instance but noticed that substitution is likely a possible option for at least some technical textile applications. This is generally in line with the conclusions reached in relation to the restriction of PFHxA, for which the Dossier Submitters suggest a derogation for filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil repellence properties, despite acknowledging that some alternatives might already be available or will become so in the near future. Some substitution might thus occur in relation to the high-performance membranes in response to a full ban of PFASs but changes to the characteristics of membranes, i.e. quality and lifetime, are likely. The use of alternatives in membrane filters could lead to a change in pressure properties (porosity) and a reduction in lifetime of the filter. In relation to fluoropolymer membranes designed for the removal of microbiological contaminants from air and process fluids, filtration efficiency would also decrease according to stakeholder information from the 2nd stakeholder consultation. Without PFASs, filters themselves are claimed to degrade which would lead to contamination downstream. In relation to filters for the removal of dusts and mists in industrial processes, non-PFAS filtration solutions are reported to be associated with lower process efficiency and a shorter lifetime of the filter by one stakeholder in the 2nd stakeholder consultation. As a result of the shorter lifetime, the use of alternative filtration solutions is associated with higher process downtimes for user according to the stakeholder. Due to higher drops in pressure across filters, the use of non-PFAS filtration solutions is also reported to lead to increases in energy use. With respect to coalescing filters, for which stakeholder information suggests that no alternatives

might be available, stakeholder information highlights that this would lead to failure or a shortened lifetime of industrial equipment. Given that such filters are required in nearly all industry sectors, the economic impacts are reported to be wide-ranging.

E.2.2.4.3. Other impacts on society

As mentioned in section E.2.2.4.1, a restriction proposal of PFASs is deemed to lead to business closures in affected sub-sectors. The share of business closures (summarised in Table E.23) is deemed to be particularly high in the professional apparel industry, the technical textile industry (more specifically with respect to the production of high-performance membranes) as well as in relation to the production of automotive textile applications. While the number of companies using PFASs is unknown to the Dossier Submitters, estimates of the number of companies active in different sub-sectors range from a few thousand to tens of thousands. Business closures can thus be expected to affect a significant number of companies in the EU. As such, a proposed restriction of PFASs will also likely lead to considerable **employment losses**.

Some information on employment losses at company level has been received in the course of the 2nd stakeholder consultation in which stakeholders were asked to provide information on the economic and social impact on their company if the use of PFASs is prohibited in three years. While the sample of quantitative estimates is limited (and therefore not deemed representative), these estimates provide some insights into possible employment losses at company level in different sub-sectors. For all relevant TULAC sub-sectors, Table E.28 presents the number of company-specific estimates for job losses provided as well as the relevant range.

Table E.28. Range of employment losses (at company level) resulting from business closures based on information provided in the 2nd stakeholder consultation.

Sub-use	Sample size, i.e. number of companies providing useable quantitative information on employment losses	Reported number of jobs lost (at company level)	Reported number of jobs lost (at company level)
		Minimum	Maximum
Home textiles	n/a	n/a	n/a
Consumer apparel	n/a	n/a	n/a
Professional apparel	6	6	2 000
Technical textiles	7	25	430
Leather	n/a	n/a	n/a
Other: Home fabric treatments (sprays)	n/a	n/a	n/a
Other: Automotive use - Noise and vibration insulation	1	20	20

Based on the information submitted to the 2nd stakeholder consultation, it thus seems reasonable to assume that job losses as a result of business closures range from less than 10 jobs to several thousand jobs per company in the TULAC industry.

Due to the uncertainty about the number of companies that would cease operation and a lack of representative data on the average number of employees in relevant companies (which might differ between sub-sectors depending on how labour-intensive the associated production process is), the magnitude of employment losses in sub-sectors could however not be estimated. The uncertainty about the number of companies that would cease operation is a particular concern in relation to the consumer apparel industry, the professional apparel industry, the technical textile industry and in relation to textiles for use in engine bays, which are the sectors with a medium or high share of business closures. Given the high total number

of affected companies in these sub-sectors and the significant share of business closures, costs associated with employment losses might be substantial. Given the high share of substitution in relation home textiles, leather applications and home fabric treatments, employment losses are deemed to be low in these sub-sectors.

No evidence pointing towards **changes in the skills and qualifications** required in the TULAC supply chain or the **job quality of workers** as a result of substitution to non-PFAS alternatives is available to the Dossier Submitters.

E.2.2.5. Summary of cost and benefit assessment

E.2.2.5.1. Home textiles

Table E.29 summarises the outcomes of the assessment of costs and benefits for home textiles. More detailed information can be found in the accompanying text following the table.

Table E.29. Home textiles - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Sufficiently strong evidence that technically feasible alternatives exist, with five of seven alternative substance groups being identified as relevant for home textiles, i.e.: • Dendrimers; • Hybrid (Silicone/hydrocarbon); • Hydrocarbons; • Polyurethanes; and • Silicones. Sufficiently strong evidence (in the form of practical examples of completed substitution) pointing to the economic feasibility of alternatives is available, e.g. from SAICM (2021). No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. As a result, there is sufficiently strong evidence to conclude that the substitution potential is high	Based on the available evidence, which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for sub-uses and PFAS groups and reasonable assumptions about environmental release, a full ban of PFAS use in TULAC will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for all TULAC sub-sectors, except automotive uses for insulation purposes (for which no volume data is available), together equals around 95% of baseline emissions for a 30-year period (2025-2055). As the environmental	Low producer surplus losses as a result of business closures [sufficiently strong evidence] due to (i) a low share of business closures [sufficiently strong evidence], (ii) low producer surplus losses at company level due to low margins [sufficiently strong evidence], (iii) a medium offsetting potential, i.e. potential producer surplus losses are balanced out to some extent by producer surplus gains by producers of alternative-based products [sufficiently strong evidence] and (iv) low producer surplus losses in the wider supply chain [sufficiently strong evidence] High producer surplus losses as a result of substitution [sufficiently strong evidence], despite comparatively low costs at company level [sufficiently strong evidence], due to (i) a medium number of companies being affected [sufficiently strong evidence], (ii) a high share of substitution [sufficiently	n/a

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		at EIF.	impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	strong evidence] and (iii) partial internalization of costs [sufficiently strong evidence] High consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence] despite comparatively low price changes [sufficiently strong evidence] resulting from medium (and comparatively low) substitution costs at company level [sufficiently strong evidence] which are only partially passed on to customers [sufficiently strong evidence], due to (i) the high annual sales volume [sufficiently strong evidence] and (ii) an exacerbation of consumer surplus losses due to a high price elasticity of demand [sufficiently strong evidence] Some welfare losses or additional costs as a result of lower functionality, e.g. in relation to oil and dirt repellence [sufficiently strong evidence] Low level of employment losses due to low share of	

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				business closures [sufficiently strong evidence]	
Ban use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion	A full ban of PFASs in home textiles with a transition period of 18 months is proposed.				

As mentioned in Section E.2.2.2.4, the Dossier Submitters consider based on the available evidence that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives for home textiles. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that technically and economically feasible alternatives exist in sufficient quantities for use in home textiles. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high under a full ban with a transition period of 18 months.

The **assessment of costs** in relation to home textiles **for a full ban with a transition period of 18 months** is based on evidence from Annex A on uses and functions, the assessment of alternatives and the substitution potential and:

- Literature and public databases, e.g. a document produced by industry providing quantitative information on the number of active companies in the textile and clothing industry in the EU as well as the share of different sub-sectors in total EU production, a study summarising information on voluntary industry commitments in different sectors, the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances and the PRODCOM database;
- Principles relating to margins, the price elasticity of demand and offsetting potential;
- Information from a limited number of stakeholder interviews, e.g. on differences in applying alternative textile finishes and changes in operating costs;
- The CfE, e.g. information on the sub-sectors with the highest use volumes of PFASs, changes in operating costs and differences in functionality; and
- Information (from a non-representative sample) from the 2nd stakeholder consultation on, for example, (i) the timeframe required for substitution, (ii) annual sales losses of individual companies in the TULAC industry in the case of a restriction, (iii) differences in the costs of alternatives in comparison to PFASs, and (iv) the total costs associated with substitution at company level.

For home textiles, the Dossier Submitters assessed (i) producer surplus losses resulting from company closures and substitution, as well as producer surplus losses in the supply chain, (ii) consumer surplus losses resulting from price changes, (iii) welfare losses and/or costs resulting from changes in the characteristics of the good, i.e. its quality and lifetime and (iv) employment losses.

Producer surplus losses for TULAC sub-sectors are determined based on an assessment of (i) the number of companies affected by the restriction, (ii) the most likely reaction of affected companies, (iii) the costs that companies face as a result of substitution or a stop of production and (iv) the ability of companies that substitute to pass on higher costs to their customers. The number of companies active in TULAC sub-sectors has, where available, been estimated based on industry data from a leading industry association on the number of companies active in the textile and clothing industry as well as the assumption that the share of the sub-sector in total EU production, provided by the same source, is a representative indicator of the number of companies active in the relevant sub-sector, i.e. that all sectors are assumed to be constituted by companies with a comparative production volume. This assumption leads to the plausible result that a comparatively high number of companies is active in sectors with lower barriers to entry, e.g. lower specialisation and certification requirements, such as the consumer apparel industry. Around 20 200 companies are estimated to be active in the home textile industry (which is only exceeded by the consumer apparel industry and comparable in magnitude to the technical textile industry). The number of companies producing articles containing PFASs could not be estimated due to a lack of quantitative information on the share of companies using PFASs. Evidence from the CfE suggests, however, that the home textile industry is one of the three biggest users within the TULAC industry. The Dossier Submitters conclude based on this evidence, which is considered to be sufficiently strong, that the number of companies affected by the proposed restriction

in the home textile industry (in comparison to other TULAC sub-sectors) is medium (and only exceeded by the consumer apparel industry - due to the bigger estimated size of the sector - and the technical textile industry - due to the lower market penetration of alternatives given the more limited availability of technically feasible alternatives).

As only one stakeholder provided information on the economic and social impacts of a restriction pro for the home textile industry in the 2nd stakeholder consultation, no conclusion on the most likely reaction of affected companies, i.e. the share of companies in the home textile sector opting for substitution in comparison to stopping production, could be drawn based on stakeholder information. The Dossier Submitters therefore relied on the conclusions concerning the substitution potential in combination with stakeholder information of the timeframe required for substitution. The Dossier Submitters also used information from literature on voluntary industry commitments⁵¹ suggesting that the market penetration of alternatives in the home textile industry is lower than in the consumer apparel industry, which makes substitution a more beneficial endeavour due to less established competition. Based on this evidence, which is considered to be sufficiently strong, the Dossier Submitters conclude that the expected share of business closures is low (and exceeded by the share of business closures in the consumer apparel industry) under a full ban with a transition period of 18 months.

Producer surplus losses associated with a stop of production are assessed based on a consideration of (i) information on typical annual sales losses reported by a limited and non-representative sample of companies in the 2nd stakeholder consultation, and (ii) margins in each sub-sector. Data on sales losses did not point to significant differences in annual sales values between different TULAC sub-sectors. Specific data on annual sales losses in relation to home textiles was not provided in the 2nd stakeholder consultation. The extent of producer surplus losses as a result of production stops in comparison to other TULAC industries has therefore solely been determined based on a consideration of margins (with low margins being associated with lower producer surplus losses). Due to a lack of quantitative information, margins were determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding the relation of the level of competition, market sizes and price elasticity of demand with margins. The size of the margin in relation to home textiles is found to be low (as for consumer apparel, leather applications, home fabric treatments, outdoor technical textiles and medical applications). The offsetting potential is determined based on a consideration of principles on the interlinkage between the offsetting potential of other actors in the market and (i) the extent of competition, (ii) the market share of affected companies, (iii) the degree of specialization and (iv) other barriers to entry as well as (v) the extent of EU competition in comparison to international competition. These principles are well-grounded and have a robust foundation in the SEAC guidance on assessing changes in producer surplus, i.e. ECHA (2021b). In relation to home textiles, the offsetting potential is found to be medium (and therefore only exceeded by the offsetting potential in the consumer apparel industry due to higher market share of affected actors in comparison to the consumer apparel industry). Given the low share of company closures and medium offsetting potential, the extent of producer surplus losses in the wider supply chain are found to be low. The Dossier Submitters consider based on the assessment of alternatives and aforementioned principles pointing to a low share of company closures, low producer surplus losses due to low margins, a medium offsetting potential and low impacts on the wider supply chain that there is sufficiently strong evidence to conclude that the socio-economic costs to industry in the form of producer surplus losses from business closures are low under a full ban with a transition period of 18 months.

Producer surplus losses resulting from substitution are assessed on the basis of considerations

⁵¹ Information on voluntary industry commitments for eliminating PFASs compiled by the Natural Resources Defense Council in a study supported by the United Nations Environment Programme reports that voluntary industry commitments are dominated by apparel brands, while the home textile sector is reported to be another sector making significant progress with phasing-out PFASs (SAICM, 2021).

of the extent to which companies will pass on higher costs to customers and considerations of R&D costs, capital costs for new equipment, changes in operating costs and re-certification costs. The extent to which companies are expected to pass on substitution costs to customers in the form of higher prices is determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding margins and the price elasticity of demand. The extent to which companies pass on costs to customers is found to be low (partial) in the home textiles industry (as for companies in the consumer apparel industry and leather industry as well as producers of home fabric treatments, outdoor technical textiles and medical applications) due to low margins and a high price elasticity of demand. Due to very limited quantitative information on substitution costs across TULAC sub-sectors, the assessment of substitution costs has focussed on assessing differences across sub-sectors, e.g. based on a consideration of differences in the complexity of applications (which is deemed to affect R&D costs) and the relevance of re-certification/validation costs. The substitution cost in relation to home textiles is found to be medium (as for consumer apparel, professional sportswear and footwear, outdoor technical textiles, medical applications and leather applications) and therefore more limited than in relation to other technical textile applications, PPE and textiles for the use in engine bays due to the lower complexity of products which limits R&D costs and (in all cases except medical applications) the absence of re-certification costs. The Dossier Submitters consider based on the aforementioned principles pointing to a high (partial) internalization of costs and medium substitution costs, the medium number of companies being affected and the high share of substitution that there is sufficiently strong evidence to conclude that socio-economic costs to industry in the form of producer surplus losses from substitution are high under a full ban with a transition period of 18 months.

Consumer surplus losses resulting from price changes associated with substitution are assessed comparatively based on consideration of (i) the magnitude of additional costs associated with substitution in each sub-sector, and the extent to which companies are expected to pass on such costs to customers, (ii) the extent to which the demand for goods produced in each sub-sector is deemed to vary with price and (iii) the total volume of goods (containing PFASs) sold to EU customers per year, also taking into account the extent to which this volume will be replaced by alternative-based products (based on a consideration of the substitution share). The volume of goods sold in TULAC sub-sectors has, where available, been estimated based on public data from the PRODCOM database and import and export data from a leading industry association as a basis for concluding on the magnitude of the volume of goods containing PFASs in each sub-sector. Based on medium substitution costs (which are lower in magnitude than substitution costs for PPE, high performance membranes and textiles for the use in engine bays) and a low (partial) extent to which costs are passed on to customers, price changes in relation to home textiles are found to be low (as for consumer apparel, outdoor technical textiles, medical applications and leather products). Due to the high price elasticity of demand, consumer surplus losses will be exacerbated by changes in the quantity demanded resulting from the price change. Demand in other sectors, for which higher price increases are expected, is deemed less sensitive to price changes than for home textiles. As such, the annual volume of goods sold to EU customers are deemed to be the main determinant of differences in the magnitude of consumer surplus losses for different sub-uses. With over three million tonnes, the estimated annual sales volume for home textiles (including PFAS-free and PFAS-containing products) is the second highest of all assessed sub-sectors. Data gaps exist for most TULAC sub-sectors resulting in a likely underestimation of volumes for these sectors. As this affects all apart from one sub-sector, comparative conclusions on the magnitude of sales volumes are however deemed to be robust. The annual sales volume of goods containing PFASs is deemed high (despite some market penetration of alternatives) and the entire volume is deemed to likely be replaced by PFAS-free products given the high share of substitution. The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of consumer surplus losses from price changes associated with substitution are high under a ban with a transition period of 18 months (and only exceeded by consumer surplus losses in the consumer apparel industry).

With respect to changes in the characteristics of goods, evidence from the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances, the CfE and 2nd stakeholder consultation suggests that the difference between PFASs and alternatives is their capacity to provide several functionalities simultaneously. While reaching broadly comparable levels of water repellence tends not to be a concern, identified alternatives reach lower levels of performance for other functionalities such as oil and dirt repellence, which might also impact the lifetime of the good. The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of welfare losses (resulting from inferior aesthetic appearance of home textiles) and/or additional costs for counteracting changes in functionality, e.g. purchasing washable covers, are likely to occur under a full ban with a transition period of 18 months.

The Dossier Submitters consider, furthermore, based on sufficiently strong evidence from mainly the assessment of the substitution potential pointing towards a low share of business closures in the home textile sector that there is sufficiently strong evidence to conclude that the socio-economic costs to society in the form of employment losses will be low under a full ban.

E.2.2.5.2. Consumer apparel

Table E.30 summarises the outcomes of the assessment of costs and benefits for consumer apparel. More detailed information can be found in the accompanying text following the table.

Table E.30. Consumer apparel - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Sufficiently strong evidence that technically feasible alternatives exist, with six of seven alternative substance groups being identified as relevant for consumer apparel, i.e.: • Dendrimers; • Hybrid (Silicone/hydrocarbon); • Hydrocarbons; • Polyurethanes; • Silicones; and • Alternative technologies. Sufficiently strong evidence (in the form of practical examples of completed substitution) pointing to the economic feasibility of alternatives, is available, e.g. from SAICM (2021)⁵² and the 2nd stakeholder consultation. No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. As a result, there is sufficiently strong evidence to conclude that the substitution potential is high at EIF.	Based on the available evidence, which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for sub-uses and PFAS groups and reasonable assumptions about environmental release, a full ban of PFAS use in TULAC will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for all TULAC sub-sectors, except automotive uses for insulation purposes (for which no volume data is available), together equals around 95% of baseline emissions for a 30-year period (2025-2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as	Low producer surplus losses as a result of business closures [sufficiently strong evidence] despite a medium share of business closures [sufficiently strong evidence], due to (i) low producer surplus losses at company level due to low margins [sufficiently strong evidence], (ii) a high offsetting potential, i.e. producer surplus losses are balanced out to some extent by producer surplus gains by producers of alternative-based products [sufficiently strong evidence] and (iv) low producer surplus losses in the wider supply chain [sufficiently strong evidence] High producer surplus losses as a result of substitution [sufficiently strong evidence], despite comparatively low substitution costs at company level [sufficiently strong evidence], due to (i) a high number of companies being affected [sufficiently strong evidence], (ii) a medium share of substitution [sufficiently strong evidence], and (iii) partial internalization of costs [sufficiently strong evidence] High consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence] despite	n/a

⁵² See also: <https://www.ehn.org/pfas-clothing-2656587709.html> and <https://www.greenpeace.org/international/press-release/17739/greenpeace-report-clothing-industry-shows-progress-in-cutting-hazardous-chemicals/>, both accessed: 2023-01-11.

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
			emissions avoided as a result of the restriction are likely underestimated.	comparatively low price changes [sufficiently strong evidence] resulting from medium (and comparatively low) substitution costs at company level [sufficiently strong evidence] which are only partially passed on to customers [sufficiently strong evidence], due to (i) the high annual sales volume [sufficiently strong evidence] and (ii) an exacerbation of consumer surplus losses due to a high price elasticity of demand [sufficiently strong evidence] Some welfare losses or additional costs as a result of lower functionality, e.g. in relation to oil repellence, which is deemed to be an important functionality in relation to sportswear and footwear, and additional costs resulting from high replacement frequencies or more frequent re-impregnation due to the lower ability of alternatives to withstand household laundering [sufficiently strong evidence] Some employment losses due to medium share of business closures [sufficiently strong evidence]	
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion	A full ban of PFASs in consumer apparel with a transition period of 18 months is proposed.				

As mentioned in Section E.2.2.2.4, the Dossier Submitters consider based on the available evidence that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives for consumer apparel. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that technically feasible alternatives exist in sufficient quantities for use in consumer apparel. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high under a full ban with a transition period of 18 months.

The **assessment of costs** in relation to consumer apparel **for a full ban with a transition period of 18 months** is based on evidence from Annex A on uses and functions, the assessment of alternatives and the substitution potential and:

- Literature and public databases, e.g. a document produced by industry providing quantitative information on the number of active companies in the textile and clothing industry in the EU as well as the share of different sub-sectors in total EU production, the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances and the PRODCOM database;
- Principles relating to margins, the price elasticity of demand and offsetting potential;
- Information from a limited number of stakeholder interviews, e.g. on differences in applying alternative textile finishes and changes in operating costs;
- The CfE, e.g. information on the sub-sectors with the highest use volumes of PFASs, changes in operating costs and differences in functionality; and
- Information (from a non-representative sample) from the 2nd stakeholder consultation on, for example, (i) the timeframe required for substitution, (ii) annual sales losses of individual companies in the TULAC industry in the case of a restriction, (iii) differences in the costs of alternatives in comparison to PFASs, and (iv) the total costs associated with substitution at company level.

For consumer apparel, the Dossier Submitters assessed (i) producer surplus losses resulting from company closures and substitution, as well as producer surplus losses in the supply chain, (ii) consumer surplus losses resulting from price changes, (iii) welfare losses and/or costs resulting from changes in the characteristics of the good, i.e. its quality and lifetime and (iv) employment losses.

Producer surplus losses for TULAC sub-sectors are determined based on an assessment of (i) the number of companies affected by the restriction, (ii) the most likely reaction of affected companies, (iii) the costs that companies face as a result of substitution or a stop of production and (iv) the ability of companies that substitute to pass on higher costs to their customers. The number of companies active in TULAC sub-sectors has, where available, been estimated based on industry data from a leading industry association on the number of companies active in the textile and clothing industry as well as the assumption that the share of the sub-sector in total EU production, provided by the same source, is a representative indicator of the number of companies active in the relevant sub-sector. This assumption leads to the plausible result that a comparatively high number of companies is active in sectors with lower barriers to entry, e.g. lower specialisation and certification requirements, such as the consumer apparel industry. Around 59 300 companies are estimated to be active in the consumer apparel industry (which is more than twice as much as the number of companies estimated to be active in technical textile industry – the sector with the second highest number of affected companies). As mentioned in section E.2.2.4.1, this is also deemed to include companies producing professional sportswear and footwear. The number of companies producing articles containing PFASs could not be estimated due to a lack of quantitative information on the share of companies using PFASs. Evidence from the CfE suggests, however, that the consumer apparel industry is the biggest user of PFASs within the TULAC industry. The Dossier Submitters conclude based on this evidence, which is considered to be sufficiently strong, that the number of companies affected by the restriction in the consumer apparel industry (in comparison to other TULAC sub-sectors) is high (despite the high market

penetration of alternatives due to big size of the sector).

For determining the most likely reaction of affected companies in relation to consumer apparel, the Dossier Submitters relied on conclusions concerning the substitution potential in combination with information from the 2nd stakeholder consultation on the economic and social impacts of a restriction proposal and the timeframe required for substitution. While the substitution potential is considered to be high (as described above), information from the 2nd stakeholder consultation suggests a mix of reactions with a rather equal split between companies indicating that they do not need to take action, and companies implementing an alternative or closing business. The timeframe available for substitution is not found to be of concern based on information from the 2nd stakeholder consultation. The Dossier Submitters also consider – based on information from literature on voluntary industry commitments⁵³ suggesting that the market penetration of alternatives in consumer apparel industry is comparatively high – that substitution is a less promising endeavour for affected companies in the consumer apparel industry due to more established competition and more price pressure. Based on this evidence, which is considered to be sufficiently strong, the Dossier Submitters conclude that the expected share of business closures is medium (and therefore higher than in the home textile and leather industries as well as in relation to home fabric treatments and outdoor technical textiles) under a full ban with a transition period of 18 months.

Producer surplus losses associated with a stop of production are, as mentioned in section E.2.2.5.1, solely determined based on a consideration of margins (with low margins being associated with lower producer surplus losses) as data on annual sales losses reported by a limited and non-representative sample of companies in the 2nd stakeholder consultation did not point to differences in annual sales values between different TULAC sub-sectors. Specific data on annual sales losses in relation to consumer apparel was not provided in the 2nd stakeholder consultation. Due to a lack of quantitative information, margins were determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding the relation of the level of competition, market sizes and the price elasticity of demand with margins. The size of the margin in relation to consumer apparel is found to be low (as for home textiles, leather applications, home fabric treatments, outdoor technical textiles and medical applications). The offsetting potential is determined based on a consideration of principles on the interlinkage between the offsetting potential of other actors in the market and (i) the extent of competition, (ii) the market share of affected companies, (iii) the degree of specialization and (iv) other barriers to entry as well as (v) the extent of EU competition in comparison to international competition. These principles are well-grounded and have a robust foundation in the SEAC guidance on assessing changes in producer surplus, i.e. ECHA (2021b). In relation to consumer apparel, the offsetting potential is found to be high especially due to the high market penetration of alternative-based products (and as a result the comparatively low market share of affected companies). Given the medium share of company closures but high offsetting potential, the extent of producer surplus losses in the wider supply chain are found to be low. The Dossier Submitters consider based on the assessment of alternatives, stakeholder information and aforementioned principles pointing to a medium share of company closures, low producer surplus losses due to low margins, a high offsetting potential and low impacts on the wider supply chain that there is sufficiently strong evidence to conclude that the socio-economic costs to industry in the form of producer surplus losses from business closures are low under a full ban with a transition period of 18 months.

Producer surplus losses resulting from substitution are, as mentioned in section E.2.2.5.1, assessed on the basis of considerations of the extent to which companies will pass on higher

⁵³ Information on voluntary industry commitments for eliminating PFASs compiled by the Natural Resources Defense Council in a study supported by the United Nations Environment Programme reports that voluntary industry commitments are dominated by apparel brands, while the home textile sector is reported to be another sector making significant progress with phasing-out PFASs (SAICM, 2021).

costs to customers and considerations of R&D costs, capital costs for new equipment, changes in operating costs and re-certification costs. The extent to which companies are expected to pass on substitution costs to customers in the form of higher prices is determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding margins and the price elasticity of demand. The extent to which companies pass on costs to customers is found to be low (partial) in the consumer apparel industry (as for companies in the home textile and leather industries as well as producers of home fabric treatments, outdoor technical textiles and medical applications) due to low margins and a high price elasticity of demand. In relation to consumer apparel, the ability to pass on costs to customers is deemed to be further limited by competition with companies that have already substituted, as these companies will likely be able to offer their products at lower prices, e.g. due to having competed the amortization of R&D and capital costs. Due to very limited quantitative information on substitution costs across TULAC sub-sectors, the assessment of substitution costs has focussed on assessing differences across sub-sectors, e.g. based on a consideration of differences in the complexity of applications (which is deemed to affect R&D costs) and the relevance of re-certification/validation costs. The substitution cost in relation to consumer apparel is found to be medium (as for home textiles, professional sportswear and footwear, outdoor technical textiles, medical applications and leather applications) and therefore more limited than in relation to other technical textile applications, PPE and automotive applications due to the lower complexity of products which limits R&D costs and (in all cases except medical applications) the absence of re-certification costs. The Dossier Submitters consider based on the aforementioned principles pointing to a high (partial) internalization of costs and medium substitution costs, the high number of companies being affected and the medium share of substitution that there is sufficiently strong evidence to conclude that socio-economic costs to industry in the form of producer surplus losses from substitution are high under a full ban with a transition period of 18 months.

As mentioned in Section E.2.2.5.1, consumer surplus losses resulting from price changes associated with substitution for TULAC sub-sectors are determined based on consideration of (i) the magnitude of additional costs associated with substitution in each sub-sector, and the extent to which companies are expected to pass on such costs to customers, (ii) the extent to which the demand for goods produced in each sub-sector is deemed to vary with price and (iii) the total volume of goods (containing PFASs) sold to EU customers per year, also taking into account the extent to which this volume will be replaced by alternative-based products (based on a consideration of the substitution share). The volume of goods sold in TULAC sub-sectors has, where available, been estimated based on public data from the PRODCOM database and import and export data from a leading industry association as a basis for concluding on the magnitude of the volume of goods containing PFASs in each sub-sector. Based on medium substitution costs (which are lower in magnitude than substitution costs for PPE, high performance membranes and textiles for the use in engine bays), and a low (partial) extent to which costs are passed on to customers, price changes in relation to consumer apparel are found to be low (as for home textiles, outdoor technical textiles, medical applications and leather products). Due to the high price elasticity of demand, consumer surplus losses will be exacerbated by changes in the quantity demanded resulting from the price change. As explained in Section E.2.2.4.2, the annual volume of goods sold to EU customers is deemed to be the main determinant of differences in the magnitude of consumer surplus losses for different sub-uses. With over four million tonnes, the estimated annual sales volume for consumer apparel (including PFAS-free and PFAS-containing products) is the highest of all assessed sub-sectors. Data gaps exist for most TULAC sub-sectors, including consumer apparel for which the estimate is only based on information on indoor and outdoor wear (and does not cover footwear, accessories and sportswear), resulting in a likely underestimation of volumes for these sectors. As this affects all apart from one sub-sector, comparative conclusions on the magnitude of sales volumes are however deemed to be robust. The annual sales volume of goods containing PFASs is deemed high, despite the high market penetration of alternative-based products (in comparison to other TULAC sub-sectors) due to big size of the sector in terms of sales volumes. The entire volume will likely be replaced

by PFAS-free products given the medium share of substitution and the potential of substituting companies to take over market shares from companies ceasing production. The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of consumer surplus losses from price changes associated with substitution are high (in comparison to other TULAC sub-sectors) under a ban with a transition period of 18 months.

With respect to changes in the characteristics of goods, evidence from the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances, the CfE and 2nd stakeholder consultation suggests that the difference between PFASs and alternatives is their capacity to provide several functionalities simultaneously. While reaching broadly comparable levels of water repellence tends not to be a concern, identified alternatives reach lower levels of performance for other functionalities such as oil and dirt repellence. As mentioned in section A.3.3.1 and Table E.14, functions other than water repellence are not deemed to be critical for consumer apparel, especially in relation to outdoor and indoor wear as well as accessories. For sportswear and footwear, oil repellence is (as for home textiles and leather applications) deemed to be important as mentioned in section A.3.3.1. Overall, quality losses in relation to consumer apparel are thus deemed to be more limited for consumer apparel than for all other TULAC applications. Changes in the lifetime of goods and associated costs due to changes in the durability of the functionality are however likely according to (i) stakeholder information from the 2nd stakeholder consultation pointing to a difference in the durability of PFASs and alternatives and (i) information from the CfE pointing to a high replacement frequency or increased re-impregnation due to the lower ability of alternatives to withstand household laundering. The lower performance level with respect to additional functionalities, e.g. oil repellence, is not deemed to contribute to the shortened lifetime and associated costs despite being mentioned in Wood (2020a) and ECHA (2021a) as an additional factor that could theoretically impact the lifetime of articles due to leading to a lower protection against staining and therefore earlier disposal. A study on PFAS coatings of school uniforms, referred to in the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances (see ECHA (2021a)), concluded that the use of stain-resistant textile finishes is not associated with a lower washing or replacement frequency. Based on this study, the Dossier Submitter for the restriction of PFHxA concluded, that these functionalities might not be as important to customers as claimed by industry (ECHA, 2021a). The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of welfare losses (e.g. small changes in product quality with respect to water repellence potentially leading to challenges under severe conditions, and differences in oil repellence for sportswear and footwear) and additional cost from higher replacement frequencies or increased re-impregnation, are likely to occur under a full ban with a transition period of 18 months.

As mentioned in section E.2.2.4, the magnitude of employment losses in different sub-sectors could not be estimated due to the significant uncertainty about the number of companies that would cease operation and a lack of representative data on the average number of employees in relevant companies (which might differ between sub-sectors depending on how labour-intensive the associated production process is). The Dossier Submitters consider based on the sufficiently strong evidence pointing towards a medium share of business closures in the consumer apparel industry that some socio-economic costs to society in the form of employment losses will occur under a full ban with a transition period of 18 months.

E.2.2.5.3. Professional apparel

Table E.31 summarises the outcomes of the assessment of costs and benefits for professional apparel. More detailed information can be found in the accompanying text following the table.

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Table E.31. Professional apparel - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Sufficiently strong evidence that technically feasible alternatives exist, with five of seven alternative (substance) groups being identified as relevant for professional sportswear and footwear, i.e.: • Dendrimers; • Hydrocarbons; • Polyurethane; • Silicones; and • Alternative technologies. Sufficiently strong evidence that technically feasible alternatives exist for seven of 13 assessed categories of PPE; four of seven alternative (substance) groups are identified as relevant for PPE, i.e.: • Hydrocarbons; • Polyurethane; • Silicones; and • Alternative technologies. Sufficiently strong evidence that alternatives are economically feasible, e.g. based on information pointing to the proven use of alternatives for	Based on the available evidence, which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for sub-uses and PFAS groups and reasonable assumptions about environmental release, a full ban of PFAS use in TULAC will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for all TULAC sub-sectors, except automotive uses for insulation purposes (for which no volume data is available), together equals around 95% of baseline emissions for a 30-year period (2025-	High producer surplus losses as a result of business closures [sufficiently strong evidence] despite low number of affected companies [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 high⁵⁴ margins [sufficiently strong evidence], (iii) a low⁵⁵ offsetting potential [sufficiently strong evidence] and (iv) high producer surplus losses in the wider supply chain [sufficiently strong evidence] Low producer surplus losses as a result of substitution [sufficiently strong evidence], despite medium to high costs at company level [sufficiently strong evidence] due to (i) a low number of companies being affected [sufficiently strong evidence], (ii) the low share of substitution [sufficiently strong evidence] and, especially, (iii) low internalization of costs [sufficiently strong evidence] Low consumer surplus losses resulting from price changes	n/a

⁵⁴ The margin for professional sportswear and footwear is deemed to be high given that this is deemed to be a niche sector with a limited number of competitors and the lower price elasticity of demand. (Professional athletes are considered to base their purchasing decisions on quality and performance rather than price.) The margin for PPE is deemed to be high given the comparatively small target market, the low level of competition resulting from high barriers to entry and higher up-front costs for suppliers, which they will likely aim to recoup through higher margins.

⁵⁵ The offsetting potential is deemed to be low for both professional sportswear and footwear and PPE due to: (i) the low extent of competition in both market segments, (ii) the low market penetration of alternatives, (iii) the high degree of specialisation, (iv) the existence of barriers to entry, i.e. long-standing customer relationships for professional sportswear and certification requirements for PPE.

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		professional sportswear and footwear and strong evidence for consumer apparel applications (which are deemed to be comparable to some extent). No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. As a result, there is sufficiently strong evidence to conclude that the substitution potential at Eif is high for professional sportswear and footwear and seven of 13 types of PPE and low for the other PPE applications.	2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	associated with substitution [sufficiently strong evidence], mainly in relation to professional sportswear and some types of PPE, despite medium to high price changes [sufficiently strong evidence] resulting from medium to high substitution costs at company level [sufficiently strong evidence], which are passed on to customers to a high extent [sufficiently strong evidence], due to (i) the low annual sales volume [sufficiently strong evidence] and (ii) the low price elasticity of demand which limits impacts on the quantity demanded [sufficiently strong evidence] High welfare losses or additional costs mainly as a result of (i) the absence of certain types of PPE due to no technically feasible alternatives being known and (ii) earlier disposal of PPE as a result of the unavailability of impregnation agents [sufficiently strong evidence] Some employment losses as a result of high share of business closures [sufficiently strong evidence]	
Ban with use-specific derogations: Derogation for (i) PPE protecting against risks specified in Risk Category III (a) and (c), (ii) PPE in professional firefighting activities	5 years	Sufficiently strong evidence that alternatives do not exist and that the substitution potential is low for six of 13 PPE applications: Based on current knowledge, PFASs are deemed to be required to achieve performance standards for six of 13 PPE applications. As no potential	A 5-year derogation of PFAAs and PFAA precursors would cause additional emissions of about 1 260 t, and of about 2 700 t assuming a 12-year derogation. Total maximum additional emissions of a	Same as under full ban	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
protecting against risks specified in Risk Category III (a) – (m), and (iii) impregnation agents for re-impregnation of aforementioned articles		alternatives are identified as of now, it is likely that they will not become available in the near future. Stakeholder information presented in Section E.2.2.4.1 suggests furthermore that between 12 and 36 months 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.	5-year derogation of fluoropolymers including PFPEs would account of about 3 860 t, and of about 5 370 t assuming a 12-year derogation, respectively. While the fraction of PPE use for risk category III in the EEA is small (about 20%), PFAS releases from textile treatment can be assumed to be high (ERC 5, 50% total release). There is sufficiently strong evidence that a derogation of PFAS use in PPE will cause substantial additional emissions, but below emission levels which would occur under a full derogation of PFAS use in PPE.		
	12 years	Unknown, depending on R&D progress, but continued R&D increases the chance that an alternative will be identified	Same as for a five-year derogation, but the total emissions can be expected to be higher.	Assuming that an alternative will be identified: Low producer surplus losses as a result of business closures [weak evidence] due to (i) a low share of business closures [weak evidence], and (ii) low producer surplus losses in the wider supply chain [weak evidence] Low producer surplus losses as a result of substitution [sufficiently	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				strong evidence], despite (i) high share of substitution [weak evidence] and (ii) medium to high costs at company level [sufficiently strong evidence], due to (i) the low number of companies being affected [sufficiently strong evidence] and (ii) low internalization of costs [sufficiently strong evidence] Low consumer surplus losses from price changes associated with substitution [sufficiently strong evidence] despite medium to high price changes [sufficiently strong evidence] resulting from medium to high substitution costs at company level [sufficiently strong evidence], which are passed on to customers to a high extent [sufficiently strong evidence], due to (i) the low annual sales volume [sufficiently strong evidence] and (ii) the low price elasticity of demand which limits impacts on the quantity demanded [sufficiently strong evidence] Some additional costs, as a result of earlier disposal of PPE as a result of the unavailability of impregnation agents for some types of PPE [sufficiently strong evidence] Low level of employment losses due to low share of business closures [weak evidence]	
Conclusion	A ban with a transition period of 18 months and a 12-year derogation is proposed for: Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) and (c);				

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
	- Personal protective equipment (PPE) in professional firefighting activities intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I, Risk Category III (a) - (m); and - Impregnation agents for re-impregnating of articles referred to above.				

As mentioned in section E.2.2.2.4, the Dossier Submitters consider that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives for professional sportswear and footwear. For PPE, the Dossier Submitters consider based on the evidence that there is sufficiently strong evidence to conclude that technically feasible alternatives exist for seven of 13 applications but do not exist for the other six applications. Based on evidence from other TULAC sub-sectors, e.g. consumer apparel, listed alternatives are also deemed to be economically feasible for PPE. As no evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters, the Dossier Submitters conclude by default that relevant alternatives exist in sufficient quantities for relevant professional apparel applications. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high for professional sportswear and footwear and seven of 13 PPE applications under a full ban with a transition period of 18 months, while the substitution potential is low for the other PPE applications.

The **assessment of costs** in relation to professional apparel **for a full ban with a transition period of 18 months** is based on evidence from the assessment of alternatives and the substitution potential and:

- Literature and public databases, e.g. a document produced by industry providing quantitative information on the number of active companies in the textile and clothing industry in the EU as well as the share of different sub-sectors in total EU production and the PRODCOM database;
- Principles relating to margins, the price elasticity of demand and offsetting potential;
- Information from a limited number of stakeholder interviews, e.g. on differences in applying alternative textile finishes and changes in operating costs;
- The CfE, e.g. changes in operating costs; and
- Information (from a non-representative sample) from the 2nd stakeholder consultation on, for example, (i) the timeframe required for substitution, (ii) annual sales losses of individual companies in the case of a restriction, (iii) differences in the costs of alternatives in comparison to PFASs, and (iv) the total costs associated with substitution at company level.

For professional apparel, the Dossier Submitters assessed (i) producer surplus losses resulting from company closures and substitution, as well as producer surplus losses in the supply chain, (ii) consumer surplus losses resulting from price changes, (iii) welfare losses and/or costs resulting from changes in the characteristics of the good, i.e. its quality and lifetime, or the absence of the product and (iv) employment losses.

Producer surplus losses for TULAC sub-sectors are determined based on an assessment of (i) the number of companies affected by the restriction, (ii) the most likely reaction of affected companies, (iii) the costs that companies face as a result of substitution or a stop of production and (iv) the ability of companies that substitute to pass on higher costs to their customers. The number of companies active in TULAC sub-sectors has, where available, been estimated based on industry data from a leading industry association on the number of companies active in the textile and clothing industry as well as the assumption that the share of the sub-sector in total EU production, provided by the same source, is a representative indicator of the number of companies active in the relevant sub-sector. This assumption leads to the plausible result that a comparatively high number of companies is active in sectors with lower barriers to entry, e.g. lower specialisation and certification requirements, such as the consumer apparel industry. Around 2 900 companies are estimated to be active (which is the lowest number among any of the sub-sectors) based on data from the industry association relating to workwear. As the data is related to workwear, the estimated number is deemed to cover PPE, while companies producing professional sportswear and footwear are deemed to be covered by the estimate for consumer apparel (presented in Section E.2.2.5.2), which is based on data for clothing and accessories, knitwear and underwear. The number of companies producing articles containing PFASs could not be estimated due to a lack of quantitative information on the share of companies using PFASs. The Dossier Submitters

conclude based on this evidence, which is considered to be sufficiently strong, that the number of companies affected by the proposed restriction in the professional apparel industry (in comparison to other TULAC sub-sectors) is low. The Dossier Submitters consider this conclusion to be robust despite the exclusion of professional apparel and sportswear. Given the comparatively small customer base for these goods, the number of relevant companies is deemed to be small and deemed to not affect the comparative conclusions on the sizes of different TULAC sub-sectors.

For determining the most likely reaction of affected companies in relation to professional apparel, the Dossier Submitters relied on conclusions concerning the substitution potential in combination with information from the 2nd stakeholder consultation on the economic and social impacts of a restriction and the timeframe required for substitution (with stakeholder information on the required timeframe solely relating to PPE). Based on this evidence, which is considered to be sufficiently strong, the Dossier Submitters conclude that the expected share of business closures in relation to professional apparel is high (especially as a result of the low substitution potential for PPE) under a full ban with a transition period of 18 months.

Producer surplus losses associated with a stop of production are, as mentioned in Section E.2.2.5.1, solely determined based on a consideration of margins (with low margins being associated with lower producer surplus losses) as data on annual sales losses reported by a limited and non-representative sample of companies in the 2nd stakeholder consultation did not point to differences in annual sales values between different TULAC sub-sectors. Data on annual sales losses at company level in relation to professional apparel (provided in the 2nd stakeholder consultation by a non-representative sample consisting of six companies) ranges from €1.2 million to €200 million. Due to a lack of quantitative information, margins were determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding the relation of the level of competition, market sizes and price elasticity of demand with margins. The size of the margin in relation to professional apparel, both professional sportswear and footwear and PPE, is found to be high (as for high performance membranes and textiles for use in engine bays). The offsetting potential is determined based on a consideration of principles on the interlinkage between the offsetting potential of other actors in the market and (i) the extent of competition, (ii) the market share of affected companies, (iii) the degree of specialization and (iv) other barriers to entry as well as (v) the extent of EU competition in comparison to international competition. These principles are well-grounded and have a robust foundation in the SEAC guidance on assessing changes in producer surplus, i.e. ECHA (2021b). In relation to professional apparel (both professional sportswear and footwear and PPE), the offsetting potential is found to be low mainly due to the high market share of affected actors. Given the high share of company closures and low offsetting potential, the extent of producer surplus losses in the wider supply chain are found to be high. The Dossier Submitters consider based on the assessment of alternatives, stakeholder information and aforementioned principles pointing to a high share of company closures, high producer surplus losses due to high margins, a low offsetting potential and high impacts on the wider supply chain, that there is sufficiently strong evidence to conclude that the socio-economic costs to industry in the form of producer surplus losses from business closures are high under a full ban with a transition period of 18 months.

Producer surplus losses resulting from substitution are, as mentioned in Section E.2.2.5.1, assessed on the basis of considerations of the extent to which companies will pass on higher costs to customers and considerations of R&D costs, capital costs for new equipment, changes in operating costs and re-certification costs. The extent to which companies are expected to pass on substitution costs to customers in the form of higher prices is determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding margins and the price elasticity of demand. The extent to which companies pass on costs to customers is found to be high for both professional sportswear and footwear as well as PPE (as for high performance membranes and textiles for use in engine bays) due to high margins and a low price elasticity of demand. Due to very limited quantitative information on substitution costs across TULAC sub-sectors, the

assessment of substitution costs has focussed on assessing differences across sub-sectors, e.g. based on a consideration of differences in the complexity of applications (which is deemed to affect R&D costs) and the relevance of re-certification/validation costs. The substitution cost in relation to professional apparel is found to be medium to high. The substitution cost for professional sportswear and footwear is found to be medium (as for home textiles, consumer apparel, outdoor technical textiles, medical applications and leather applications) due to the lower complexity of products which limits R&D costs and (in all cases except medical applications) the absence of re-certification costs. Due to higher R&D costs and costs for re-certification, substitution costs in relation to PPE are deemed to be high. The Dossier Submitters consider based on the aforementioned principles and information from the 2nd stakeholder consultation pointing to a low internalization of costs and medium to high substitution costs that there is sufficiently strong evidence to conclude that socio-economic costs to industry in the form of producer surplus losses from substitution are low under a full ban with a transition period of 18 months.

As mentioned in Section E.2.2.5.1, consumer surplus losses resulting from price changes associated with substitution for TULAC sub-sectors are determined based on consideration of (i) the magnitude of additional costs associated with substitution in each sub-sector, and the extent to which companies are expected to pass on such costs to customers, (ii) the extent to which the demand for goods produced in each sub-sector is deemed to vary with price and (iii) the total volume of goods (containing PFASs) sold to EU customers per year, also taking into account the extent to which this volume will be replaced by alternative-based products (based on a consideration of the substitution share). The volume of goods sold in TULAC sub-sectors has, where available, been estimated based on public data from the PRODCOM database and import and export data from a leading industry association as a basis for concluding on the magnitude of the volume of goods containing PFASs in each sub-sector. Based on medium to high substitution costs and a high extent to which costs are passed on to customers, price changes in relation to professional apparel are found to be medium to high (whereby high price changes are also expected high performance membranes and in relation to textiles for use in engine bays). Due to the low price elasticity of demand, consumer surplus losses will not be exacerbated by changes in the quantity demanded resulting from the price change. As explained in Section E.2.2.4.2, the annual volume of goods sold to EU customers is deemed to be the main determinant of differences in the magnitude of consumer surplus losses for different sub-uses. With around 100 000 t (of PPE), the estimated annual sales volume for professional apparel (including PFAS-free and PFAS-containing products) is the lowest of all assessed sub-sectors. Data gaps exist for most TULAC sub-sectors, including professional apparel for which the estimate is only based on information on PPE, resulting in a likely underestimation of volumes for these sectors. As this affects all apart from one sub-sector, comparative conclusions on the magnitude of sales volumes are however deemed to be robust. The annual sales volume of goods containing PFASs is deemed low and given that substitution is only an option for some types of PPE, consumer surplus losses from price changes will likely only be incurred in relation of a share of the estimated volume of around 100 000 t. As substitution is also expected to take place in relation to professional sportswear and footwear, the estimated annual sales volume is however deemed to be a good basis for estimating the magnitude of consumer surplus losses. The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of consumer surplus losses from price changes associated with substitution are low (in comparison to other TULAC sub-sectors) under a ban with a transition period of 18 months.

Changes in the characteristics of goods are of less relevance in relation to professional apparel, especially PPE. As revealed by the assessment of alternatives, PFASs are deemed to be required for several types of PPE. As the provision of products of lower quality (below the set standard) is not acceptable for such products, a complete restriction of PFASs would result in the complete unavailability of suitable PPE for these types instead of changes to the quality of PPE on the market. For types of PPE, for which alternatives are able to reach performance levels prescribed by legal standards, some quality changes could however occur, e.g. changes

in water vapour permeability and tear strengths. Information from the 2nd stakeholder consultation furthermore suggests that downstream users of PPE would incur additional costs for replacing PPE earlier than planned given that PPE that is already on the market relies on re-impregnation to provide its protective function. The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of welfare losses and costs resulting especially from the absence of certain types of PPE and the associated impacts on industrial production processes as well as earlier disposal of PPE would be high under a full ban with a transition period of 18 months.

As mentioned in section E.2.2.4, the magnitude of employment losses in different sub-sectors could not be estimated due to the significant uncertainty about the number of companies that would cease operation and a lack of representative data on the average number of employees in relevant companies (which might differ between sub-sectors depending on how labour-intensive the associated production process is). The Dossier Submitters consider based on sufficiently strong evidence pointing towards a high share of business closures in the professional apparel industry (especially in relation to PPE) that some socio-economic costs to society in the form of employment losses will occur under a full ban with a transition period of 18 months.

While all types of PPE that are already on the market rely on re-impregnation to provide its protective function, a derogation of impregnation agents for re-impregnating all types of PPE (and not only the articles referred to in the derogations mentioned in Table E.31) is not proposed as it is not deemed to significantly improve the balance between the costs and benefits of a full ban with a transition period of 18 months for the following reasons:

- The benefits of the full ban (in terms of reduced emissions) and consequently the effectiveness of the restriction would be lowered in exchange for avoiding negative environmental impacts from increased resource use resulting from earlier disposal. Given the challenges and significant costs associated with remediation of PFASs once emitted, the benefit of preventing PFASs emissions is deemed to be greater than the benefit of limiting resource use through a derogation.
- The cost to industry for replacing PPE before the end of its life cycle is deemed comparatively low.

E.2.2.5.4. Technical textiles

Table E.32 summarises the outcomes of the assessment of costs and benefits for technical textiles. More detailed information can be found in the accompanying text following the table.

Table E.32. Technical textiles - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Sufficiently strong evidence that technically feasible alternatives exist for outdoor technical textiles, with at least one of seven alternative substance groups being identified as relevant, i.e. • Polyurethane. Inconclusive evidence on whether technically feasible alternatives exist for all medical textile applications, with one of seven alternative substance groups being a possible alternative for membranes employed in medical textile applications, i.e.: • Polyurethane. Sufficiently strong evidence that technically feasible alternatives do not exist for all types of high performance membranes, with one of the seven alternative substance groups potentially being a relevant alternative for some applications, i.e.	Based on the available evidence, which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for sub-uses and PFAS groups and reasonable assumptions about environmental release, a full ban of PFAS use in TULAC will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for all TULAC sub-sectors, except automotive uses for insulation purposes (for which no volume data is available), together equals around 95% of baseline emissions for a 30-year period (2025-2055). As the environmental impact assessment	High producer surplus losses as a result of business closures [sufficiently strong evidence] due to (i) a high number of affected companies [sufficiently strong evidence], (ii) a high share of business closures (especially in relation to high performance membranes) [sufficiently strong evidence], (iii) high producer surplus losses at company level due to high margins (for high performance membranes) [sufficiently strong evidence], (iv) a low offsetting potential [sufficiently strong evidence] and (iv) high producer surplus losses in the wider supply chain [sufficiently strong evidence] Medium producer surplus losses as a result of substitution [sufficiently strong evidence], despite medium (and therefore comparatively low) substitution costs (for outdoor technical textiles) due to (i) the high share of substitution in relation to outdoor technical textiles [sufficiently strong evidence],	A derogation for filtration and separation media used in high performance air and liquid applications that require a combination of water-and oil repellence properties is proposed for the REACH restriction on PFHxA, its salts and related substances

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		Polyurethane. Sufficiently strong evidence that alternatives are economically feasible for outdoor technical textiles, e.g. based on stakeholder information on the proven use of alternative membranes and strong evidence for consumer apparel applications (which are deemed to be comparable to some extent) No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. As a result, there is sufficiently strong evidence to conclude that the substitution potential is high for outdoor technical textiles at EiF and low for high performance membranes. The substitution potential for medical applications at EiF is unclear.	does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	(ii) the likely considerable number of substituting companies [sufficiently strong evidence], (iii) partial internalization of costs [sufficiently strong evidence] and (iv) information on annual sold production volumes (of outdoor technical textiles) of EU producers of > 1 million tonnes [sufficiently strong evidence], which are classified as medium in comparison to other TULAC sub-sectors Medium consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence], mainly in relation to outdoor technical textiles, despite comparatively low price changes [sufficiently strong evidence] resulting from medium (and comparatively low) substitution costs at company level [sufficiently strong evidence] which are only partially passed on to customers [sufficiently strong evidence], due to (i) the medium annual sales volume [sufficiently strong evidence] and (ii) an exacerbation of consumer	

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				surplus losses due to a high price elasticity of demand [sufficiently strong evidence] High welfare losses or additional costs as a result of (i) the non-existence of technically feasible alternatives for some filtration applications, with impacts the lifetime of industrial equipment, (ii) changes in filtration efficiencies for other filtration applications, (iii) higher energy use in relation to these applications, (iv) more frequent replacement (and associated higher process downtimes) due to shorter lifetimes of filters, (v) some welfare losses as a result of lower functionality leading to inferior aesthetic appearance for outdoor technical textiles (or additional costs for counteracting changes in functionality), and (vi) additional costs in relation to outdoor technical textiles due to changes in the lifetime of goods [sufficiently strong evidence] Some employment losses as a result of high share of business closures [sufficiently strong evidence]	

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Ban with use-specific derogations: Derogation for textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence	5 years	Sufficiently strong evidence (based on stakeholder information and the Annex XV dossier for PFHxA) pointing to a high substitution potential for high performance membranes given that alternatives are already in the R&D stage and that available information on the timeframe required for approval and commercialization is in line with the available timeframe: As mentioned in Section E.2.2.4.2, the Dossier Submitter of the Annex XV dossier for PFHxA, its salts and related substances suggests the same derogation as this dossier, despite acknowledging that some alternatives might already be available or will become so in the near future. Stakeholder information (described in section E.2.2.2.1) suggests that alternatives to PTFE membranes and PFAS-coated products are produced but that PFASs are used for the	Filters/membranes are likely to cause emissions to a lesser extent compared to professional apparel applications for which a derogation is proposed, for example due to an assumed lower release factor (ERC12a, low release). If wear occurs under a high mechanical impact (ERC12b) emissions would be higher (ERC 20% instead of 2.5%) and may then not be considered negligible. There is sufficiently strong evidence that additional emissions of a time-limited derogation can be expected to be significantly below additional emissions under maximum additional emission scenarios. As the environmental impact assessment does not cover the waste phase, additional emissions as a result of	If trials and approval processes for alternatives in the R&D stage are successful, substitution will be encouraged by the high margins and low price elasticity of demand allowing affected companies in the filtration industry to pass on substitution costs to their customers: Low producer surplus losses as a result of business closures [sufficiently strong evidence], despite the high number of affected companies in the technical textile industry [sufficiently strong evidence] and high producer surplus losses at company level due to high margins (for high performance membranes) [sufficiently strong evidence] and a low offsetting potential [sufficiently strong evidence], due to (i) a low share of business closures [sufficiently strong evidence], and (ii) low producer surplus losses in the wider supply chain [sufficiently strong evidence] Medium producer surplus losses as a result of substitution [sufficiently strong evidence], despite low	n/a

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		production process. While filter media can also be produced without PFASs, such alternatives still need to be trialled, tested and validated. Stakeholder information presented in Section E.2.2.4.1 suggests furthermore that between three and 36 months might be needed for testing and approval, while a supplier of filters for mist and dust removal suggests that at least three years are required for commercializing an alternative technology and receiving customer validation and approval.	the derogation are likely underestimated.	internalization of high substitution costs in relation to high performance membranes [sufficiently strong evidence], due to (i) the high number of affected companies [sufficiently strong evidence] (ii) the high share of substitution for both applications [sufficiently strong evidence], and (iii) medium substitution costs in relation to outdoor technical textiles, which are partially internalized [sufficiently strong evidence] Medium (possibly high⁵⁶) consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence], due to (i) the medium sales volume for outdoor technical textiles alone, and the exacerbation of consumer surplus losses resulting from comparatively low price changes due to a high price elasticity of demand [sufficiently strong evidence], and (ii) additional consumer surplus	

⁵⁶ Sales volumes are deemed to be the main determinant of the magnitude of consumer surplus losses as mentioned in Section E.2.2.4.2. Due to a lack of data on sales volumes of high performance membranes, no definite conclusion on whether consumer surplus losses will be medium or high in comparison to other TULAC sub-sectors can be drawn as it is not clear whether the sales volume of high performance membranes results in a total sales volume of technical textiles that is comparable in magnitude to consumer apparel and home textiles, for which consumer surplus losses are found to be high.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				losses in relation to high performance membranes resulting from high price changes caused by high substitution costs, which are fully passed on to customers [sufficiently strong evidence] Some welfare losses or additional costs as a result of (i) changes in filtration efficiencies for some filtration applications, (ii) higher energy use in relation to these applications, (iii) more frequent replacement (and associated higher process downtimes) due to shorter lifetimes of such filters, (iv) some welfare losses as a result of lower functionality leading to inferior aesthetic appearance for outdoor technical textiles (or additional costs for counteracting changes in functionality), and (vi) additional costs in relation to outdoor technical textiles due to changes in the lifetime of goods [sufficiently strong evidence] Low level of employment losses due to low share of business closures [sufficiently strong evidence]	

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
	12 years	n/a	n/a	n/a	n/a
Conclusion	A ban with a transition period of 18 months and a 5-year derogation is proposed for: Textiles for the use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence.				

As mentioned in Section E.2.2.2.4, the Dossier Submitters consider based on the available evidence for outdoor technical textiles (and evidence underlying the assessment of alternatives for other TULAC applications) that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that technically feasible alternatives exist in sufficient quantities. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high under a full ban with a transition period of 18 months.

With respect to medical textile applications, the Dossier Submitters consider based on the available evidence that the evidence on the technical feasibility of alternatives for relevant applications is inconclusive. No conclusion on the substitution potential under a full ban with a transition period of 18 months can thus be drawn, but conclusions relating to the substitution potential for home textiles might be relevant to some extent given that medical applications include articles such as mattress protectors and curtains around beds.

With respect to high performance membranes, the Dossier Submitters consider based on the available evidence that there is sufficiently strong evidence that technically feasible alternatives do not exist for all types of high performance membranes, and that the substitution potential is low under a full ban with a transition period of 18 months.

The **assessment of costs** in relation to technical textiles **for a full ban with a transition period of 18 months** is based on evidence from the assessment of alternatives and the substitution potential and:

- Literature and public databases, e.g. a document produced by industry providing quantitative information on the number of active companies in the textile and clothing industry in the EU as well as the share of different sub-sectors in total EU production, an industry Risk Management Option Analysis (RMOA), the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances, and the PRODCOM database;
- Principles relating to margins, the price elasticity of demand and offsetting potential;
- Information from a limited number of stakeholder interviews, e.g. on differences in applying alternative textile finishes and changes in operating costs;
- The CfE, e.g. information on the sub-sectors with the highest use volumes of PFASs, the timeframe required for substitution and changes in operating costs; and
- Information (from a non-representative sample) from the 2nd stakeholder consultation on, for example, (i) the timeframe required for substitution, (ii) annual sales losses of individual companies in the case of a restriction, (iii) differences in the costs of alternatives in comparison to PFASs, (iv) the total costs associated with substitution at company level and (v) changes in the quality of articles, e.g. its lifetime.

For technical textiles, the Dossier Submitters assessed (i) producer surplus losses resulting from company closures and substitution, as well as producer surplus losses in the supply chain, (ii) consumer surplus losses resulting from price changes, (iii) welfare losses and/or costs resulting from changes in the characteristics of the good, i.e. its quality and lifetime and (iv) employment losses.

Producer surplus losses for TULAC sub-sectors are determined based on an assessment of (i) the number of companies affected by the restriction, (ii) the most likely reaction of affected companies, (iii) the costs that companies face as a result of substitution or a stop of production and (iv) the ability of companies that substitute to pass on higher costs to their customers. The number of companies active in TULAC sub-sectors has, where available, been estimated based on industry data from a leading industry association on the number of companies active in the textile and clothing industry as well as the assumption that the share of the sub-sector in total EU production, provided by the same source, is a representative indicator of the number of companies active in the relevant sub-sector. This assumption leads to the plausible result that a comparatively high number of companies is active in sectors with

lower barriers to entry, e.g. lower specialisation and certification requirements, such as the consumer apparel industry. Around 24 500 companies are estimated to be active in the technical textile industry (which is only exceeded by the consumer apparel industry and comparable in magnitude to the home textile industry). Given the high barriers to entry in relation to some types of technical textiles, e.g. high performance membranes, the estimated number of companies might be deemed comparatively high but given that the technical textile sector is composed of several specialised sub-sectors, including sectors with likely less barriers to entry such as the market for outdoor technical textiles, the existence of a high number of companies cannot be ruled out. The number of companies producing articles containing PFASs could not be estimated due to a lack of quantitative information on the share of companies using PFASs. Evidence from the CfE suggests, however, that the technical textile industry is one of the three biggest users within the TULAC industry. The Dossier Submitters conclude based on this evidence, which is considered to be sufficiently strong, that the number of companies affected by the proposed restriction in the technical textile industry (in comparison to other TULAC sub-sectors) is high (as for consumer apparel, and thereby higher than for the home textile industry due to the more limited market penetration of alternative-based products).

For determining the most likely reaction of affected companies in relation to technical textiles, the Dossier Submitters relied on:

- Conclusions concerning the existence of technically feasible alternatives and the substitution potential (summarised at the beginning of this section);
- Information from the 2nd stakeholder consultation on the economic and social impacts of a restriction (which is dominated by information relating to high performance membranes); and
- Information from the CfE and 2nd stakeholder consultation on the timeframe required for substitution (with stakeholder information on the required timeframe relating to medical applications and high-performance membranes).

Information (from a small and non-representative sample of less than 10 stakeholders) on the economic and social impacts of the restriction at company level suggests a clear tendency towards business closures. With respect to the timeframe required for substitution, no clear conclusion on the required timeframe could be drawn for technical textiles for medical applications due to the large variations in the timeframe reported to be required for approval alone (with reported timeframes ranging from days to ten years). In relation to filtration applications, reported timeframes for testing and approval range from three months to three years, while reported timeframes for the entire substitution process range from at least three years up to ten years, whereby the estimate of up to ten years is based on past experience with substitution from C8 to C6 substances. Substitution might thus be feasible in the timeframe available until the restriction takes full effect, but some uncertainty prevails – especially based on practical experiences from the past.

Based on this evidence, which is considered to be sufficiently strong, the Dossier Submitters conclude that the expected share of business closures in relation to technical textiles is high for high performance membranes under a full ban with a transition period of 18 months, due to the limited implementation of alternatives on the market, information pointing to challenges with the replication of the multitude of functionalities provided by PFAS, information on economic and social impacts from the 2nd stakeholder consultation pointing to a high share of business closures, as well as the potentially long timeframe that is required for substitution.

With respect to outdoor technical textiles, the Dossier Submitters conclude based on the available evidence, which is considered to be sufficiently strong, that the expected share of business closures is low, due to the high substitution potential, only limited and weak evidence from the 2nd stakeholder consultation pointing to business closures and the absence of evidence pointing to challenges with respect to the timeframe required for substitution. No conclusion on the share of business closures can be drawn for technical textiles for medical

applications due to the unclear substitution potential, only limited and weak evidence from the 2nd stakeholder consultation pointing to business closures and the unclarity on the timeframe required for substitution.

Producer surplus losses associated with a stop of production are, as mentioned in Section E.2.2.5.1, solely determined based on a consideration of margins (with low margins being associated with lower producer surplus losses) as data on annual sales losses reported by a limited and non-representative sample of companies in the 2nd stakeholder consultation did not point to differences in annual sales values between different TULAC sub-sectors. Data on annual sales losses at company level in relation to technical textiles (provided in the 2nd stakeholder consultation by a non-representative sample consisting of five companies) ranges from €10 million and €50 million. Due to a lack of quantitative information, margins were determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding the relation of the level of competition, market sizes and price elasticity of demand with margins. In relation to technical textiles, the size of the margin differs across applications. It is found to be high for high performance membranes (as for professional apparel and textiles for use in engine bays) and low for outdoor technical textiles and medical applications (as for home textiles, consumer apparel, leather applications and home fabric treatments). The offsetting potential is determined based on a consideration of principles on the interlinkage between the offsetting potential of other actors in the market and (i) the extent of competition, (ii) the market share of affected companies, (iii) the degree of specialization and (iv) other barriers to entry as well as (v) the extent of EU competition in comparison to international competition. These principles are well-grounded and have a robust foundation in the SEAC guidance on assessing changes in producer surplus, i.e. ECHA (2021b). In relation to technical textiles, the offsetting potential is found to be low, mainly due to the high market share of affected companies. Given the high share of company closures (for at least some applications) and low offsetting potential, the extent of producer surplus losses in the wider supply chain are found to be high. The Dossier Submitters consider based on the assessment of alternatives, stakeholder information and aforementioned principles pointing to a high number of affected companies, a high share of company closures (especially in relation to high performance membranes), high producer surplus losses due to high margins (for high performance membranes), a low offsetting potential and high impacts on the wider supply chain that there is sufficiently strong evidence to conclude that the socio-economic costs to industry in the form of producer surplus losses from business closures are high under a full ban with a transition period of 18 months.

Producer surplus losses resulting from substitution are, as mentioned in Section E.2.2.5.1, assessed on the basis of considerations of the extent to which companies will pass on higher costs to customers and considerations of R&D costs, capital costs for new equipment, changes in operating costs and re-certification costs. The extent to which companies are expected to pass on substitution costs to customers in the form of higher prices is determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding margins and the price elasticity of demand. The extent to which companies pass on costs to customers is found to be high for high performance membranes (as for professional apparel and textiles for use in engine bays) due to high margins and a low price elasticity of demand. For outdoor technical textiles and medical applications the extent to which companies pass on costs to customers is found to be low (partial) (as for companies in the home textile, consumer apparel and leather industries as well as producers of home fabric treatments) due to low margins and a high price elasticity of demand. Due to very limited quantitative information on substitution costs across TULAC sub-sectors, the assessment of substitution costs has focussed on assessing differences across sub-sectors, e.g. based on a consideration of differences in the complexity of applications (which is deemed to affect R&D costs) and the relevance of re-certification/validation costs. The substitution cost in relation to technical textiles is found to be medium to high, with the substitution cost for outdoor technical textiles deemed to be medium (as for home textiles, consumer apparel, professional sportswear and footwear and leather applications) and thereby lower than for other technical textile applications. The

substitution cost for outdoor technical textiles is found to be medium due to the lower complexity of products which limits R&D costs and the absence of re-certification costs. The Dossier Submitters consider based on the high share of substitution for outdoor technical textiles, the likely considerable number⁵⁷ of substituting companies, the aforementioned principles and information from consultations pointing to a high (partial) internalization of costs and medium substitution costs as well as an annual sales volume of >1 million tonnes (which is classified as medium in comparison to other TULAC sub-sectors) that there is sufficiently strong evidence to conclude that socio-economic costs to industry in the form of producer surplus losses from substitution are medium under a full ban with a transition period of 18 months.

As mentioned in Section E.2.2.5.1, consumer surplus losses resulting from price changes associated with substitution for TULAC sub-sectors are determined based on consideration of (i) the magnitude of additional costs associated with substitution in each sub-sector, and the extent to which companies are expected to pass on such costs to customers, (ii) the extent to which the demand for goods produced in each sub-sector is deemed to vary with price and (iii) the total volume of goods (containing PFASs) sold to EU customers per year, also taking into account the extent to which this volume will be replaced by alternative-based products (based on a consideration of the substitution share). The volume of goods sold in TULAC sub-sectors has, where available, been estimated based on public data from the PRODCOM database and import and export data from a leading industry association as a basis for concluding on the magnitude of the volume of goods containing PFASs in each sub-sector. As mentioned above, substitution is mainly of relevance in relation to outdoor technical textiles under a full ban with a transition period of 18 months. Based on medium substitution costs in relation to outdoor technical textiles (which are lower in magnitude than substitution costs for PPE, other types of technical textiles and textiles for the use in engine bays) and a low (partial) extent to which costs are passed on to customers, price changes in relation to technical textiles (more specifically outdoor technical textiles) are found to be low (as for home textiles, consumer apparel and leather products). Due to the high price elasticity of demand for outdoor technical textiles, consumer surplus losses will be exacerbated by changes in the quantity demanded resulting from the price change. As explained in Section E.2.2.4.2, the annual volume of goods sold to EU customers is deemed to be the main determinant of differences in the magnitude of consumer surplus losses for different sub-uses. With around 1.3 million tonnes, the estimated annual sales volume for technical textiles (including PFAS-free and PFAS-containing products), which only covers outdoor technical textiles and imports of textiles for medical applications (accounting for around 125 000 t), is medium and exceeded by home textiles and consumer apparel. The annual sales volume of goods containing PFAS is also deemed to be medium (in comparison to other TULAC sub-sectors). The entire volume will likely be replaced by PFAS-free products given the high share of substitution in relation to outdoor technical textiles and the potential of substituting companies to take over market shares from companies ceasing production. The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of consumer surplus losses from price changes associated with substitution in the outdoor technical textile industry are medium (in comparison to other TULAC sub-sectors) under a ban with a transition period of 18 months.

With respect to changes in the characteristics of goods, evidence from stakeholders from the 2nd stakeholder consultation, Drohmann et al. (2021) and the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances points to possible negative impacts on the lifetime of outdoor technical textiles (ECHA, 2021a). In relation to PTFE membranes used in outdoor technical textiles, for which polyurethane- and polyester-based membranes are, for example, reported as a proven alternative, no information on differences in the quality and

⁵⁷ Due to the high number of affected companies in the technical textile industry and the low barriers to entry in the outdoor technical textile industry, the number of substituting companies might be considerable.

lifetime is available. In relation to textile finishes, e.g. PFAS-based top coat finishes for applications such as outdoor upholstery and tents, stakeholder information however points to significant changes in the lifetime of products. The lifetime of articles is reported to be around three to five times shorter if the PFAS-based top coat finish is not applied on the PVC-coated fabrics. The PFAS-based coatings themselves are furthermore reported to be significantly more durable than other coating technologies (Drohmann et al., 2021). A reduced lifetime of outdoor technical textiles, such as outdoor cushions and seating, was also mentioned in stakeholder responses to the Annex XV report consultation conducted in relation to the restriction on PFHxA as a result of the lower dirt, oil and soil repellence of alternatives and the resulting visual impairments (ECHA, 2021a). The Dossier Submitters consider based on that evidence (and the evidence for home textiles) that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of welfare losses (resulting from inferior aesthetic appearance) and additional costs for counteracting changes in functionality and durability, e.g. purchasing washable covers and more frequent re-coating, or more frequent replacement are likely to occur under a full ban with a transition period of 18 months.

In relation to high performance membranes, available evidence (based on stakeholder information) points to the non-existence of alternatives for some applications, e.g. coalescing filters as well as membranes for the filtration of very fine particles. For coalescing filters, the absence of such filters is reported to lead to the failure or shortened lifetime of industrial equipment, with wide-ranging economic consequences due to the widespread use of such filter in nearly all industry sectors. The proven use of polyurethane (as well as polyester-based membranes) in high performance membranes is however also reported. While the overall substitution potential is thus low, as described in Section E.2.2.2.4, some substitution might be feasible. Changes in quality and lifetime are however likely under a full ban with transition period of 18 months. Stakeholder information points to possible changes in pressure properties (porosity), filtration efficiency (e.g. in relation to the removal of microbiological contaminants from air and process fluids and the removal of dusts and mists in industrial processes). Due to higher drops in pressure across filters, the use of alternatives is also reported to increase energy use. Stakeholder information also points to changes in the lifetime of filters and possible degradation of filters leading to contamination downstream. The lower lifetime of alternative filtration solutions is reported to lead to increased costs to industrial end users due to higher process downtimes. The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of welfare losses (e.g. changes in filtration efficiency) and additional costs, including increased energy costs as well as costs resulting from higher replacement frequencies of filters, higher process downtimes and shortened lifetimes of industrial equipment would be high under a full ban with a transition period of 18 months.

As mentioned in section E.2.2.4, the magnitude of employment losses in different sub-sectors could not be estimated due to the significant uncertainty about the number of companies that would cease operation and a lack of representative data on the average number of employees in relevant companies (which might differ between sub-sectors depending on how labour-intensive the associated production process is). The Dossier Submitters consider based on the sufficiently strong evidence pointing towards a high share of business closures in relation to high performance membranes that some socio-economic costs to society in the form of employment losses will occur under a full ban with a transition period of 18 months.

E.2.2.5.5. Leather

Table E.33 summarises the outcomes of the assessment of costs and benefits for leather applications. More detailed information can be found in the accompanying text following the table.

Table E.33. Leather - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Sufficiently strong evidence that technically feasible alternatives exist, with four of seven alternative substance groups being identified as relevant for leather applications, i.e.: • Hybrid (Silicone/hydrocarbon); • Hydrocarbons; • Polyurethanes; and • Silicones. No practical examples of completed substitution are available but the sufficiently strong evidence for consumer apparel, which includes practical examples of completed substitution, suggests that listed alternatives are economically feasible. No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. As a result, there is sufficiently strong evidence to conclude that the substitution potential is high at EiF.	Based on the available evidence, which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for sub-uses and PFAS groups and reasonable assumptions about environmental release, a full ban of PFAS use in TULAC will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for all TULAC sub-sectors, except automotive uses for insulation purposes (for which no volume data is available), together equals around 95% of baseline emissions for a 30-year period (2025-2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Low producer surplus losses as a result of business closures [sufficiently strong evidence], despite low offsetting potential [sufficiently strong evidence], due to (i) a low share of business closures [sufficiently strong evidence], (ii) low producer surplus losses at company level due to low margins [sufficiently strong evidence] and (iii) low producer surplus losses in the wider supply chain [sufficiently strong evidence] Medium producer surplus losses as a result of substitution [sufficiently strong evidence], despite comparatively low costs at company level [sufficiently strong evidence], due (i) a high share of substitution [sufficiently strong evidence], (ii) partial internalization of costs [sufficiently strong evidence] and (iii) information on annual sold production volumes of EU producers of around 900 000 t [sufficiently strong evidence] Medium consumer surplus losses resulting from price changes associated with substitution [sufficiently strong evidence] despite comparatively low price changes [sufficiently strong evidence] resulting from medium (and comparatively low) substitution costs at company level [sufficiently strong evidence] which are only	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				partially passed on to customers [sufficiently strong evidence], due to (i) the medium annual sales volume [sufficiently strong evidence] and (ii) an exacerbation of consumer surplus losses due to a high price elasticity of demand [sufficiently strong evidence] Some welfare losses or additional costs as a result of lower functionality, e.g. in relation to oil and dirt repellence [sufficiently strong evidence] Low level of employment losses due to low share of business closures [sufficiently strong evidence]	
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion	A full ban of PFASs in leather applications with a transition period of 18 months is proposed.				

As mentioned in Section E.2.2.2.4, the Dossier Submitters consider based on the available evidence for leather applications and the evidence for consumer apparel pointing to the economic feasibility of named alternatives that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives for leather applications. The evidence is, however, considered to be somewhat weaker than for home textiles and consumer apparel due the existence of some conflicting evidence. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that technically and economically feasible alternatives exist in sufficient quantities for use in leather applications and that the substitution potential is high under a full ban with a transition period of 18 months.

The **assessment of costs** in relation leather applications **for a full ban with a transition period of 18 months** is based on evidence from Annex A on uses and functions, the assessment of alternatives and the substitution potential and:

- Literature and public databases, e.g, the Annex XV dossier proposing a restriction for PFHxA, its salts and related substance, the PRODCOM database and an industry RMOA;
- Principles relating to margins, the price elasticity of demand and offsetting potential;
- Information from a limited number of stakeholder interviews, e.g. on differences in applying alternative textile finishes and changes in operating costs;
- The CfE, e.g. changes in operating costs and differences in functionality; and
- Information (from a non-representative sample) from the 2nd stakeholder consultation on, for example, (i) the timeframe required for substitution, (ii) annual sales losses of individual companies in the TULAC industry in the case of a restriction, (iii) differences in the costs of alternatives in comparison to PFASs, and (iv) the total costs associated with substitution at company level.

For leather applications, the Dossier Submitters looked into assessing (i) producer surplus losses resulting from company closures and substitution, as well as producer surplus losses in the supply chain, (ii) consumer surplus losses resulting from price changes, (iii) welfare losses and/or costs resulting from changes in the characteristics of the good, i.e. its quality and lifetime and (iv) employment losses.

Producer surplus losses for TULAC sub-sectors are determined based on an assessment of (i) the number of companies affected by the restriction, (ii) the most likely reaction of affected companies, (iii) the costs that companies face as a result of substitution or a stop of production and (iv) the ability of companies that substitute to pass on higher costs to their customers. The number of companies active in TULAC sub-sectors has, where available, been estimated based on industry data from a leading industry association on the number of companies active in the textile and clothing industry as well as the assumption that the share of the sub-sector in total EU production, provided by the same source, is a representative indicator of the number of companies active in the relevant sub-sector. As data for leather applications was not covered by this set of data, the number of companies active in this industry branch has not been estimated. Quantitative information on the share of companies using PFASs is not available but the share is deemed to be comparatively high as cases of completed substitution do not seem to be as widespread as for home textiles, for which evidence points to voluntary industry commitments. As a result, the Dossier Submitters conclude that there is no evidence on the magnitude of companies (in comparison to other TULAC sub-sectors) that is affected by the restriction.

As no conclusion on the most likely reaction of affected companies, i.e. the share of companies in the leather industry opting for substitution in comparison to stopping production, could be drawn based on stakeholder information, the Dossier Submitters relied solely on conclusions concerning the substitution potential in combination with information from the 2nd stakeholder consultation on the timeframe required for substitution. The Dossier Submitters consider that there is sufficiently strong evidence that the substitution potential is high under a full ban with a transition period of 18 months. As between two and three years are reported as being required for completing substitution in relation to leather-based apparel after identification of

a relevant alternative, the timeframe available is not found to be of concern. Based on this evidence, which is considered to be sufficiently strong, the Dossier Submitters conclude that the expected share of business closures is low under a full ban with a transition period of 18 months (as for home textiles, outdoor technical textiles and home fabric treatments).

Producer surplus losses associated with a stop of production are, as mentioned in Section E.2.2.5.1, solely determined based on a consideration of margins (with low margins being associated with lower producer surplus losses) as data on annual sales losses reported by a limited and non-representative sample of companies in the 2nd stakeholder consultation did not point to differences in annual sales values between different TULAC sub-sectors. Specific data on annual sales losses in relation to leather applications was not provided in the 2nd stakeholder consultation. Due to a lack of quantitative information, margins were determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding the relation of the level of competition, market sizes and the price elasticity of demand with margins. The size of the margin in relation to leather applications is found to be low (as for home textiles, consumer apparel, home fabric treatments, outdoor technical textiles and medical applications). The offsetting potential is determined based on a consideration of principles on the interlinkage between the offsetting potential of other actors in the market and (i) the extent of competition, (ii) the market share of affected companies, (iii) the degree of specialization and (iv) other barriers to entry as well as (v) the extent of EU competition in comparison to international competition. These principles are well-grounded and have a robust foundation in the SEAC guidance on assessing changes in producer surplus, i.e. ECHA (2021b). In relation to leather applications, the offsetting potential is found to be low especially due to the high market share of affected companies. Given the low share of company closures, the extent of producer surplus losses in the wider supply chain are found to be low. The Dossier Submitters consider based on the assessment of alternatives and aforementioned principles pointing to a low share of company closures, low producer surplus losses due to low margins, a low offsetting potential and low impacts on the wider supply chain that there is sufficiently strong evidence to conclude that the socio-economic costs to industry in the form of producer surplus losses from business closures are low under a full ban with a transition period of 18 months.

Producer surplus losses resulting from substitution are, as mentioned in Section E.2.2.5.1, assessed on the basis of considerations of the extent to which companies will pass on higher costs to customers and considerations of R&D costs, capital costs for new equipment, changes in operating costs and re-certification costs. The extent to which companies are expected to pass on substitution costs to customers in the form of higher prices is determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding margins and the price elasticity of demand. The extent to which companies pass on costs to customers is found to be low (partial) in relation to leather applications (as for companies in the home textile and consumer apparel industry as well as producers of home fabric treatments, outdoor technical textiles and medical applications) due to low margins and a high price elasticity of demand. Due to very limited quantitative information on substitution costs across TULAC sub-sectors, the assessment of substitution costs has focussed on assessing differences across sub-sectors, e.g. based on a consideration of differences in the complexity of applications (which is deemed to affect R&D costs) and the relevance of re-certification/validation costs. The substitution cost in relation to leather applications is found to be medium (as for home textiles, consumer apparel, professional sportswear and footwear, and outdoor technical textiles and medical applications) and therefore more limited than in relation to other technical textile applications, PPE and textiles for the use in engine bays due to the lower complexity of products which limits R&D costs and (in all cases except medical applications) the absence of re-certification costs. The Dossier Submitters consider based on the aforementioned principles pointing to a high (partial) internalization of costs, medium substitution costs, no evidence on the number of companies being affected, but a medium annual sales volume described in Section E.2.2.4.2, and the high share of substitution that there is sufficiently strong evidence to conclude that socio-economic costs to industry in the form of producer surplus losses from substitution (in

comparison to other TULAC sub-sectors) are medium under a full ban with a transition period of 18 months.

As mentioned in Section E.2.2.5.1, consumer surplus losses resulting from price changes associated with substitution for TULAC sub-sectors are determined based on consideration of (i) the magnitude of additional costs associated with substitution in each sub-sector, and the extent to which companies are expected to pass on such costs to customers, (ii) the extent to which the demand for goods produced in each sub-sector is deemed to vary with price and (iii) the total volume of goods (containing PFASs) sold to EU customers per year, also taking into account the extent to which this volume will be replaced by alternative-based products (based on a consideration of the substitution share). The volume of goods sold in TULAC sub-sectors has, where available, been estimated based on public data from the PRODCOM database and import and export data from a leading industry association as a basis for concluding on the magnitude of the volume of goods containing PFASs in each sub-sector. Based on medium substitution costs (which are lower in magnitude than substitution costs for PPE, high performance membranes and textiles for the use in engine bays), and a low (partial) extent to which costs are passed on to customers, price changes in relation to leather-based products are found to be low (as for home textiles, consumer apparel, outdoor technical textiles and medical applications). Due to the high price elasticity of demand, consumer surplus losses will be exacerbated by changes in the quantity demanded resulting from the price change. As explained in Section E.2.2.4.2, the annual volume of goods sold to EU customers is deemed to be the main determinant of differences in the magnitude of consumer surplus losses for different sub-uses. With around 900 000 t, the estimated annual sales volume (estimated without consideration of imports and exports due to a lack of information) for leather-based products (including PFAS-free and PFAS-containing products) is the second lowest of all assessed sub-sectors. Data gaps exist for most TULAC sub-sectors including leather-based products for which the estimate is only based on only three of four relevant product categories (as no data was available for professional sportswear and footwear), resulting in a likely underestimation of volumes for these sectors. As this affects all apart from one sub-sector, comparative conclusions on the magnitude of sales volumes are however deemed to be robust. The annual sales volume of goods containing PFASs is deemed medium. The entire volume will likely be replaced by PFAS-free products given the high share of substitution. The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of consumer surplus losses from price changes associated with substitution are medium (in comparison to other TULAC sub-sectors) under a ban with a transition period of 18 months.

With respect to changes in the characteristics of goods, evidence from the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances, the CfE and 2nd stakeholder consultation suggests that the difference between PFASs and alternatives is their capacity to provide several functionalities simultaneously. While reaching broadly comparable levels of water repellence tends not to be a concern, identified alternatives reach lower levels of performance for other functionalities such as oil and dirt repellence, which might also impact the lifetime of the good. As mentioned in Section A.3.3.1, oil repellence is (as for home textiles as well as sportswear and footwear) deemed to be important for leather-based products. As such, some changes to the quality are likely. This is also confirmed by information from one stakeholder submitting information relating to leather to the 2nd stakeholder consultation reporting that they have been able to identify an alternative whose oil and soil repellence properties are *close enough*, and not identical. In relation to the use of fluoropolymers (for anti-soiling purposes) in the manufacture of leather products, silicone-based products are furthermore reported by Drohmann et al. (2021) to be an alternative that could provide a comparable performance with respect to soil repellence with resistance to coffee being the sole exception. The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of welfare losses (resulting from inferior aesthetic appearance) and/or additional costs for counteracting changes in functionality, e.g. more frequent replacement, are likely to occur under a full ban with a transition period of 18 months.

The Dossier Submitters consider, furthermore, based on sufficiently strong evidence from the assessment of alternatives pointing towards a low share of business closures in relation to leather applications that there is sufficiently strong evidence to conclude that the socio-economic costs to society in the form of employment losses will be low under a full ban.

E.2.2.5.6. Other: Home fabric treatments (sprays)

Table E.34 summarises the outcomes of the assessment of costs and benefits for home fabric treatments (sprays). More detailed information can be found in the accompanying text following the table.

Table E.34. Home fabric treatments (sprays) - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Sufficiently strong evidence that technically feasible alternatives exist, with one of seven alternative substance groups being identified as relevant for home fabric treatments, i.e.: • Silicones. Sufficiently strong evidence that identified alternatives are also economically feasible based on information from other TULAC sub-sectors No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. As a result, there is sufficiently strong evidence to conclude that the substitution potential is high at EiF.	Based on the available evidence, which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for sub-uses and PFAS groups and reasonable assumptions about environmental release, a full ban of PFAS use in TULAC will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for all TULAC sub-sectors, except automotive uses for insulation purposes (for which no volume data is available), together equals around 95% of baseline emissions for a 30-year period (2025-2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Low producer surplus losses as a result of business closures [sufficiently strong evidence] due to (i) a low share of business closures [sufficiently strong evidence], (ii) low producer surplus losses at company level due to low margins [sufficiently strong evidence], and (iii) low producer surplus losses in the wider supply chain [sufficiently strong evidence] No evidence on the magnitude of producer surplus losses as a result of substitution, due to no evidence on the number of affected companies and the magnitude of substitution costs No evidence on the magnitude of consumer surplus losses resulting from price changes associated with substitution, due to no evidence on magnitude of price changes and no evidence on annual sales volumes Some welfare losses or additional costs as a result of lower functionality, e.g. in relation to oil and dirt repellence [sufficiently strong evidence] Low level of employment losses due to low share of business closures [sufficiently strong evidence]	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion	A full ban of PFASs in home fabric treatments with a transition period of 18 months is proposed.				

As mentioned in Section E.2.2.2.4, the Dossier Submitters consider based on the available evidence resulting from an extensive literature review taking into account information from a variety of actors, no contradictory evidence from consultation with stakeholders (and evidence relating to home textiles and consumer apparel) that there is sufficiently strong evidence for the existence of technically feasible alternatives for home fabric treatments. No information on the economic feasibility of alternatives for this specific application is available. Based on strong evidence for home textiles and consumer apparel pointing to the economic feasibility of the named alternative group, the Dossier Submitters however consider that alternatives are also economically feasible. As no evidence is available to the Dossier Submitters that points to a shortage in supply of alternatives, the Dossier Submitters conclude by default that technically and economically feasible alternatives exist in sufficient quantities for use in home fabric treatments. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high under a full ban with a transition period of 18 months.

The **assessment of costs** in relation to home fabric treatments **for a full ban with a transition period of 18 months** is based on evidence from the assessment of alternatives and the substitution potential and:

- Literature, e.g, the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances;
- Principles relating to margins, the price elasticity of demand and offsetting potential;
- The CfE, e.g. information on differences in functionality; and
- Information (from a non-representative sample) from the 2nd stakeholder consultation on, for example, (i) annual sales losses of individual companies in the TULAC industry in the case of a restriction, and (ii) the total costs associated with substitution at company level.

For home fabric treatments, the Dossier Submitters looked into assessing (i) producer surplus losses resulting from company closures and substitution, as well as producer surplus losses in the supply chain, (ii) consumer surplus losses resulting from price changes, (iii) welfare losses and/or costs resulting from changes in the characteristics of the good, i.e. its quality and lifetime and (iv) employment losses.

Producer surplus losses for TULAC sub-sectors are determined based on an assessment of (i) the number of companies affected by the restriction, (ii) the most likely reaction of affected companies, (iii) the costs that companies face as a result of substitution or a stop of production and (iv) the ability of companies that substitute to pass on higher costs to their customers. The number of companies active in TULAC sub-sectors has, where available, been estimated based on industry data from a leading industry association on the number of companies active in the textile and clothing industry as well as the assumption that the share of the sub-sector in total EU production, provided by the same source, is a representative indicator of the number of companies active in the relevant sub-sector. As data for home fabric treatments was not covered by this set of data, the number of companies active in this industry branch has not been estimated. No information on the market penetration of alternative-based products and consequently the share of relevant companies manufacturing products containing PFASs is available. As a result, the Dossier Submitters conclude that there is no evidence on the magnitude of companies (in comparison to other TULAC sub-sectors) that is affected by the restriction.

For determining the most likely reaction of affected companies in relation to home fabric treatments, the Dossier Submitters relied solely on the conclusions concerning the substitution potential (summarised at the beginning of this section) as no sub-sector-specific information on the economic and social impacts of a restriction and the timeframe required for substitution was available from consultations. Based on this evidence, which is considered to be sufficiently strong, the Dossier Submitters conclude that the expected share of business closures in relation to home fabric treatments is low (as for home textiles, outdoor technical textiles and leather applications) under a full ban with a transition period of 18 months.

Producer surplus losses associated with a stop of production are, as mentioned in Section E.2.2.5.1, solely determined based on a consideration of margins (with low margins being associated with lower producer surplus losses) as data on annual sales losses reported by a limited and non-representative sample of companies in the 2nd stakeholder consultation did not point to differences in annual sales values between different TULAC sub-sectors. Specific data on annual sales losses in relation to home fabric treatments was not provided in the 2nd stakeholder consultation. Due to a lack of quantitative information, margins were determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding the relation of the level of competition, market sizes and price elasticity of demand with margins. The size of the margin in relation to home fabric treatments is found to be low (as for home textiles, consumer apparel, leather applications, outdoor technical textiles and medical applications). The offsetting potential is determined based on a consideration of principles on the interlinkage between the offsetting potential of other actors in the market and (i) the extent of competition, (ii) the market share of affected companies, (iii) the degree of specialization and (iv) other barriers to entry as well as (v) the extent of EU competition in comparison to international competition. These principles are well-grounded and have a robust foundation in the SEAC guidance on assessing changes in producer surplus, i.e. ECHA (2021b). In relation to home fabric treatments, no conclusion on the offsetting potential could be drawn due to a lack of evidence on the market penetration of alternative-based products and consequently the market share of affected actors. Given the low share of company closures, the extent of producer surplus losses in the wider supply chain are found to be low. The Dossier Submitters consider based on the assessment of alternatives and aforementioned principles pointing to a low share of company closures, low producer surplus losses due to low margins, and low impacts on the wider supply chain that there is sufficiently strong evidence to conclude that the socio-economic costs to industry in the form of producer surplus losses from business closures are low under a full ban with a transition period of 18 months.

Producer surplus losses resulting from substitution are, as mentioned in Section E.2.2.5.1, assessed based on considerations of the extent to which companies will pass on higher costs to customers and considerations of R&D costs, capital costs for new equipment, changes in operating costs and re-certification costs. The extent to which companies are expected to pass on substitution costs to customers in the form of higher prices is determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding margins and the price elasticity of demand. The extent to which companies pass on costs to customers is found to be low (partial) in relation to home fabric treatments (as for companies in the home textile, consumer apparel and leather industries as well as producers of outdoor technical textiles and medical applications) due to low margins and the high price elasticity of demand. Due to very limited quantitative information on substitution costs across TULAC sub-sectors, the assessment of substitution costs has focussed on assessing differences across sub-sectors, e.g. based on a consideration of differences in the complexity of applications (which is deemed to affect R&D costs) and the relevance of re-certification/validation costs. Information from consultations on the magnitude of capital costs and changes in operating costs associated with substitution are not deemed of relevance for home fabric treatments as available information refers to the application of textile finishes. The magnitude of substitution costs in relation to home fabric treatments is therefore unknown. As a result, the Dossier Submitters consider based on the aforementioned principles pointing to a high (partial) internalization of costs, the high share of substitution, no evidence on the number of companies being affected and no evidence on the magnitude of substitution costs (in comparison to other TULAC sub-sectors), that there is no evidence on the magnitude of socio-economic costs to industry in the form of producer surplus losses from substitution (in comparison to other TULAC sub-sectors) under a full ban with a transition period of 18 months.

As mentioned in Section E.2.2.5.1, consumer surplus losses resulting from price changes associated with substitution for TULAC sub-sectors are determined based on consideration of

(i) the magnitude of additional costs associated with substitution in each sub-sector, and the extent to which companies are expected to pass on such costs to customers, (ii) the extent to which the demand for goods produced in each sub-sector is deemed to vary with price and (iii) the total volume of goods (containing PFASs) sold to EU customers per year, also taking into account the extent to which this volume will be replaced by alternative-based products (based on a consideration of the substitution share). The volume of goods sold in TULAC sub-sectors has, where available, been estimated based on public data from the PRODCOM database and import and export data from a leading industry association as a basis for concluding on the magnitude of the volume of goods containing PFASs in each sub-sector. As data for home fabric treatments was not covered by this set of data, annual sales volumes could not be estimated. As the magnitude of substitution costs for home fabric treatments is unknown, the magnitude of price changes for home fabric treatments (in comparison to other TULAC sub-sectors) is also unknown. As a result, the Dossier Submitters consider that there is no evidence on the magnitude of socio-economic costs to customers in the form of consumer surplus losses from price changes associated with substitution (in comparison to other TULAC sub-sectors).

With respect to changes in the characteristics of goods, evidence from the Annex XV dossier proposing a restriction for PFHxA, its salts and related substances, the CfE and 2nd stakeholder consultation suggests that the difference between PFASs and alternatives is their capacity to provide several functionalities simultaneously. While reaching broadly comparable levels of water repellence tends not to be a concern, identified alternatives reach lower levels of performance for other functionalities such as oil and dirt repellence. The Dossier Submitters consider based on that evidence that there is sufficiently strong evidence to conclude that socio-economic costs to customers in the form of welfare losses (resulting from inferior performance of home fabric treatment sprays) and/or additional costs for counteracting changes in functionality, e.g. purchasing washable covers, are likely to occur under a full ban with a transition period of 18 months.

The Dossier Submitters consider, furthermore, based on sufficiently strong evidence from the assessment of the substitution potential pointing towards a low share of business closures in relation to home fabric treatments that there is sufficiently strong evidence to conclude that the socio-economic costs to society in the form of employment losses will be low under a full ban.

E.2.2.5.7. Other: Automotive use - Noise and vibration insulation

Table E.35 summarises the outcomes of the assessment of costs and benefits for textiles used in engine bays in automobiles for the purpose of noise and vibration insulation. More detailed information can be found in the accompanying text following the table.

Table E.35. Automotive use (Noise and vibration insulation) - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Weak evidence that technically feasible alternatives do not exist and that the substitution potential is low at EIf.	Based on the available evidence, which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for sub-uses and PFAS groups and reasonable assumptions about environmental release, a full ban of PFAS use in TULAC will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for all TULAC sub-sectors, except automotive uses for insulation purposes (for which no volume data is available), together equals around 95% of baseline emissions for a 30-year period (2025-2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	High producer surplus losses as a result of business closures [weak evidence] due to (i) a high share of business closures [weak evidence], (ii) high producer surplus losses at company level due to high margins [sufficiently strong evidence], (iii) a low offsetting potential, i.e. producer surplus losses are not balanced out by producer surplus gains by producers of alternative-based products [weak evidence] and (iv) high producer surplus losses in the wider supply chain [weak evidence] No producer surplus losses as a result of substitution, due to no substitution taking place as result of the lack of technically feasible alternatives [weak evidence] High socio-economic costs to customers due to the unavailability of textiles for use in engine bays for insulation	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				purposes [weak evidence] Some employment losses as a result of high share of business closures [weak evidence]	
Ban with use-specific derogations: Derogation for textiles for the use in engine bays for noise and vibration insulation used in the automotive industry	5 years	Weak evidence that the substitution potential is low due to the inability of companies to complete substitution before the full ban takes effect after the time-limited derogation: Information from one stakeholder submitting information to the 2 nd stakeholder consultation suggests that a minimum of 10 to 15 years would be required for developing and evaluating components once an alternative is identified.	There is no evidence on the expected environmental impacts of the potential derogation (that is marked for reconsideration).	Same as under full ban	n/a
	12 years	Weak evidence that the substitution potential might be high: The timeframe for the time-limited derogation is higher than the minimum timeframe reported to be required for substitution.	There is no evidence on the expected environmental impacts of the potential derogation (that is marked for reconsideration).	If alternatives are identified, substitution will be encouraged by the high margins and low price elasticity of demand allowing affected companies in the automotive industry to pass on substitution costs to their customers: Low producer surplus losses as a result of business closures due to low share of business closures as a result of the	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				high substitution potential [weak evidence] Low producer surplus losses as a result of substitution [weak evidence], despite high share of substitution [weak evidence] and comparatively high costs at company level [sufficiently strong evidence] due to low internalization of costs [sufficiently strong evidence] Consumer surplus losses resulting from price changes associated with substitution [weak evidence] resulting from high share of substitution [weak evidence], comparatively high substitution costs at company level [sufficiently strong evidence], which are fully passed on to customers [sufficiently strong evidence] Low level of employment losses due to low share of business closures [weak evidence]	
Conclusion	In light of the weak evidence pointing to the unavailability of technically feasible alternatives at EIF, a 12-year derogation is not proposed at this point, but marked for reconsideration for:				

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
	[Textiles for the use in engine bays for noise and vibration insulation used in the automotive industry] A derogation might be proposed at a later stage if additional information on alternatives becomes available, e.g. information on the existence of technically feasible alternatives and the R&D efforts that have been undertaken in this field so far.				

As mentioned in Section E.2.2.2.4, the Dossier Submitters consider based on the available evidence that the evidence is weak that technically feasible alternatives do not exist for textiles for the use in engine bays and that the substitution potential is low under a full ban with a transition period of 18 months. The evidence is considered to be weak due to only being based on one source type, i.e. the 2nd stakeholder consultation, and due to being based on information from one stakeholder only.

The **assessment of costs** in relation to textiles for the use in engine bays **for a full ban with a transition period of 18 months** is based on evidence from the assessment of alternatives and:

- Principles relating to margins and offsetting potential; and
- Information (from a non-representative sample) from the 2nd stakeholder consultation on, for example, (i) the timeframe required for substitution, and (ii) annual sales losses of individual companies in the TULAC industry in the case of a restriction.

For textiles for the use in engine bays, the Dossier Submitters looked into assessing (i) producer surplus losses to companies directly affected by a full ban with a transition period of 18 months as well as producer surplus losses in the supply chain, (ii) impacts on customers, and (iii) employment losses.

Producer surplus losses for TULAC sub-sectors are determined based on an assessment of (i) the number of companies affected by the restriction, (ii) the most likely reaction of affected companies, (iii) the costs that a company faces as a result of substitution or a stop of production and (iv) the ability of companies that substitute to pass on higher costs to their customers. The number of companies active in TULAC sub-sectors has, where available, been estimated based on industry data from a leading industry association on the number of companies active in the textile and clothing industry as well as the assumption that the share of the sub-sector in total EU production, provided by the same source, is a representative indicator of the number of companies active in the relevant sub-sector. As data for textiles used in engine bays was not covered by this set of data, the number of companies active in this industry branch has not been estimated. As a result, the Dossier Submitters conclude that there is no evidence on the magnitude of companies (in comparison to other TULAC sub-sectors) that is affected by the restriction.

For determining the most likely reaction of affected companies in relation to textiles for use in engine bays, the Dossier Submitters relied on the conclusion concerning the existence of technically feasible alternatives reached in the assessment of alternatives. As a result, the Dossier Submitters conclude based on this weak evidence that the expected share of business closures is high under a full ban with a transition period of 18 months.

Producer surplus losses associated with a stop of production are, as mentioned in Section E.2.2.5.1, solely determined based on a consideration of margins (with low margins being associated with lower producer surplus losses) as data on annual sales losses reported by a limited and non-representative sample of companies in the 2nd stakeholder consultation did not point to differences in annual sales values between different TULAC sub-sectors. Specific data on annual sales losses in relation to textile for use in engine bays was not provided in the 2nd stakeholder consultation. Due to a lack of quantitative information, margins were determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding the relation of the level of competition, market sizes and price elasticity of demand with margins. The size of the margin in relation to textiles for use in engine bays is found to be high (as for professional apparel and high-performance membranes). The offsetting potential is determined based on a consideration of principles on the interlinkage between the offsetting potential of other actors in the market and (i) the extent of competition, (ii) the market share of affected companies, (iii) the degree of specialization and (iv) other barriers to entry as well as (v) the extent of EU competition in comparison to international competition. These principles are well-grounded and have a robust foundation in the SEAC guidance on assessing changes in producer surplus, i.e. ECHA

(2021b). In relation to textiles for use in engine bays, the offsetting potential is found to be low. Given the high share of company closures and low offsetting potential, the extent of producer surplus losses in the wider supply chain are found to be high. The Dossier Submitters consider, based on the assessment of alternatives and aforementioned principles pointing to a high share of company closures, high producer surplus losses due to high margins, a low offsetting potential and high impacts on the wider supply chain that the evidence is weak that the socio-economic costs to industry in the form of producer surplus losses from business closures are high under a full ban with a transition period of 18 months. The main shortcoming of the evidence base is the weak evidence underlying the assessment of alternatives (which is used to estimate the share of business closures and has implications on the conclusions on the offsetting potential and the magnitude of producer surplus losses in the wider supply chain).

The Dossier Submitters consider based on evidence from the assessment of alternatives that the evidence is weak that the socio-economic costs to customers will be high under a full ban with a transition period of 18 months due to the non-existence of technically feasible alternatives which would lead to the unavailability of textiles for use in engine bays.

As mentioned in section E.2.2.4, the magnitude of employment losses in different sub-sectors could not be estimated due to the significant uncertainty about the number of companies that would cease operation and a lack of representative data on the average number of employees in relevant companies (which might differ between sub-sectors depending on how labour-intensive the associated production process is). The Dossier Submitters consider based on weak evidence from the assessment of alternatives pointing towards a high share of business closures that some socio-economic costs to society in the form of employment losses will occur under a full ban with a transition period of 18 months.

The **assessment of alternatives** in relation to textiles for the use in engine bays in relation to a **ban with (a transition period of 18 months and) a time-limited derogation of a duration of five years** is, as the evidence for the assessment in relation to a full ban, based on evidence from:

- The 2nd stakeholder consultation, during which three stakeholders reported the use of PFASs in relation to textiles used in engine bays for insulation purposes. Information on alternatives was only provided by one of these stakeholders.

The stakeholder reports that once alternatives are identified, a minimum of 10 to 15 years would be required for substitution given the significant amount of time required for developing and evaluating components and vehicles meeting type approval requirements.

The Dossier Submitters consider based on the above evidence that the evidence is weak that the substitution potential is low under a ban with (a transition period of 18 months and) a time-limited derogation of a duration of five years due to the inability of companies to complete substitution before the full ban takes effect after the time-limited derogation.

The Dossier Submitters consider based on the evidence underlying the assessment of alternatives that the evidence is weak that the socio-economic costs to industry, customers and society are high under a ban with (a transition period of 18 months and) a time-limited derogation of a duration of five years (as under a ban with a transition period of 18 months).

The **assessment of alternatives** in relation to textiles for the use in engine bays in relation to a **ban with (a transition period of 18 months and) a time-limited derogation of a duration of 12 years** is, as the evidence for the assessment in relation to a full ban with (a transition period of 18 months and) a time-limited derogation of five years, based on evidence from:

- The 2nd stakeholder consultation, during which three stakeholders reported the use of PFASs in relation to textiles used in engine bays for insulation purposes. Information

on alternatives was only provided by one of these stakeholders.

The Dossier Submitters consider based on the evidence that a minimum of 10 to 15 years would be required for substitution after an alternative is identified that the evidence is weak that the substitution potential is high due to the duration of the time-limited derogation being higher than the minimum timeframe reported to be required for substitution.

The **assessment of costs** in relation to textiles for the use in engine bays for a **full ban with (a transition period of 18 months and) a time-limited derogation of 12 years** is based on evidence from the assessment of alternatives and:

- Principles relating to margins and the price elasticity of demand,
- Information from the 2nd stakeholder consultation on re-validation requirements for new products.

For textiles for the use in engine bays, the Dossier Submitters looked into assessing (i) producer surplus losses resulting from company closures and substitution, as well as producer surplus losses in the supply chain, (ii) consumer surplus losses resulting from price changes, and (iii) employment losses.

As mentioned under the assessment of a full ban, producer surplus losses for TULAC sub-sectors are determined based on an assessment of (i) the number of companies affected by the restriction, (ii) the most likely reaction of affected companies, (iii) the costs that a company faces as a result of substitution or a stop of production and (iv) the ability of companies that substitute to pass on higher costs to their customers. As mentioned in relation to the assessment of a full ban with a transition period of 18 months, no information on the number of companies affected by a ban is available in relation to textiles for use in engine bays. For determining the most likely reaction of affected companies under a full ban with (a transition period of 18 months and) a time-limited derogation of 12 years, the Dossier Submitters have relied on the conclusion concerning the substitution potential reached in the assessment of alternatives. The Dossier Submitters consider based on weak evidence pointing to a high substitution potential that the expected share of business closures is low under a full ban with a transition period of 12 years, and that the vast majority of affected companies substitute.

Producer surplus losses from business closures are thus expected to be limited, as are producer surplus losses in the wider supply chain. Producer surplus losses resulting from substitution are, as mentioned in Section E.2.2.5.1, assessed on the basis of considerations of the extent to which companies will pass on higher costs to customers and considerations of R&D costs, capital costs for new equipment, changes in operating costs and re-certification costs. The extent to which companies are expected to pass on substitution costs to customers in the form of higher prices is determined based on a consideration of well-grounded principles (considered to have robust foundations in the theory of economics) surrounding margins and the price elasticity of demand. The extent to which companies pass on costs to customers is found to be high (as for professional apparel and high-performance membranes) due to high margins and low-price elasticity of demand. Due to very limited quantitative information on substitution costs across TULAC sub-sectors, the assessment of substitution costs has focussed on assessing differences across sub-sectors, e.g. based on a consideration of differences in the complexity of applications (which is deemed to affect R&D costs) and the relevance of re-certification/validation costs. The substitution costs in relation to textiles in engine bays is found to be high (as for PPE and high-performance membranes) due to the higher complexity of products which heightens R&D costs and information from the 2nd stakeholder consultation pointing to re-validation requirements. The Dossier Submitters consider based on the aforementioned principles and information from the 2nd stakeholder consultation pointing to a limited internalization of costs and high substitution costs that the evidence is weak that socio-economic costs to industry in the form of producer surplus losses from substitution are low under a full ban with (a transition period of 18 months and) a time-limited derogation of 12 years. The main shortcoming of the evidence base is the weak

evidence underlying the assessment of alternatives (which is used to determine the share of substitution).

As mentioned in Section E.2.2.5.1, consumer surplus losses resulting from price changes associated with substitution for TULAC sub-sectors are determined based on consideration of (i) the magnitude of additional costs associated with substitution in each sub-sector, and the extent to which companies are expected to pass on such costs to customers, (ii) the extent to which the demand for goods produced in each sub-sector is deemed to vary with price and (iii) the total volume of goods sold to EU customers per year. The volume of goods sold in TULAC sub-sectors has, where available, been estimated based on public data from the PRODCOM database and import and export data from a leading industry association. As data for textiles used in engine bays was not covered by this set of data, annual sales volumes could not be estimated. As explained in Section E.2.2.4.2, the annual volume of goods sold to EU customers is deemed to be the main determinant of differences in the magnitude of consumer surplus losses for different sub-uses. The Dossier Submitters consider based on that evidence that the evidence is weak that socio-economic costs to customers in the form of consumer surplus losses from price changes will occur under a ban with (a transition period of 18 months and) a time-limited derogation of 12 years. Due to a lack volume data, the magnitude of these losses (in comparison other sub-sectors) cannot be determined.

The Dossier Submitters consider, furthermore, based on weak evidence from the assessment of alternatives pointing towards a low share of business closures that the evidence is weak that the socio-economic to society in the form of employment losses will be low under a ban with (a transition period of 18 months and) a time-limited derogation of 12 years.

E.2.3. Food contact materials and packaging

This section addresses the use of PFAS in food contact materials and packaging, covering the following uses:

- Food contact packaging and packaging more generally where PFAS are largely used to confer oil and grease resistance. This includes baking papers whether they are for commercial or domestic use.
- The use of PFAS as processing aids in the production of plastic film.
- Consumer cookware where PFAS primarily provide non-stick surfaces
- Industrial food and feed production where PFAS are used for non-stick surfaces, inert pipes and seals, provision of oil and grease resistance and as polymer processing additives such as emulsifiers to enable poorly soluble monomers to be made available for polymerisation

More detailed information on uses and tonnages of PFAS is provided in Annex A.3.4.

Information presented here covers the manufacture of goods in each sector and use of those goods. Production of PFAS and management of materials at end of life are addressed in Section E.2.1 respectively.

Each sector breaks down to several subsectors. For example, PFAS used in industrial food and feed production ranges from non-stick surface coatings used in industrial bakeries and baking papers to fluoropolymer pipes and seals in machinery. Packaging includes paper and plastic products, and various items for holding fresh and cooked food for human consumption and pet food. The possibility that there are niche applications in the broad areas considered that have not been addressed is recognised, though the assessment has accounted for information received through a major consultation exercise to which all affected parties were invited to contribute.

E.2.3.1. Baseline

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, it had risen to 41.4 million tonnes, representing a compound annual growth rate of 1.5%/y. The Circular Economy could affect the use of PFAS in paper and board packaging in a number of ways. For example, increased recycling may lead to further cross contamination with PFAS. Overall, 64.4% of packaging waste was recycled in 2020 in the EU⁵⁸. Data show that 82% of paper and board packaging is recycled (EURACTIV, 2022) but that rates for plastic packaging are lower, around 41% in 2019⁵⁹. It is anticipated that recycling rates for packaging (as well as for other sectors) will continue to increase because of the Green Deal and Circular Economy agenda. The potential for cross-contamination is illustrated by recent work demonstrating the presence of PFAS in drinking straws (Timshina et al., 2021) at sub-functional concentrations that are more likely to have arisen through cross-contamination than deliberate addition. A trend towards the use of less laminated packaging (packaging containing several bonded layers, which may be difficult to recycle) could promote the use of PFAS (Trier et al., 2018).

Based on increased demand for plastics packaging (Geijer, 2019) (see Annex A) PFAS volumes

⁵⁸ https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Packaging_waste_statistics&oldid=580504#Recycling_and_recovery_target_s_and_rates, date of access: 2023-01-11.

⁵⁹ <https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20211027-2>, date of access: 2023-01-11.

for plastic packaging can be assumed to increase as well. The total demand for plastic in the EU-28 in 2018 was 51.2 million tonnes, of which 40% (20.4 million tonnes) was used in packaging (Plastics Europe, 2019). Of this, 8.2 million tonnes is estimated to have been used in food packaging Geijer (2019). Across the EU-28 in 2017 42% of plastic packaging was recycled (Eurostat, 2019). Increased awareness of the problems of plastics in the environment are expected to lead to a reduction in their use for packaging, linked for example to the EU's Single Use Plastics Directive (EC, 2019). This will, naturally, feed through into the quantity of PFAS used in plastic packaging, with possible consequences also for PFAS use in paper and board. However, moves away from plastic packaging could lead to increased use of PFAS in paper packaging. A possible consequence of the EU's Single Use Plastics Directive (2019/904) is the use of more moulded fibre products (e.g. plates, bowls, cup holders) for food service applications. Nearly 100% of packaging made up of moulded fibre products for heat and grease resistance is understood to contain PFAS.

With regard to consumer cookware it is estimated that 3 500 t of fluoropolymers were sold in the EU28 in 2015, representing sales of €60 million to the fluoropolymer industry and with associated goods generating a production value of €2 billion. The figure of €60 million represented just under 8% of the fluoropolymer market in the EU for the year 2015 (Plastics Europe, 2017). The global non-stick cookware market is expected to continue to grow, with growth rates being between 5% and 7%/y. At the same time, the demand for alternative non-stick solutions (particularly ceramics) that could substitute PFAS based cookware is expected to grow as well (Grand View Research, 2021a).

For industrial applications of PFAS in the sector some growth in the market for PFASs can be expected, particularly on the component side (rather than coatings) given stricter legislation on food quality and the use of more severe conditions for cleaning and sterilisation of food processing equipment. Estimates of growth rates range from 10 to 20% by the year 2025 relative to the year 2015. A growth rate of 1 - 2% seems appropriate in future years. According to stakeholders, growth is also expected in the industrial bakeware segment. Applied to the 3 000 t/y usage for the EU28 in the year 2015 (Plastics Europe, 2017) demand would increase between 3 300 and 3 700 t/y (noting that this range covers both food and pharmaceutical operations, and that it has not been possible to disaggregate the quantities for each application).

Table E.36 summarizes available information about economic growth rates for relevant sub-sectors.

Table E.36. Assumptions for projecting tonnage volumes and emissions for food contact materials and packaging.

PFAS substance	Assumption about annual growth rate (2020 – 2070)
Packaging (food and non-food)	1.5%
Consumer cookware	6%
Industrial food and feed processing and transport equipment	1-2%

For assessing the time path of PFAS use (tonnage) and emissions in food contact materials and packaging, using the information discussed above, a mean real growth rate of 4%/y was assumed. This growth rate was derived from information about market growth rates in specific sub-sectors as shown in the table below. Emissions represent releases during the use phase only and do not cover emissions occurring at the end-of-life (waste) stage of food contact materials. Table E.37 provides a projection of the yearly PFAS use and emissions during the use phase of food contact materials. The start year of the projection is 2020.

Table E.37. Projected yearly PFAS use and emissions in the food contact materials and packaging sector of the EEA between 2020 and 2070 in tonnes (mean values based on market data).

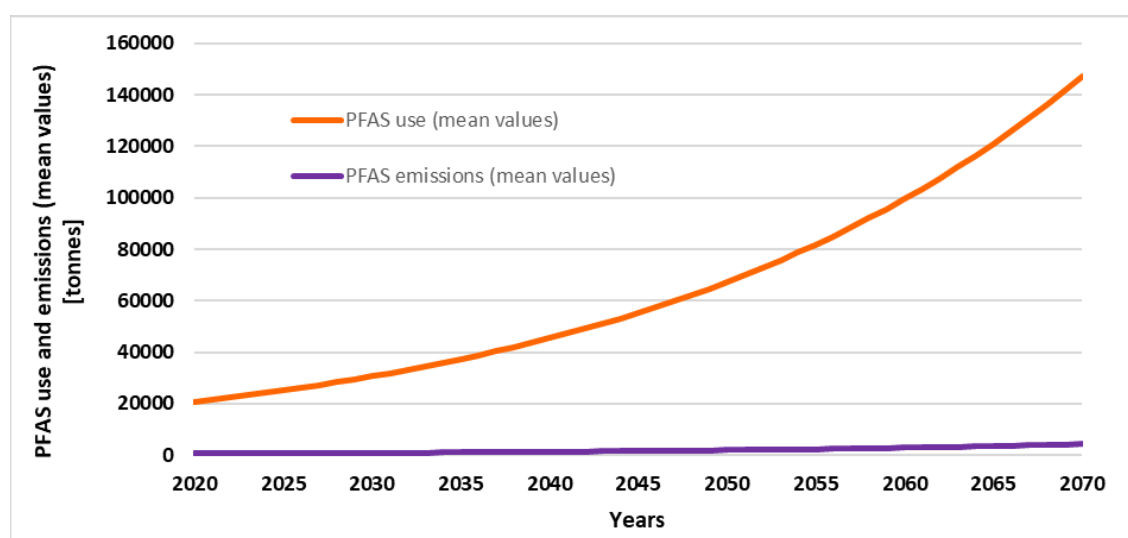
PFAS substance group	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	20 725	25 215	30 677	37 325	45 411	55 248	67 218	99 499	147 282
PFAS emissions	606	737	896	1 091	1 327	1 614	1 914	2 907	4 303

Source: Own calculations based on market data from (Cepi, 2020; Plastics Europe, 2019; Trier et al., 2018) (FoodDrinkEurope, 2019; Geijer, 2019; IndustryARC, 2020; ReportLinker, 2019) as well as the CfE.

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage).

Based on the assumptions set out in Table E.37 above, PFAS use and emissions in the sector food contact materials and packaging are expected to grow considerably under the baseline scenario. By 2040 PFAS use and emissions will have broadly doubled. Though market growth beyond 2050 is highly uncertain, and PFAS use and emission estimates have therefore to be treated with care, it is likely that PFAS use (and, in turn, emissions) will continue to grow in the long term without a restriction. This growth is largely caused by continued demand for fluoropolymers used for beverage can coatings, in consumer cook and bakeware, and for car wrapping.

Figure E.3 shows expected PFAS use and emissions for the sector as a whole, based on market data documented in section E.2.3.4, and assumptions on growth rates shown in Table E.36. Since emission estimates are derived from PFAS uses (applying ERCs), emission trends, therefore, mirror the trends for PFAS use.

**Figure E.3. Expected PFAS use and emissions in EEA under the baseline in the food contact materials and packaging sector (mean values) [tonnes].**

Source: Own assessment based on market data reported in (Cepi, 2020; FoodDrinkEurope, 2019; FoodDrinkEurope, 2020; Geijer, 2019; IndustryARC, 2020; Plastics Europe, 2019; ReportLinker, 2019; Trier et al., 2018) as well as information from the CfE.

E.2.3.2. Alternatives

The existence of technically feasible non-PFAS alternatives is one key factor determining the impact of the proposed restriction of PFASs on society as it determines the options available to companies to achieve compliance. Where technically feasible alternatives exist, substitution is a possible option for affected companies. Whether substitution is chosen as the preferred reaction to the proposed restriction depends – amongst other factors – on whether individual companies consider it economically viable for them to substitute. Where technically feasible alternatives do not exist, company closures could occur as a result of the proposed restriction. Given the importance of the most likely behavioural reaction of companies to understand the costs associated with the restriction, the extent to which technically feasible alternatives are available for different sub-uses is described below.

E.2.3.2.1. Packaging

In the 2nd stakeholder consultation, 62 out of 110 respondents (56%) mentioned they were actively work on finding alternatives. 47 responses (43%) were not actively looking for alternatives. One response was blank.

The primary role of PFAS in packaging for both food and non-food items is for moisture, oil and grease repellence, to prevent the product from sticking to the packaging and also to provide a moisture barrier and to prevent leakage (Maffini, 2020). PFAS are used for hot and cold foods, pet food, animal feed and packaging more generally. The non-stick qualities of PFAS are also important in some food packaging applications (e.g. baked goods).

Alternatives to PFAS-paper and board are broadly divided into two categories to achieve the same performance: physical or chemical barriers. Physical barriers are where the paper itself serves as barrier, by means of its physical manufacture (e.g. refining paper to make cellulose fibres very fine). Chemical barriers are achieved by either adding chemicals during paper production (internal sizing) or adding them as a surface treatment (external sizing) (OECD, 2020).

Some additional functionalities have been identified through discussion with stakeholders, including for some packaging, the improved flow of cans coated with PFAS through processing and vending systems and the creation of a more luxurious feel or appearance for packaging.

A recent study by the Washington State Department of Ecology (Department of Ecology, 2021a) provides a systematic analysis for food packaging for freshly prepared food, covering a range of packaging forms. This included evaluation of chemical hazards, exposure, performance, cost, and availability. The assessment considered alternatives to PFAS in food packaging that are intended for direct food contact and are comprised, in substantial part, of paper, paperboard, or other materials originally derived from plant fibres. Almost 90 stakeholders contributed to the assessment representing government, industry, NGOs, consumers and waste handlers. Ten food packaging applications designed to hold and serve freshly prepared food were selected:

- Food contact paper:
 - Wraps & liners
 - Bags & sleeves.
- Dinnerware:
 - Plates
 - Bowls
 - Food boats
 - Trays.
- Take-out Containers:

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- Pizza boxes
- French fry cartons
- Clamshells
- Interlocking folded containers (also called food cartons or food pails).

Assessment of cost and availability considered whether alternatives were currently used for the application of interest, and whether they were available in sufficient quantity to meet demand. Options were found for all of the applications considered, with PFAS free options available for some already. Alternatives of comparable price were also present on the market for some applications. A constraint on the assessment concerned a lack of data on the exact chemical composition of alternatives. In particular, many alternative products are labelled as 'poly-coated', a term that includes substances such as PE, PET, polyvinyl alcohol (PVOH), ethylene vinyl alcohol (EVOH), polypropylene, polyacrylate, or combinations thereof.

A problem encountered in the assessment for moulded fibre products concerned the use of PFAS as mould release agents: for this application the PFAS is intended to enable faster processing times through faster and more reliable release of moulded packaging at the point of manufacture, though some PFAS inevitably transfers from the mould to the packaging. PFAS in this case is intentionally added to the system but is present in quantities too low to provide the necessary level of performance to confer properties such as moisture or grease resistance.

Some alternatives were not considered by the study: single use plastics, polystyrene products, and substitution of one form of food wrapping by another.

Assessment of alternatives was carried out as follows:

- The hazard assessment used the online system Greenscreen® which evaluates 18 hazards including carcinogenicity endocrine activity, neurotoxicity, eye irritation, chronic and acute aquatic toxicity, persistence, bioaccumulation and physical risks⁶⁰
- Exposure assessment focused on persistence, bioaccumulation and toxicity (PBT) characteristics and whether there were substantive differences between the comparator and the possible alternatives that are likely to increase exposure concerns for the any of the alternatives.
- Performance was assessed relative to oil and grease resistance (OGR) and leak resistance.
- Cost and availability were assessed through investigation of the availability and price of goods on the market. To be readily available in sufficient quantity, an alternative product must meet one of the following criteria:
 - The percentage of PFAS-free alternative products in a specific food packaging application is above 50% and at least two manufacturers (or one large manufacturer), make a PFAS-free version of this alternative product, OR
 - The percentage of PFAS-free alternative products in a specific food packaging application is at or below 50% and at least three manufacturers (or one large manufacturer), make a PFAS-free version of this alternative product.
 - Alternatives were considered cost comparable when data suggested the price of a PFAS-free alternative would not be more than 10% greater than the cost of a comparable PFAS-containing product. Inspection of the results of the study demonstrated that in cases where cost was considered comparable, there was not a systematic price difference between products containing PFAS and those that did not.

Table E.38 contains a summary of the assessment for alternative substances for various food contact applications.

⁶⁰ <https://www.greenscreenchemicals.org/learn/full-greenscreen-method>, date of access: 2023-01-11.

Table E.38. Assessment summary for alternative substances for various food contact applications (Department of Ecology, 2021a).

	Hazard	Exposure	Performance	Availability ⁴	Cost ⁴
Uncoated paper	Low concern	Low concern	Good ¹	Yes	Yes/No
Waxes (petroleum- or bio-based)	Low concern	Low concern	Good	Yes	Yes
Kaolin Clay	Low concern	Low concern	Good	Yes	Yes
Polyvinyl alcohol (PVOH)	Low concern	Low concern	Good	Insufficient data	Insufficient data
Siloxanes (by analogy to Vinyl dimethylsiloxo-terminated polydimethylsiloxane) ⁵	Avoid – Chemical of High Concern	vPvB	Good	Insufficient data	Insufficient data
Poly(lactic acid) (PLA) (by analogy to the monomer lactide [CAS Nos. 4511-42-6; 615-95-2])	Use but still opportunity for improvement	Low concern	Good ²	Yes/No	Yes/No
Polypropylene (PE)	Insufficient data	Insufficient data	Good ³	Insufficient data	Insufficient data
Polyethylene terephthalate (PET)	Insufficient data	Insufficient data	Good	Insufficient data	Insufficient data
Ethylene vinyl alcohol (EVOH) copolymers	Insufficient data	Insufficient data	Good	Insufficient data	Insufficient data

Notes: 1) Moulded fibre products may not perform well under high heat and very oily conditions. 2) PLA plastics not suitable for high heat applications (>40 °C) due to low melting point. 3) PE coated products performed well except for interlocking folded containers. 4) In some cases there was insufficient data available to assess performance on cost or availability. The ratings of 'Yes' or 'No' reflect data across a several product types, hence 'Yes/No' reflects the result where availability or cost was comparable with PFAS containing goods in some cases ('Yes') but not in others ('No'). 5) D4, D5, D6 siloxanes which could be present as residues, are classified as substances of very high concern may need to be authorised under REACH in the future (ECHA, 2019).

A further assessment was performed of the cost-comparability of re-usable plates, bowls, trays and food boats (Department of Ecology, 2021a), covering 12 different types of establishments serving food (pizza shop, gelateria, restaurant, elementary school, etc.) based on a series of case studies from 2014 to 2019. Analysis found payback periods typically under 1 year (for all except the elementary school where payback took 3.5 years) with annual cost savings after the payback period in the order of several thousand USD or greater, and large reductions in waste generation.

The alternatives to PFAS in food and feed contact and generic packaging applications as oil, grease and moisture barriers in paper that have been identified for further consideration are presented in Table E.39 drawing information from various sources (Mokwena and Tang, 2012; OECD, 2020; Singh et al., 2021). They cover physical alternatives, chemical alternatives and alternatives which constitute a different technological approach or material. Precise functionality and suitability for use in different applications as substitutes for PFAS will vary between the alternatives listed.

Table E.39. Summary of the Identified Alternatives to PFAS Barrier Coatings in Packaging.

	Baking paper, liners, bag	Heat resistant packaging	Pet food and feed packaging	Non-paper based food packaging	Generic paper and board packaging	Generic non-paper packaging
1. Natural greaseproof paper	✓	✓	✓			
2. Vegetable parchment	✓	✓	✓			
3. Clay coatings		✓				
4. Silicone	✓	✓	✓		✓	
5. Biopolymers (e.g. chitosan, starch, cellulose, polyvinyl alcohol, bioplastics such as polylactic acid (PLA), biowaxes)	✓	✓	✓	✓	✓	✓
6. Synthetic plastics (e.g. low-density polyethylene (LDPE), linear low-density polyethylene (LLDPE), high density polyethylene (HDPE), polypropylene (PE), ethylene vinyl alcohol (EVOH), polyvinyl alcohol (PVOH), polyvinylidene chloride (PVDC), polyethylene terephthalate (PET))	✓	✓	✓	✓	✓	✓
7. Microfibrillar cellulose (MFC), cellulose nanofibrils (CNFs), cellulose nanocrystals (CNCs)	✓	✓	✓		✓	
8. Aqueous dispersions of co-polymers (e.g. styrene acrylic emulsion (SAE))	✓	✓	✓			
9. Aqueous dispersions of waxes (e.g. TopScreen)	✓	✓	✓			
10. Water soluble hydroxyethylcellulose (HEC)	✓	✓	✓			
11. Alkyl succinic anhydride (ASA), alkyl ketene dimer (AKD)	✓	✓	✓			
12. Aluminium foil	✓					
13. Lamination using impermeable barriers	✓	✓	✓	✓		✓
14. Other plant fibres (miscanthus, etc.)	✓	✓	✓	✓	✓	

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	Baking paper, liners, bag	Heat resistant packaging	Pet food and feed packaging	Non-paper based food packaging	Generic paper and board packaging	Generic non-paper packaging
15. Bitumen coating					✓	
16. Re-usable materials	✓	✓	✓	✓		✓

(Trier, Taxvig, Rosenmai, & Pedersen, 2017)

The OECD reported that the key reason for the current lack of market share of non-fluorinated alternatives for paper and board is their higher cost. Their study indicated that PFAS-free paper and board for food packaging is 11-32% more expensive than food packaging using short chain PFAS (OECD, 2020).

However, the analysis suggests that costs of switching away from PBT substance to alternatives in the food packaging market is proportionate to the reduction in risk, based on comparison with the indicative benchmarks (€1 000/kg of substance) that have been used previously in REACH. This is supported by evidence of growing investment in PFAS free packaging, for example in moulded fibre products⁶¹.

Alternatives are also available for use as polymer processing aids (PPAs) in the production of plastic films for packaging⁶². PPAs were reported by stakeholders (2nd stakeholder consultation) as having the following specific functions:

- Smoothing flow of extruded parts in film production, injection moulding, tubes manufacturing, etc. enabling faster and less energy efficient production of goods. Their use also facilitates production of thinner and lighter packaging.
- Improving hydrophobic qualities of plastic goods, including in blister packaging for pharmaceuticals
- Strengthening plastic packaging of plant protection products to improve barrier properties

The stakeholders concerned were a mix of masterbatch producers and manufacturers of plastic goods and components.

Examples of both fluorinated and non-fluorinated options are cited by e.g. Kulikov (2005) and as presented in the footnote⁶³. One example of a PFAS free option is boron nitride. On their website, Saint Gobain⁶⁴ reports that research (e.g. (Kazatchkov et al., 2000; Rathod and Hatzikiriakos, 2004)) revealed boron nitride to be a highly effective polymer process aid. Dispersing boron nitride powder into molten polymers can increase the threshold shear rate at which distortions in plastic films appear by several orders of magnitude, enabling much higher throughput during production without distortions and instabilities appearing in the polymer. Boron nitride powder has been shown to be effective in the production of films used

⁶¹ <https://www.paperfirst.info/kemira-joins-4evergreen-alliance-for-the-fibre-based-packaging-value-chain/> and <https://www.papnews.com/stora-enso-starts-the-production-of-new-generation-formed-fiber-products-free-from-plastic-and-pfas/>, both accessed: 2023-01-11.

⁶² <http://www.plastemart.com/plastic-technical-articles/polymeric-processing-aid-performs-better-than-conventional-waxes/1592>, date of access: 2023-01-11.

⁶³ See also: <http://www.plastemart.com/plastic-technical-articles/polymeric-processing-aid-performs-better-than-conventional-waxes/1592#>, date of access: 2023-01-11.

⁶⁴ <https://www.bn.saint-gobain.com/blog/how-boron-nitride-polymer-processing-aids-enable-pfas-free-food-packaging#>, date of access: 2023-01-11.

for food packaging including polyethylene and m-LLDPE films. However, one respondent to the 2nd stakeholder consultation regarded boron nitride as not suitable for pipe manufacture as hard 'foreign' particles could lead to premature pipe failure. Despite the identification of alternatives, 7 out of 8 respondents to the 2nd stakeholder consultation considered that alternatives to PFAS were not technically feasible as substitutes. Reasons provided included that halogen-free polymers do not provide the same level of moisture protection. The use of boron nitride as an alternative was specifically criticised as hard 'foreign' particles could lead to premature pipe failure, though it was not stated whether this applied to all grades of boron nitride.

For thin film plastic extrusion, production without PFAS processing aids was said in the CfE to be possible but to lead to (much) lower yield and lower product quality. Alternatives were also criticised in the 2nd stakeholder consultation on economic grounds due to:

- Whilst the substances identified for the consultation process were generally cheaper than PFAS they do not impart the same properties as PFAS and don't fulfill all roles of the PFAS PPAs.
- These lower costs for alternative PPAs were offset by additional costs due to the higher material consumption for the alternative coextruded barrier layer during production and additional costs due to the taxes on non-recyclable packaging envisaged in the EU.
- The use of other polymers (e.g. polyamide) in addition to polyethylene results in multi-layer packaging, which unfortunately is currently difficult to recycle, leading to further additional costs.
- Metal packaging as an alternative to packaging produced using PPAs is more expensive than plastic packaging.

Alternatives that are technically feasible appear to be available already for many applications, though not all, where PPAs are used. However, no data on the costs of these alternatives relative to PFAS has been identified. No data has been identified to establish the availability of alternatives of the appropriate quality in sufficient quantities for the EU plastics market at the present time.

Whilst alternatives are available little is known if non PFAS processing aids are available to keep high yields and good product quality without PFAS being used. 5 companies stated that they were actively working on alternatives, 2 were not and 1 did not reply to the question.

A total of 11 US states have introduced legislation to ban or restrict the use of PFAS in food packaging using a definition of PFAS similar to that used here with legislation becoming active at various dates in the next 2 years (up to 31/12/2024) (Baughan et al., 2022). Different provisions apply in different States. California, for example, includes provision not only for PFAS added intentionally to food packaging but also for food packaging containing PFAS at or above 100 ppm as measured in total organic fluorine. Rhode Island states that intentional introduction of PFAS covers use as a processing agent, mould release agent or intermediate. Variability in legislation between States is clear, making assessment of compliance for individual companies more complex.

E.2.3.2.2. Consumer cookware

A wide range of alternatives for PFAS is available including:

- Ceramic, silicone coatings
- Stainless steel
- Silicone bakeware (not just coated)
- Anodised aluminium

Other options (e.g. copper) have little penetration into the market or are not yet widely available/tested (e.g. superhydrophobic coatings).

Some of these alternatives to the use of fluoropolymer-coated cookware have significant market share already. There is little evidence for systematic differences in price between these options.

Comparative assessments of products with different coatings have been made, especially for frying pans. However, the results of these studies must be treated with caution for several reasons:

- They may not be up to date. Given the focus of the non-stick cookware industry for many years on fluoropolymer-based coatings, it is to be expected that tests of a few years ago would favour fluoropolymer-based pans disproportionately over ceramic pans simply because of the extent of research on the two materials. Whilst results may be interesting, they do not necessarily provide robust guidance at the present time. A life cycle analysis available from Tefal compares fluoropolymer-based and ceramic frying pans but is dated 2011 (Tefal, 2011): both types of coating have developed significantly in the intervening years and there is evidence⁶⁵ that good quality ceramic pans can compete with fluoropolymer pans.
- Comparisons may not be made on a like-for-like basis. Whilst a good quality pan with a fluoropolymer-based coating will outperform a bad quality pan with a ceramic coating on tests for non-stick, durability, evenness of cooking, etc., the same applies in reverse with good quality ceramic pans outperforming bad quality fluoropolymer-coated pans, as demonstrated by results of recent consumer analysis in the UK⁷².
- It is often not clear what coatings are made from. The phrase 'PFOA free' is widely used on pans, reference to PFASs or fluoropolymers is not. Consumer testers have also found a lack of clarity, applying to pans also made from alternative materials⁶⁶.
- Reports from different manufacturers can provide conflicting results⁶⁷.
- Test conditions inevitably differ from consumer behaviour. This may be particularly true with respect to the lifetime of products. The manufacturers' view may be that consumers will replace their pans once non-stick performance has degraded to an appreciable degree. The view of consumers may be different – some using pans indefinitely. This may lead to significant loss of the coating during use.

Some respondents to the CfE cited extremely short service lifetimes for ceramic coated pans, though these views were not substantiated through the review. It is possible that such views were developed for earlier versions of the ceramic pans and that current models are considerably more durable. Some alternatives, such as stainless steel are considerably more durable than any coated pan and may be better suited to some applications (e.g. saucepans rather than frying pans).

E.2.3.2.3. Industrial applications

The use of fluoropolymers in the industrial food and feed sectors is complicated by a wide variety of applications from baking tin coatings to pipes, pipe coatings and various types of seal in large and small machines, with differing potential for PFAS release and population exposure. The ease of substituting alternatives will be similarly variable. The selection of alternatives needs to consider operating conditions which may include:

- High temperatures and thermal cycling as components are heated and cooled
- High pressures
- Use of strong cleaning agents
- High material throughput
- Automated production

⁶⁵ <https://www.which.co.uk/reviews/cookware/article/best-non-stick-frying-pans-aS2U36a9dld8>, date of access: 2023-01-11.

⁶⁶ <https://thecookwareadvisor.com/whats-that-pan-made-of/>, date of access: 2023-01-11.

⁶⁷ <https://www.asa.org.uk/rulings/imperial-international-ltd.html>, date of access: 2023-01-11.

The broad range of applications of PFAS in the food and feed industry leads to a range of possible alternatives for replacement including:

- Ceramic, silicone coatings (e.g. industrial cookware)
- Stainless steel (e.g. industrial cookware, production line components)
- Silicone bakeware (e.g. industrial cookware, lubricants, seals)
- Synthetic rubbers (e.g. seals, gaskets, pipes, tubes for liquid processing)

The list is not exhaustive: there are likely to be (possibly many) niche applications where further alternatives are possible. These options are applied for different uses, e.g. ceramic or silicone coatings to bakeware, or synthetic rubbers for components such as gaskets and tubing.

Different views have been expressed regarding alternatives to the use of fluoropolymers in the industrial baking sector. A number of companies manufacturing equipment for the food and drink sector specialise in fluoropolymers and do not supply alternatives. Responses to the stakeholder consultation indicated that a number of these companies do not appear to have investigated alternatives to a significant extent and would thus be highly exposed to a wide-ranging restriction.

In contrast, some companies market a range of options. The Weilburger Greblon range for example⁶⁸ includes different coatings made from silicone, PFA, PEEK, PTFE, FEP and SolGel (ceramic). The different options provide different characteristics (the following information is taken from the Weilburger website):

- Silicone: Offers durability of the end products through their flexible surface and good resistance to chemicals. Particularly suited for pastry with sugar content.
- SolGel: Abrasion resistance, very good non-stick properties and easy end product cleaning.
- PTFE: Non-stick properties, very good resistance to chemicals, easy to clean and durable. Some products are ceramically reinforced to improve abrasion and corrosion resistance.
- PFA: Resistant to chemicals (in particular, alkaline solutions) and good release performances. Easy to clean (by virtue of the non-stick properties). High corrosion resistance and good durability.
- PEEK: Abrasion resistance and non-stick, in particular for lye rolls (pretzels, etc.). Resistant to alkali and chemicals (in particular, lye).
- FEP: Non-stick and resistant to chemicals, particularly well-suited to baking and cake trays.

It is notable that different surfaces are recommended for different bakery products (pastry with sugar content, lye rolls, etc.). The views of companies that market a range of options are typically that each option has its place in the market (according to information received in the CfE in 2020).

Several respondents to the consultation process have indicated that fluoropolymers are more expensive than the alternatives listed above, and hence are used in cases for various application-dependent reasons where it is felt that alternatives do not perform so well. Common responses concerned improved durability, non-stick qualities, ease of cleaning, chemical resistance and thermal stability, in addition to compliance for use of materials in the production of food and feed.

Some parts of the market (e.g. some industrial bakeries) are already using alternatives to fluoropolymer coatings in bakeware. Analysis has been presented by one company

⁶⁸ <https://www.weilburger.com/en/products/coatings/non-stick-industrial-bakery-coatings>, date of access: 2023-01-11.

demonstrating that whilst the coatings do not last as long as fluoropolymer coatings, and hence need more frequent re-coating, the overall cost of re-coating operations is significantly cheaper. Another company providing a similar service, however, claims that the use of fluoropolymer coatings is essential. There are several possible reasons for this difference in opinion, for example:

- Differences in the products manufactured in different parts of Europe or in different parts of the baked goods market, with varying fat or sugar content
- Differences in cooking temperatures and times
- Difficulties for SMEs to transition to the use of alternatives where additional investment and R&D is required
- Reluctance of customers to move away from a trusted product.

E.2.3.2.4. Other uses

For PTFE (wax) coated beverage cans specific alternatives have not been identified. Likely an alternative is to leave out the PTFE (wax) as cans were also on the market before PTFE (wax) was applied. This may slow down production, or prompt investigation of non-PFAS alternatives.

Recent research (EPA-US, 2022) highlights the potential for PFAS leakage from f-HDPE (fluorinated high-density polyethylene, a sturdier version of HDPE) containers. These are used, for example, to safely transport pesticides and chemicals; most use is industrial, though there is some possibility of consumer use as well. Traditional alternatives to f-HDPE include stainless steel, though these may be heavier, more expensive or involve other compromises such as a worse carbon footprint. One producer also mentioned it has a fluorination process in which no PFAS are formed. This is currently under investigation at US EPA level. US EPA mentioned that the creation of PFAS during fluorination is not universal: "It is during certain types of fluorination (e.g. the presence of oxygen) that the manufacture of PFAS has occurred".

Alternatives are available such as PE, PVC, polyester, PET and polyurethane for plastic coating in the form of a temporary protective layer applied to new cars.

E.2.3.2.5. Human health and environmental hazards

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log K_{ow}) and bioconcentration factor (BCF) was assessed. Additionally, it was assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHAs dissemination site.

In relation to food contact material and packaging, the list of alternatives contained 20 unique CAS numbers. Seven (7) of the substances with unique CAS were classified according to CLP (harmonised classification or self-classification). For none of the substances with unique CAS number, data on PBT or vPvB properties were available. No other hazard properties were mentioned.

The list contained an additional 21 substances with unique substance names for which no CAS numbers were available. For these substances, no information on classification or PBT and vPvB assessments were available. Two of these 21 substances may contain residues of D4, D5 and D6, cyclic siloxanes. D4, D5 and D6, and cyclic siloxanes are considered to be PBT/vPvB substances and D4 is considered to be an endocrine disruptor. These substances were: Silicone coating and Silicone cookware. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.3.2.6. Substitution potential

As mentioned above, the existence of technically feasible alternatives determines the options available to affected companies to achieve compliance, e.g. substitution or closure of business (or business unit). Whether substitution takes place depends – amongst other factors such as the availability of alternatives – on whether individual companies consider that it is economically viable for them to substitute. Like other sectors, the substitution potential for food contact materials and packaging is thus dependent on the technical and economic feasibility of alternatives and their availability in sufficient quantities.

With a view of informing the assessment of the impacts of the restriction, which are heavily determined by the extent to which companies substitute, this section draws overall conclusions on the information provided above, based on the evidence from:

- Literature;
- Legislation outside of Europe;
- The CfE, supplemented with information from stakeholder interviews; and
- The 2nd stakeholder consultation, more specifically answers (from a non-representative sample of stakeholders) to the question whether the listed alternatives known to the Dossier Submitters are technically feasible in the product/process of the responding stakeholder. It is noted that there is a likely bias in response towards those companies that are dependent on PFAS, rather than suppliers of alternatives.

With respect to **paper and board packaging**, a range of alternatives have been identified across various applications. The Department of Ecology (2021b) study demonstrates that technically and economically feasible alternatives are on the market for food contact packaging. No evidence has been found to indicate that there would be a shortage of supply in the event of a restriction. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high under a full ban with a transition period of 18 months, and no derogation is considered and further assessed for paper and board packaging.

With respect to **plastic packaging**, PFAS are used as polymer processing aids (PPAs) to assist in the extrusion of plastic sheet and other forms, and also to provide improved moisture protection. A number of alternatives that are already on the market have been identified. However, most respondents for this use in the 2nd stakeholder consultation considered that alternatives were not technically feasible on grounds including provision of inferior moisture, reduced processing speed and limits on the quality and thickness of thin plastic film. Precise details, and information on the performance of alternatives were, however, lacking. The Dossier Submitters consider that there is weak evidence to conclude that the substitution potential is low under a full ban with a transition period of 18 months. As a result, a derogation is considered for the use of PFAS-PPAs in the production of plastic packaging.

In relation to **consumer cookware**, for example frying pans, saucepans and baking trays, the Dossier Submitters consider that there is sufficiently strong evidence for the existence of technically and economically feasible alternatives on the market for non-stick products. The market for alternative coatings has expanded in recent years, and there is no indication that the supply of alternatives would be problematic following a restriction. As a result, the Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high under a full ban with a transition period of 18 months. As a result, no derogation is considered and further assessed for consumer cookware.

For **industrial applications** (excluding non-stick coatings on bakeware, see below), such as the use of fluoropolymers in seals, tubing etc. in production equipment where components need to address stresses from, for example, high temperatures and pressures and strong cleaning agents, it is concluded that there is sufficiently strong evidence for low substitution potential, and a derogation is therefore considered.

With respect to **non-stick coatings in industrial and professional bakeware**, alternatives are available on the market. However, they may not be suitable for all products or production systems. Based on limited and contrasting responses from stakeholders, it is concluded that there is weak evidence for low substitution potential, and a derogation is therefore considered.

E.2.3.3. Environmental impacts

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.3.3., assuming business-as-usual and, thus, on-going PFAS use and emissions. The analysis of environmental impacts focuses on two restriction options:

1. **RO1**, adopting a ban of all PFAS groups used in food contact materials and packaging;
2. **RO2**, adopting a ban on PFAS in combination with use-specific derogations. Regarding the duration of the derogations two variants are distinguished, i.e. a 5-year derogation and a 12-year derogation.

Environmental impacts of RO1 are analysed quantitatively. In contrast, for the use-specific derogations emission data were largely lacking. Therefore, environmental impacts of RO2 are evaluated qualitatively in relation to a worst-case additional emission scenario, assuming a full derogation of the relevant PFAS group. Note that this reference scenario does not represent a restriction option but is used for comparative purposes only. Table E.40 below summarizes the characteristics of the restriction options.

Table E.40. Characteristics of restriction options benchmark scenarios.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---
RO2	Ban with use-specific derogations	(i) Proposed derogation: Food contact materials for the purpose of industrial and professional food and feed production – 5 years (ii) Potential derogation marked for reconsideration: Non-stick coatings in industrial and professional bakeware – no specific derogation period mentioned	18 months	5 years, 12 years
Maximum additional emission scenario	Ban with use-specific derogations	Derogations of all fluoropolymers	18 months	5 years
Maximum additional emission scenario	Ban with use-specific derogations		18 months	12 years

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, restriction options are expected to be implemented in 2027. The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers

tonnage and use estimates during manufacture and the use phase (thus not the waste stage). Table E.41 shows mean emissions and the expected emission reduction for the baseline, RO1 and maximum additional emission scenarios. All emission estimates represent mean values.

Table E.41. Total mean emissions and emission reduction of RO1 and maximum additional emission scenarios (food contact materials and packaging sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	43 708	---	---
RO1	1 563	42 145	96
Maximum additional emission scenario '5-year derogation of fluoropolymers incl. PFPEs'*	2 822	40 887	94
2025-2070			
Baseline	93 468	---	---
RO1	1 563	91 905	98
Maximum additional emission scenario '5-year derogation of fluoropolymers incl. PFPEs'*	2 822	90 646	97

*Maximum additional emission scenarios denote worst-case emission scenarios (assuming a full derogation of a particular PFAS group) against which emissions of proposed use-specific derogations are evaluated qualitatively. They do not represent restriction options.

Source: Own calculations based on data reported in (Cepi, 2020; FoodDrinkEurope, 2019; FoodDrinkEurope, 2020; Geijer, 2019; IndustryARC, 2020; Plastics Europe, 2019; ReportLinker, 2019; Trier et al., 2018) as well as information from the CfE.

Based on available data, results underline that the expected emission reduction is highest (about 96%) under a full ban of PFAS use (RO1). Under RO2, a ban on PFAS use is combined with the following use-specific derogation:

(i) Proposed derogation: Food contact materials for the purpose of industrial and professional food and feed production

A 5-year derogation is proposed. The derogation affects the use of fluoropolymers. Emission data for quantifying expected additional emissions are not available at the level of the proposed derogation. No evidence is available about the precise amount of additional emissions for this specific derogation. However, maximum additional emissions assuming a full derogation of fluoropolymers can be estimated and account of 2 822 t (30-year period, see Table E.41). In relation to this reference scenario, additional emissions of the proposed derogation are considered to be small.

(ii) Potential derogation marked for reconsideration: Non-stick coatings in industrial and professional bakeware

A 5-year derogation is proposed. No evidence is available about the precise amount of additional emissions for this specific derogation. However, maximum additional emissions assuming a full derogation of fluoropolymers can be estimated and account of 2 822 t (30-year period, see Table E.41). In relation to this reference scenario, additional emissions of the proposed derogation are considered to be small.

Figure E.4 shows the time path of mean emissions of the baseline, RO1 and of maximum additional emission scenarios.

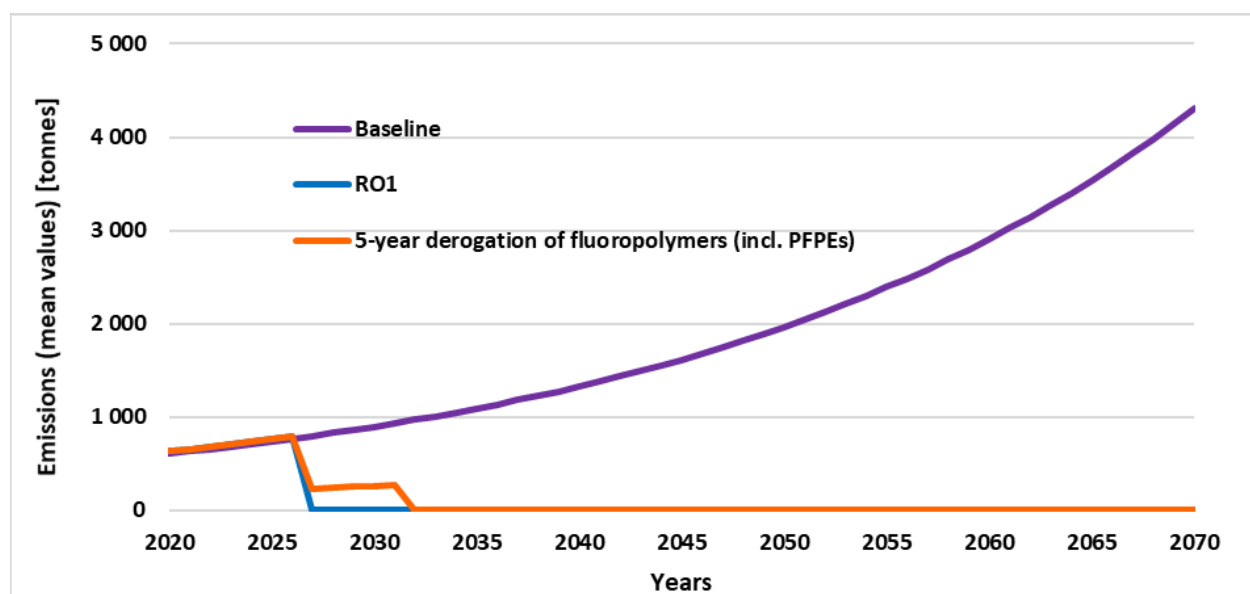


Figure E.4. Time path of mean emissions under the baseline, RO1, and maximum additional emission scenarios (food contact materials and packaging sector, in tonnes).

Source: Own assessment based on data reported in (Cepi, 2020; FoodDrinkEurope, 2019; FoodDrinkEurope, 2020; Geijer, 2019; IndustryARC, 2020; Plastics Europe, 2019; ReportLinker, 2019; Trier et al., 2018) as well as information from the CfE.

E.2.3.4. Economic and other impacts

E.2.3.4.1. Food contact packaging and packaging more generally

Impacts on industry

It has been concluded in a study for the Nordic Council that alternatives to the use of fluorinated materials are available and functional for almost all uses of paper and board Food Contact Materials (FCMs) intended for various foods, and close to cost-neutral for retailers, and hence likely also for manufacturers (Trier et al., 2018). These conclusions are reflected also in the findings of the Washington State study (Department of Ecology, 2021a), where food contact packaging materials with and without PFAS and available on the market were compared for functionality, safety and cost.

As noted already, given the breadth of the packaging market there may be niche applications where products using PFAS have an advantage over alternatives that could justify their continued use, but data for their evaluation has not been identified. Possible examples of such niche applications relevant to some extent to packaging and food contact applications that were identified in the CfE and the 2nd stakeholder consultation are as follows:

- Application of PTFE to the outside of drinks cans to reduce friction on the production line and speed processing.
- Use in inks for packaging to improve wear and rub resistance, and to avoid blockages in ink jet nozzles.
- Use in packaging for extreme environments (e.g. space)

A further use identified by stakeholders concerned machinery manufacturing corrugated card, where greases need to withstand high temperatures to maintain performance of machinery

and reduce maintenance frequency. Similar uses are considered under Lubricants (section E.2.14).

Quantification of the economic impacts of a ban on PFAS in the food and feed packaging sector has several elements, of which the following are likely to be of most concern:

- The costs of input materials and processing for producing packaging that protect against grease, water and water vapour in different ways.
- The costs of R&D for new products and adaptation of production facilities.
- Redistribution of sales and revenues between businesses currently manufacturing packaging with and without PFAS.
- In cases where packaging failure is made more likely as a result of the substitution of PFAS or the elimination of PFAS use, the associated loss of goods prior to sale.

An OECD study (OECD, 2020) reports that the key reason for the current lack of market share of non-fluorinated alternatives is their higher cost. The study indicated that PFAS-free paper and board for food packaging is 11-32% more expensive than food packaging using short chain PFAS estimate. This range is supported by evidence submitted to the Call for Evidence where a cost difference between PFAS treated papers and natural greaseproof paper of approximately 10-30% was provided, resulting mainly from differences in the speed of processing during manufacture.

Table E.42. Comparison of the Costs of Alternatives Used in Paper and Board Food Packaging.

Paper/board product	Average* cost and treatment (€/t paper)	Average cost differential between base paper and PFAS-treated and non-fluorinated paper (€/t paper)	Average difference between base paper and PFAS- treated and non-fluorinated paper (%)	Average difference between PFAS-treated and non-fluorinated paper (%)
Base paper	1 250	Not applicable	Not applicable	Not applicable
Short-chain PFAS	1 400	+150	+12	+11 to +32
Chemical alternative	1 550	+300	+24	+11
Physical alternative	1 850	+600	+48	+32

Source: (OECD, 2020)

A conclusion from the OECD study (OECD, 2020) was that whilst PFAS formulations used for food packaging paper are usually significantly more expensive than competitor chemical alternatives on a kilogramme for kilogramme basis, after producing the paper for food packaging this cost differential is reversed resulting in the costs/tonne of paper produced described in Table E.42. This position is challenged by data elsewhere that indicated that packaging materials for fresh food at least were of a similar price whether they contained PFAS or not (Department of Ecology, 2021a). However, the data shown in Table E.42 are used below in a proportionality assessment to test the implications of this level of additional cost.

The OECD data in Table E.42 can be used to provide an indicative cost-effectiveness assessment for greaseproof paper. In addition to the information provided in Table E.42 it is necessary to know how much PFAS is loaded into paper to provide the necessary level of protection. Data from stakeholders indicated a maximum loading of 4% with reference to regulatory positive lists such as (BfR, 2020) and the Inventory of Effective Food Contact

Substance Notifications⁶⁹ (see Overview Module, page 7). However, data identified from these positive lists indicates maximum permitted concentrations of PFAS in a range of 0.4 - 1.2% (dry weight).

Taking this range permits quantification of the mass of PFAS per tonne of paper (Table E.43). Substitution costs per tonne of paper from Table E.42 are €150 for the chemical alternative and €450 for the physical alternative (calculated as the cost of each alternative subtracted by the cost of the PFAS treated paper). Dividing these figures by the estimated mass of PFAS per tonne of paper generates estimates of the substitution costs per kg PFAS to be substituted. This indicates a range for the substitution cost per kg of €37.5 to €112.5/kg for a PFAS content of the paper of 0.4%, and €12.5 to €37.5/kg for a PFAS content of the paper of 1.2%. These estimates are well below the figure of €1 000 per kilogram PBT substance observed by Oosterhuis et al. (2017) in a study designed to assess benchmark indicator for cost effectiveness. This suggests that costs of switching away from the PBT substance to alternatives in the food packaging market (for greaseproof paper at least) is proportionate to the reduction in risk based on comparison with the indicative benchmarks that have been used previously in REACH, assuming these are appropriate to the quantity of material used.

Table E.43. Assessment of substitution costs per kg for PFAS used in greaseproof paper based on OECD (2020).

PFAS content of paper (A)	0.4%	1.2%
Mass per tonne of paper (kg) (B)=(A)x1000kg	4	12
Substitution cost per tonne of paper (€), low (C) (industry estimate)	150	150
Substitution cost per tonne of paper (€), high (D) (industry estimate)	450	450
Substitution cost per kg PFAS used (€) low (E)=(C)/(B) to producers	37.5	12.5
Minimum % emission for substitution cost per kg PFAS released not to exceed €1 000/kg PFAS (lower bound)	3.75%	1.25%
Substitution cost per kg PFAS used (€) high (F)=(D)/B) to producers	112.5	37.5
Minimum % emission for substitution cost per kg PFAS released not to exceed €1 000/kg PFAS (upper bound)	11.3%	3.75%

Note: Date for cost data not specified but assumed to be representative of costs at the time of the OECD report.

Analysis to this point does not take account of the amount of PFAS released as a result of its inclusion in packaging, which as noted elsewhere is subject to significant uncertainty. A minimum figure of a release of 0.3% to 0.6% was obtained considering only the use phase. Accounting for emissions during the manufacture of paper containing PFAS provided a larger estimate, of the order of 12%. indicates that the minimum quantity of PFAS released to not to exceed the €1 000/kg benchmark of Oosterhuis et al. (2017) would be between 1.25% and 11.3%, higher than the release estimated from use alone, but lower than the estimate for emissions during manufacture. These release figures do not account for emissions at the waste phase.

⁶⁹ <https://www.fda.gov/food/packaging-food-contact-substances-fcs/inventory-effective-food-contact-substance-fcs-notifications>, date of access: 2023-01-13.

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The costs of a restriction to companies currently marketing PFAS for use in packaging were provided by several companies during the consultation process. Given that the companies involved:

- Are part of a large sector
- Operate at different steps of production (e.g. polymer processing aids, surface treatments for different types of packaging)
- Operate in different parts of the market (food, pharmaceutical, industrial (etc.) packaging)
- Do not represent companies already successful at providing alternatives
- Are not a randomised sample across affected subsectors, and hence may not provide a representative view of effects

It is not possible to use the responses provided to give a reliable overall estimate of the costs to EU manufacturers of a restriction. Whilst data are available to indicate the overall size of some relevant industry sectors (e.g. paper and pulp), information to indicate the extent of companies that use or don't use PFAS in the production of packaging, and the extent to which their products were reliant on PFAS, was not identified.

However, from the responses provided, several similar issues are observed as for other sectors involved in PFAS use, for example:

- Several companies state that they consider that there are no alternatives to the use of PFAS, or likely to be in the coming years,
- Amongst those companies considering a transition may be possible, that it would be necessary to transition over a period of between 2 and 10 years
- That costs to each of these companies would be in the order of €1 million to several million.
- Some companies have a large range of products that would each need to go through the R&D and product development cycle.

Costs linked to the failure of food packaging could be substantial and it is possible that PFAS are technically the most effective solution. However, the marginal benefit of using PFAS may be small given the efficiency of modern systems for managing what is known as the 'cold-chain', whereby food is protected through the maintenance of appropriate temperatures throughout its movement from production to processing to sale to consumers. No detailed information was collected to be able to make a judgement on this point.

Table E.44. Comments from the stakeholder consultation for packaging applications on the costs, etc. of a transition to alternative non-PFAS-products (PFAS manufacturers).

Company	Activity	Time	Cost	Status
1	Polymer processing aids for production of food packaging materials	If an alternative non-fluoro substance is to be developed, it is expected to take at least two years to obtain EU EFSA and/or US FDA permits. At least 5 years is also foreseen for production process/technologies changes at downstream users	R&D: ca. €1.6 million EFSA application process: €0.8 million Capital investment: €0.4 million	Not started
2	Surface treatments for water resistance or grease-repellence	Find alternative providing similar product performance & production proof (12 months) Certification (food contact & compostability) (12 months)	About €3.5 million (EU aggregated value) About €7 million (EU aggregated value)	Early stage
3	Surface treatments for water resistance or grease-repellence, production of colourants and inks and low friction coatings	More than 5-10 years covering the processes of finding substitute, testing, purchase of new lab equipment to be able to evaluate the new substances, providing samples for customers to test and evaluate, FDA regulations etc.	€4-5 million for one location: large number of products would need development, certification, adjustment of production lines, promotion to customers	Process not started; chance of a good alternative considered very low
4	Surface treatments for water resistance or grease-repellence and use as polymer processing aids	2-5 years	€0.5 to 1 million	Early stage of process with no alternative yet identified
5	Various niche applications			Companies do not believe that there is an alternative for their niche in the market

From information provided by industry (Table E.44), at least some companies that are currently dedicated to working with FPs would have difficulties if the introduction of a restriction took place on a short time scale (e.g. 2 years) because they do not currently have alternatives identified for substitution of PFAS. The substitution process would involve several activities, for example finding one or more substitutes, testing substitutes, purchasing new

laboratory equipment to be able to evaluate the new substances, providing samples for customers to test and evaluate, gaining approval from regulatory bodies, modifying production lines and marketing new product to customers. The situation is of increasing complexity the more products that a company produces. These companies would therefore find a restriction more practicable if there was a delay in its implementation, though the time period suggested by some businesses, of up to 10 years or possibly longer, may be considered too long by other stakeholders considering the disbenefit of continued emission of PFAS.

With respect to distributional impacts, companies that have yet to investigate the use of alternatives would be vulnerable to a loss of market share, whilst others already producing alternatives would be able to profit from a restriction. One producer of PFAS commented during the consultation process that discontinuing certain FPs would impact the overall profitability of manufacturing operations and directly impact the manufacturing costs of other FPs as well - due to the capital-intensive nature of FP manufacturing and high break-even points. A restriction would also discourage future investments in other FP products by the company and downstream industries. It is also possible that a restriction could lead to further innovation in packaging for European companies which may be of benefit to those trading in other parts of the world.

One challenge to the practicability of a restriction concerns the import of goods from outside the EU in packaging that would not conform to the restriction. This potentially creates a problem downstream through the addition of packaging contaminated with PFAS into recycling systems, leading to the spread of PFAS through the paper market.

Monitorability may be problematic for several reasons including:

- The high volume of packaging involved
- The number of companies working in the manufacture and use of food packaging

Monitoring effort would clearly need to be targeted to ensure that it is properly focused on areas where risk is most likely to be present.

As noted above, there may be specific niches for which switching to alternatives is either difficult or not possible.

Impacts on consumers

Any cost of the proposed restriction to EU and non-EU businesses could be passed down through the supply chain, although an increase in cost is not guaranteed across the sector (Department of Ecology, 2021b). For most articles, the cost of packaging will be a small component of the cost of the goods bought and impacts on price (assuming that additional costs are incurred) may not be evident to consumers, though the aggregate cost across all consumers may be large. The ability of companies to pass an increase in cost down through the supply chain is of course dependent on the relative strength of the companies involved during negotiation on price.

More significant may be costs associated with the failure of packaging. However, these are mitigated for consumers by the 'cold chain' that exists in Europe, keeping food fresh by keeping it refrigerated as it moves from producer to processor to retailer to customer. For non-food goods, consumer protection legislation should ensure that damage to goods through the failure of packaging is not borne by customers but by the suppliers.

Impacts on society

Social impacts associated with a restriction may relate to impacts on employment within the

sector; either an increase in employment through the development of innovative product lines or reduced employment through loss of market share for EU companies as companies find it difficult to adapt.

It has not been possible here to estimate the number of workers that could be affected by a restriction on the use of PFAS in the packaging sector. A portion of those directly employed in the European fluoropolymer industry (2 200 in 2015, (Amec Foster Wheeler, 2017)) would be affected by a restriction on the sector. However, the size of this impact is dependent on the overall scope of the PFAS restriction proposal.

Downstream of the FP producers, impacts on employment seem most likely to be experienced by those working in companies manufacturing coatings, sizing agents, etc. rather than either producers of paper and board or the companies fabricating packaging. Most (>90%) of the paper and board in Europe is produced in Europe (Cepi, 2020), and this situation is extremely unlikely to be affected by decisions on permissible substances for treatment of packaging and board to provide it with the qualities required for food (etc.) packaging. Some of the companies that are manufacturing coatings, sizing agents, etc. are understood to be very specialised and focus entirely on products associated with FPs. These companies would be more exposed to the effects of a restriction.

Negative impacts on employment can be mitigated by allowing companies more time before a restriction comes into effect. Such a decision would of course involve emission of PFAS over a longer period.

Further social impacts could arise for consumers through a loss of functionality in packaging, perhaps leading to a loss of product shelf life. This effect will vary from product to product. Effects will be very limited for the fast-food market, given the nature of the product (once sold it is almost always consumed immediately). Such impacts are considered here to be of limited significance given the effectiveness of the cold chain in Europe and the near-universal availability of refrigeration.

E.2.3.4.2. Consumer cookware

Impacts on industry

Quantification of the impacts of a ban on PFAS in the production of consumer cookware has several elements, as the following information shows, taking the example of non-stick cookware:

- Changes in the cost of input materials.
- Additional investments in R&D and new, or adapted production lines.
- Distributional impacts on suppliers of different types of coating and alternative cookware options.
- Impacts on manufacturers of FP-coated cookware such as costs of R&D, capital costs, operating costs, changes in market share.
- Economic impacts on consumers from changes in non-stick properties, and the durability and the cost of cooking equipment.

Information on several of these elements is unavailable. It has been estimated that 3 500 t of fluoropolymers were sold into the cookware market of the EU28 in 2015, representing sales of €60 million to the fluoropolymer industry and with associated goods generating a production value of €2 billion (Amec Foster Wheeler, 2017). The figure of €60 million represented just under 8% of the FP market in the EU for 2015 (Amec Foster Wheeler, 2017).

Market analysis for the European FP sector found a lack of publicly available EU-wide statistics that were specific to the sector (Amec Foster Wheeler, 2017). The report identified 20 EU companies involved in the manufacturing or distribution of PTFE coatings for use in the manufacturing of cookware and other goods in 2015, though acknowledged that these were

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likely to represent only a small fraction of the total number of companies involved. Reference to the same source used in the AFW report (EuroPages, 2021) now lists 20 suppliers in the EU27, 16 of which are in Germany, 2 in Austria and 1 each in Belgium and France. Outside of the EU the same source identifies 13 Chinese companies, 11 in the UK and 2 each in Ukraine and Turkey. Many of the companies listed are SMEs (Small and Medium Enterprises) in terms of the number of employees (<250). However, inspection of the companies listed shows an absence of the major cookware manufacturers. It also shows that the companies listed are not restricted to coating of kitchen goods.

Responding to the CfE, FEC (the Federation of European manufacturers of Cookware and cutlery) referred to 40 members producing cookware and manufacturing raw materials and commented that this covered most of the main European producers.

At the other extreme, APPLIA (representing European home appliance businesses, some of whom will manufacture products using FPs though they are unlikely to cover the whole domestic cookware market) referred to its membership of 22 direct members (large companies and national associations), 3 337 enterprises, 927 400 direct and indirect employees and €72 billion valued added. It was acknowledged that only part of this would be affected by a PFAS restriction. Given the lack of data on the number of companies involved in the production of FP-cookware and the share of their production that involves FP-coatings, it is not possible to provide quantitative estimates of the companies that would be affected by a full or partial restriction, or of the number of staff working for them.

The above data are summarised in Table E.45. They do not provide a complete overview of the use of fluoropolymers in the sector but do provide some useful insight, particularly:

- Numbers of coating suppliers and the quantity and value of fluoropolymer sales to the sector
- Production value of fluoropolymer treated goods
- An indication of the number of large companies involved, and an order of magnitude estimate of the number of smaller companies involved.

Table E.45. Business data on the European market. Results are not limited to cookware.

Source	Data
(Plastics Europe, 2017)	20 PTFE coating suppliers in EU 3 500 t of fluoropolymer sold into the EU28 cookware market in 2015 valued at €60 million Production value of related goods = €2 billion
(EuroPages, 2021)	20 PTFE coating suppliers in EU 28 coating suppliers outside EU but selling to EU
FEC	40 companies producing cookware and raw materials
APPLIA	22 large companies and national associations serving the home appliance market 3 337 enterprises 927 400 direct and indirect employees €72 billion value added

Several companies have production sites spread around the globe. One stakeholder commented that goods for the European market tend to be manufactured in Europe, with a smaller amount made in Asia. No responses were received from retailers selling unbranded or own-branded goods, which may be more likely to be produced outside of Europe, particularly in Asia. Information provided to the CfE suggested that European production was focused on more high-end products, with the lower end serviced mainly by non-European producers.

The businesses at most risk from a restriction are expected to be the suppliers of coatings, especially if their work is focused on the production of coatings made from PFAS. Those offering a broader range of coatings and other products will, naturally be at lower risk. The same applies to the producers of cookware. Information from the 2nd stakeholder consultation indicates that many have diversified in recent years to provide goods with a range of coatings. However, the extent of diversification is variable, leaving some more vulnerable to the impacts of a restriction than others.

One respondent to the 2nd stakeholder consultation remarked that ceramic technology (Sol-Gel) is already occupying a significant share of the non-stick market without significant cost-impact for cookware producers or for consumers following 14 years of production. They considered that a restriction would not lead to supply or economic constraints, noting the number of companies already offering such cookware products. With respect to the coating process, they added that Sol-Gel is cured in a shorter time at lower curing temperatures, improving productivity and process economics. They stated that there is no price difference between fluoropolymer and Sol-Gel on housewares, which has largely been confirmed through our own observations on the market (see below).

Given the number of companies involved in the cookware market it is to be expected that the sector is highly competitive. Branding is one tool for helping companies stand out from their competitors and will influence the extent to which companies are able to recoup the costs of substitution where they are present.

One supplier of fluoropolymers stated that it would take at least 5 years for R&D on a new product, with investment required in the region of €2.4 million for the company concerned. Others have not provided data on costs of adaptation to a restriction. Though several have expressed concern that their businesses would be significantly impacted given the extent of existing commitment to the use of fluoropolymers, no further information was provided on the costs of transition to alternatives.

Another producer commented that their company makes more than 100 different materials from fluoropolymers, each with its own specifications and properties. For each of these it would be necessary to identify an alternative, investigate its properties, investigate whether it is acceptable under EU and FDA food compliance regulations, change manufacturing processes within the company and then convince customers to use the alternative.

Stakeholders have stressed the high price of the fluoropolymers, stating that they are used specifically where operating conditions justify their use, and that they would use alternatives if they were considered able to provide a similar level of service. New entrants to the market (noting that there are a number of new companies marketing ceramic and other alternatives) naturally regard alternatives much more favourably.

Impacts on consumers

Given widespread availability of non-PFAS non-stick products, final price on the market for goods provides a partial basis for evaluation of the economic impacts of a restriction as this will reflect many of the issues listed above. A review of the price of 24cm frying pans on Amazon UK in March 2021 found most pans costing between €10 and €35, with PFAS and non-PFAS options spread throughout this range. Stainless steel pans start from approximately the mid-point of this range and extend beyond it. A lack of clarity in the description of the materials used prevents conclusions being drawn on the price brackets for silicone-coated and anodised aluminium pans. Similarly, review of internet prices for products such as muffin tins or frying pans indicates that there is no clear difference in price to consumers of products made with and without PFAS. Brand, design, quality and appearance of goods appear to be far more important in determination of price than the option selected for achieving non-stick properties. One important issue that is not evident at the time of purchase is of course the durability of products.

Consumer reviews of products are useful for assessing whether there is any effect, positive or negative, of alternatives on consumer surplus. Information from various websites e.g. (BBC, 2020) indicates that users find little difference between the products. Given that most reviews, whether by individuals or consumer groups, tend to focus on new products, issues of durability may not be adequately reflected in results. This may lead to a disadvantage for fluoropolymer-coated pans relative to those using other, potentially less durable non-stick coatings for the price comparison. However, it would favour fluoropolymer-coated pans relative to more durable options such as stainless steel.

Little difference was found in the price of alternative pans, though this could change if differences in product lifespan were taken into account. Some alternatives, especially low-quality options, may have a short product lifespan and hence may need to be replaced more frequently than the fluoropolymer alternative in order to retain the non-stick performance. This is of course dependent on the quality of the articles considered (again, noting that some FP treated articles are low quality⁷²).

Several factors have been highlighted for the benefits to consumers of fluoropolymer coated pans:

- Potential for low-fat or fat free cooking
- Better control over cooking, potentially improving the flavour and quality of food
- Reduced time and effort spent in cleaning cookware
- Durability
- Price.

The first three elements are all user-dependent: some will derive these benefits others will not. Increasingly, of course, these benefits are not restricted to those using fluoropolymer-treated pans, given the availability of alternatives.

The durability of fluoropolymer coatings has been mentioned as a clear benefit by several stakeholders that are still using fluoropolymers. However, alternative non-stick coatings have improved in durability over time, as indicated by recent test data⁷².

Another factor relating to consumer behaviour concerns differing views on the lifetime of cookware. Whilst some may dispose of it as soon as non-stick properties start to deteriorate, others will continue to use it with little concern for either the non-stick performance or risks linked to the shedding of PFAS (Figure E.5). This problem is likely to be particularly important with respect to low quality fluoropolymer coatings. Unfortunately, variation in quality is not apparent at point of sale.



Figure E.5. Bun tin with severely degraded coating during prolonged use.

With respect to health impacts for consumers, the use of pans with FP-based non-stick coatings will increase PFAS exposure to some degree, whilst the use of pans with less efficient non-stick properties (noting that it is not accepted here that this applies to all alternatives) may lead to increased use of oil or burning of food, both of which may have consequences for health. Again, there is a link to product quality, with low-quality FP pans unlikely to retain their potential health advantages for long.

An additional impact for consumers is linked to the amenity value of a good quality non-stick surface through:

- Better control over cooking, potentially improving the flavour and quality of food
- Reduced time and effort spent in cleaning cookware.

Both elements are user-dependent. Some will derive value from the non-stick qualities, whereas others will not. Increasingly, of course, these benefits are not restricted to those using fluoropolymer-treated pans, given the availability of alternatives.

Impacts on society

The main social impact to consider concerns employment in the sector:

- Increased employment in some companies through the development of innovative product lines that do not use FPs, leading to increased market share.
- Reduced employment through loss of market share for some EU companies as they find it difficult to adapt sufficiently quickly to a restriction.

The two effects may coexist, and if so, would clearly counteract one another. Overall demand for cookware may not be affected, so the impact on business overall may be small, though there would be winners and losers in the market. For reasons discussed earlier, it is not possible to estimate the number of workers that could be affected by a restriction, given a lack of data disaggregated sufficiently to describe those working in relevant parts of cookware manufacturing. The fact that several companies already offer a range of products using PFAS

and non-PFAS coatings indicates that it is possible to make the switch, though this could mean that some lose their current position in the market.

Several respondents to the stakeholder consultation commented that there was a risk of job losses linked to a restriction. However, the responses overall were largely from companies using or making FPs. Companies providing alternatives are likely to take the opposite view. Overall, given that the restriction would not affect demand for cooking and baking services, effects on employment are forecast to be small at the EU level.

Cost-effectiveness

Assessment of the cost-effectiveness of alternatives should capture all elements of cost associated with a possible restriction, including R&D, changes to production sites, costs of launching new products, differences in material costs, impacts on consumers, public health and the environment, and so on. A problem for the present analysis is that data are unavailable for several elements, including the size of the sector in terms of companies and workers that could be affected. Another issue is that the market is mixed, with some manufacturers selling only fluoropolymer based non-stick products, others selling only ceramic coated products, others selling both, and yet more others selling further alternatives. In each case the R&D etc. required to launch alternative products onto the market will vary significantly from zero through to several perhaps many, millions of Euro. Extrapolation from the data that have been collected to the full market is thus prone to substantial uncertainty, even for those elements where data are available.

The approach taken here is therefore to consider what level of cost increase for cookware could be justified against the change in emission of fluoropolymer to the environment using an indicative benchmark cost per unit of PBT of €1 000 per kilogramme provided by Oosterhuis et al. (2017). This change in cost can then be compared with market data. Analysis presented in this section focuses on frying pans, intended to be representative of the broader market for non-stick cookware.

Analysis is best focused on emissions of substance rather than use, as this is clearly more relevant to human and environmental risk. The exposure assessment indicates in-use release of 0.2 t of fluoropolymer per year, which is equivalent to <0.01% of the 3 500 t of FP sold onto the consumer cook and bakeware market annually. However, this is potentially a significant underestimate given observations of the state of some pans at end of life (see, for example Figure E.5). Also, other parts of the lifecycle are relevant to the case for or against restriction, most notably end-of-life. Two positions are considered here. Both take account of the release of material from the use phase. The second extends analysis to the waste phase and assumes complete release.

A first step is to quantify the mass of fluoropolymer used per pan. Industry sources during the 2nd stakeholder consultation provided an estimate of 6-10 g fluoropolymer for a 26 cm frying pan (equivalent to 7 to 11 g for a 28 cm pan), though this was not referenced. Further calculations were therefore undertaken as a check on this range. Analysis is shown in Table E.46 for an illustrative pan measuring 28 cm in diameter with a 5 cm sidewall. The thickness of the coating is variable, depending on how many coats are applied. A range of 35 to 100 microns is adopted in the table⁷⁰.

Table E.46. Quantification of the mass of a fluoropolymer coating on a 28 cm diameter frying pan with 5 cm deep walls.

		Thickness of coating	
		Low	High
PTFE density	g/m ³	2 200 000	

⁷⁰ <http://www.ptfec coatings.com/what-we-do/faq.php>, date of access: 2023-01-13.

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		Thickness of coating	
		Low	High
Surface area of pan		$616 + 440 = 1\,056\text{ cm}^2 = 0.11\text{ m}^2$	
Thickness of PTFE coating	µm	35	100
Volume of PTFE coating	m ³	3.69E-06	1.06E-05
Mass of PTFE coating/pan estimated here	g	8.1	23.2
Pans per kg coating	Number	123	43
Mass of PTFE coating/pan estimated by industry	g	7	11
Pans per kg coating	Number	142	90

Results indicate that 1 kg of coating could be used to produce between 43 and 123 frying pans of this size, with thick and thin coating depths respectively. The data provided by industry during the consultation is used to generate a second estimate of between 90 and 142 frying pans. Acknowledging uncertainties, analysis continues with the extremes from the two ranges (43 to 142 pan/kg of fluoropolymer).

The next stage is to consider what this means in terms of an acceptable price differential per pan, taking the figure of €1 000/kg where controls are usually accepted). This is calculated by dividing €1 000 by the number of pans per kg of coating shown in Table E.47. Two sets of calculations are presented in Table E.47. The first assumes that over the lifecycle all fluoropolymer is lost to the environment, the second assumes that only 1% of fluoropolymer is emitted. Results scale linearly in proportion to the assumed percentage loss of fluoropolymer, so alternative positions can easily be calculated. The very broad ranges that result reflect uncertainty in emissions, particularly linked to emissions at end-of-life. As noted earlier, these are addressed elsewhere.

Table E.47. Estimates of the price increase per pan required for costs to equal the indicative benchmarks of €1 000 and €50 000 per kg PBT substance, assuming equal durability.

	Thickness of coating	
	Low	High
Assume release of all (100%) fluoropolymer to environment over the lifecycle (3,500 t/y)		
Pans per kg of fluoropolymer released	142	43
Acceptable price increase per pan at substitution cost of €1 000/kg	€7.04	€23.26
Acceptable price increase per pan at substitution cost of €50 000/kg	€352	€1 162
Assume release of 1% of fluoropolymer to environment over the lifecycle (34.2 t/y)		
Pans per kg of fluoropolymer released	14 200	4 300
Acceptable price increase per pan at substitution cost of €1 000/kg	€0.07	€0.23
Acceptable price increase per pan at substitution cost of €50 000/kg	€3.52	€11.62

These results mean that, in the case that a benchmark of €1 000/kg emission is considered appropriate, and that all fluoropolymer is lost to the environment over the product lifecycle, a price increase per pan of between €7.04 and €23.26 between the fluoropolymer option and the alternative could be considered proportional. If only 1% of the fluoropolymer is released, this range falls to between €0.07 and €0.23 per pan. Assuming equal service life of the pans, a negligible (€0.07) to high (€23.26) increase in the price of a pan could be justified, the

range reflecting differences in the quantity of material used per pan and the amount of that material that is released.

If it is assumed that ceramic pans have a shorter lifetime than fluoropolymer pans the situation changes. Assuming that a fluoropolymer pan lasts twice as long as a ceramic pan⁷¹ any possible price differential is likely to disappear given the range identified earlier for the price of pans of between €10 and €35 (this range only exceeding the case where it is assumed a thick coating of fluoropolymer is used, and all is lost to the environment over the lifecycle). However, there are several caveats to the view that fluoropolymer PFAS coatings are more durable than ceramic:

- There is a lack of reliable information on the durability of the latest formulations of non-fluoropolymer coatings.
- Poor quality fluoropolymer coatings will not outlast good quality ceramics⁷².
- There may be more potential for significant improvement in ceramic coatings than for fluoropolymer coatings, given the difference in maturity of the two technologies.

Some of the alternatives, such as those made of stainless steel, have a longer lifespan than the fluoropolymer coated pans. Although more expensive initially, the costs of these pans over their lifespan will be lower than for fluoropolymer coated equivalents (assuming that the latter are replaced periodically when the coating ceases to function adequately). The difference in price is also reduced through a willingness to pay for some people to avoid PBT exposure.

Practicability and monitorability

Given the existence on the market of alternatives to consumer cooking products containing PFAS, a restriction on these products is clearly feasible. The practicability of the restriction would be largely dependent on the time frame for compliance, noting that a short timeframe could be problematic for some producers as they would need to research new solutions, adapt or replace production lines and promote new lines to their customers.

Monitorability for the cookware sector may be problematic, given a lack of clarity on the materials used in coatings.

E.2.3.4.3. Industrial food and feed production

Economic Impacts

Table E.48 provides an overview of the European food and drink industry. Whilst the industry contains a number of major global companies in the food and drinks market, SMEs provide a large share of both employment and turnover.

Table E.48. Statistics for the European food and drink industry⁷³.

Number of companies	289 000 99% SMEs
Employment	4.5 million 58% SMEs
Turnover	€1.1 trillion 43% SMEs
Value added	€222 billion

⁷¹ <https://prudentreviews.com/how-long-do-non-stick-pans-last/>, date of access: 2022-12-20.

⁷² <https://www.which.co.uk/>, date of access: 2023-01-13.

⁷³ <https://www.fooddrinkurope.eu/>, date of access: 2023-01-11.

As noted above, fluoropolymers are very widely used in the industry. No examples of companies that do not use fluoropolymers at some point in their processing facilities have been identified. Many standard components for handling food and drink are made from, or coated, with fluoropolymers, including pipes, valve linings, seals and gaskets, tanks and conveyor belts. A restriction that targeted use of fluoropolymers in existing equipment would clearly have a substantial impact on the industry and affect supply of food and drink. Phasing out fluoropolymers from new equipment will also take some time, given the extent to which the industry has become reliant upon them and hence the need for R&D and certification of alternatives.

Most of the responses received in the 2nd stakeholder consultation for food contact materials came from companies linked to the production of equipment for the food and drink sector. European production of food processing equipment market was estimated to be worth €13 billion in 2014⁷⁴, with Italian and German producers accounting for about half this figure. Standardisation of hygiene requirements has been introduced to the sector through EHEDG (European Hygienic & Design Group) certification and the 3-A sanitary standards. This part of the market in food and drink production seems very likely to be more sensitive to a PFAS restriction, even allowing for potential for derogation on Entry Into Force, than the production of food and beverages.

Another part of the sector concerns maintenance of equipment. One sub-sector that could be significantly affected by restriction concerns the recoating of industrial bakeware. This is of particular interest given the potential for significant emission of fluoropolymers when bakeware is cleaned and existing coating removed, in preparation for recoating. There were limited responses from this subsector to the 2nd stakeholder consultation, with mixed views:

- (i) One provider, supplying both silicone and fluoropolymer non-stick coatings, provided case study data drawing on work carried out over 20 years. Their business recoats bakeware to maintain non-stick performance and has developed a database covering over 1 million baking trays at 500 bakeries, recording the lifespan of coatings. About 1/3 of the trays are coated with fluoropolymers, the remainder with silicone. The fluoropolymer coating has a 30% longer lifetime than the silicone equivalent but a higher price. Over the lifecycle, the cost of the silicone option is 30% cheaper. The company has tested other parameters also including contact angle (a measure of non-stick properties), temperature durability, steam durability and strength of the aluminium base material of baking trays. For the latter it was noted that the high curing temperatures required for fluoropolymers lead to a rapid weakening of aluminium, leading in turn to reduced lifetime and higher costs.
- (ii) A second re-coater took the opposite view, that the performance of fluoropolymers was far superior, and that switching away from them would be highly problematic, likely leading to the closure of the company.
- (iii) A third stakeholder concluded that both positions may be true. The second business, favouring fluoropolymers, was likely to be an SME that has developed its business over several years. The reinvestment needed to switch to alternatives may be unaffordable for the company on a short-medium timescale. Noting the information presented by Weilburger in 2021⁶⁸ on how the choice of baked product can affect the choice of coating, it is also possible that the second company may be dealing with bakers producing different types of baked good, for which silicone coatings may not be so well suited.

Most food and drink producers would opt for substitution when alternatives became available. An immediate ban of all PFAS use in the sector would not be practicable given the extent to

⁷⁴ <https://www.cbi.eu/market-information/metal-parts-components/metal-parts-food-processing-equipment>, date of access: 2023-01-11.

which PFAS are embedded in the machinery and production processes. Alternatives need to be identified and machinery and operating processes (maintenance, speed of production, frequency of cleaning, etc.) adapted as necessary. As in other sectors, the longer the period permitted for transition, the lower the costs to business and the risk of business closure. The high proportion of food and drink producers that are SMEs may increase the risk of business closure, but quantification of this risk is not possible from the information available.

The Dossier Submitters expect the proposed restriction to be implemented in 2025 with an entry into force in 2027. Therefore, the expected job losses do not take place before 2027, and depending on the position taken regarding derogations could be delayed a further 5 or 12 years. Table E.49 applies a discount rate of 3% to estimate the NPV (2020) of societal costs due to job losses of the proposed restriction for component manufacturers responding to the consultation for the food contact and packaging sector with a view that business closure was a likely response to the proposed restriction.

Table E.49. Estimated cost of job losses for some component manufacturers for the food and drink industry that consider themselves at risk of closure in response to a PFAS restriction (NPV, 2020 assuming that they are unable to introduce alternatives or otherwise adapt their businesses).

Company	Turnover (EUR million)	Jobs	Value (EUR million) for derogations of		
			0 years	5 years	12 years
A	120	750	79	68	56
B	75	360	38	33	27
C	320	2 000	211	182	148
D	15 - 20	40 - 50	5	4	3
E	11.5	400	42	36	30
Totals	544	3 555	376	324	264

Interpretation of these results is not straightforward. The following should be noted:

- The decline in NPV between the 0 and 12 year derogation periods only reflects the impact of discounting.
- The table assumes that companies are so dependent on the use of fluoropolymers that they are unable to develop and market alternatives or otherwise adapt: this position is increasingly unrealistic as the derogation period increases given the extra time available for R&D. Results for the 5 and 12 year derogations are therefore biased to overestimation. During consultation, questions were raised on the benefits to businesses of delaying the introduction of the restriction by 3 and 10 years. However, the question was widely misinterpreted, with respondents typically providing an estimate of lost turnover over 3 and 10 years respectively assuming closure at the start of the period, giving the impression that costs to industry would be higher if the introduction of the restriction was delayed. The extent to which impacts on business would be reduced by delayed implementation cannot therefore be estimated.
- The extent to which results reflect the impact for the whole sector is not known. Results are based only on information from companies that responded to the consultation process. This may bias to underestimation of impacts if other companies are similarly at risk.
- However, the component manufacturers are not limited to supplying the food and drink sector, but also work in fields such as transportation and medical devices. This biases to overestimation of impact for the food and drink sector.
- The likelihood of business closure may be exaggerated simply because there has been to date an absence of drivers to encourage research into alternatives.

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- Food and drink production will not cease as a result of the restriction. Job losses at the companies providing fluoropolymer seals, tubing, etc. are therefore likely to be compensated by increased employment elsewhere, though this may be outside of the EU.
- Given their knowledge of the food and drink market the companies concerned have at least some competitive advantage over competitors for the development of alternatives.

Results are therefore intended only to be indicative, but some general conclusions can be reached based on the analysis presented in Table E.49:

There is potential for significant impacts on component suppliers and their employees, particularly if a restriction was introduced on a short timescale. This could have consequences for the food drink producers downstream if alternatives matching the performance of fluoropolymers are not available, for example through reduced speed of production or increased rejection of product.

In considering cost issues, the question of the time permitted for manufacturers to switch to alternatives is of key importance, along with the issue of whether replacement articles would be permitted for placing on the market for the servicing of existing equipment. Stakeholders expressing a view cited a minimum estimate of 5 years for a transition away from fluoropolymers once satisfactory alternatives had been identified, based in part on experience with chromium (VI). One producer provided the following timeline (Table E.50):

Table E.50. Indicative estimate of time for transition away from fluoropolymers in production of equipment for the food and drink sector.

R&D for new polymer at suppliers	5 years
Develop new rubber/plastic compounds	2 years
Develop new products e.g. seals	1 year
Test products in house	6 months
Obtain food approval	6 months
Test products with customers	1 - 2 years
Total	10 – 11 years

There was significant variation in estimates of the time taken to obtain approval from stakeholders identifying as supplying goods to the food and drink market (2nd stakeholder consultation), from one month to several years. However, some of the suppliers were providing goods (seals, hoses, pipes, valve linings, etc.) across a range of sectors including medical and automotive. The estimate of 6 months shown in Table E.50 is considered here to be appropriate for the food and drink sector.

A key factor in determining the time taken to develop alternatives concerns the identification of options that provide an acceptable level of performance. In some areas this may be straightforward, such as alternative coatings for baking pans (though some in the industry would dispute this). In other areas where there is no current alternative on the market, it may take considerably longer to either identify an alternative that provides the necessary level of service, or one that comes closest to it.

Non-fluoropolymer options are clearly available on the market to perform the same general functions as items containing or made from fluoropolymers (pipes, seals, etc.). However, several respondents to the CfE and the 2nd stakeholder consultation indicated that the price differential between fluoropolymer products and alternatives provided an effective disincentive to fluoropolymer use in cases where they did not provide a significant benefit. Particular concerns for alternatives related to hygiene and durability, which would affect the costs of food and drink producers.

A detailed breakdown of the costs of developing alternatives and introducing them to the market has not been provided by stakeholders. The cost calculation made by manufacturers of equipment and food and feed products and the companies using this equipment factors in several elements, such as those listed below. Respondents were mainly from companies providing or using fluoropolymers, rather than producers and users of alternatives, or food and drink producers. The following summarises the limited cost data obtained going through the chain from identification of alternative polymers through to the generation of wastes:

- The costs of R&D to develop new solutions for (e.g.) a series of different coatings used for different jobs, such as bakeware for different types of foodstuffs. One stakeholder reported producing more than 100 different PFAS based substances, each with its own specifications and properties, each of which would require its own R&D process. One manufacturer of seals, O-rings and gaskets estimated R&D costs of €4 million with annual recurring costs (e.g. for testing) of €50 000, though it is not clear whether the latter should be considered additional as presumably the testing would be required for any product. Other stakeholders supported the view that the costs of R&D for their companies would be in the order of EUR millions.
- The costs of validation of alternatives for use with foodstuffs for both the component/solution manufacturer and their customers were raised, but further details were not given.
- Some data on the cost of components made of different materials was provided by (Amec Foster Wheeler, 2017), indicating a cost for PTFE in the region of €17 000 to €20 000/t and of fluoropolymer more generally averaging around €15 000/t. This was said to lead to a factor 3 increase in the costs of some components (specifically, pipes and tubing were identified, though noting that the cost of the alternative materials was not given) relative to the use of non-PFAS alternatives. The additional cost of the PFAS option is considered justified because of lower maintenance costs and improved durability (see below).
- Consideration was given to adaptation to machinery to facilitate use of alternatives, possibly leading to differences in processing times and productivity. One stakeholder likened the necessary transition to starting a new company, requiring investment for one site in the region of €4 to 5 million. This could be repeated at many locations across the EU. Another highlighted practical issues on retrofitting alternatives, giving the example of the use of stainless steel expansion joints which could be extremely problematic given a lack of space at some facilities.
- One company estimated that the use of fluoropolymers reduced downtime linked to cleaning by 50-70%.
- Alternatives would likely generate additional cost for replacement of parts when they are no longer functioning as required, as they were considered by stakeholder respondents to have a shorter service life than fluoropolymers.
- There could also be potential impacts linked to increased wastage of product, for example through poor performance of non-stick coatings.

Detailed analysis providing sufficient information to estimate additional capital and operating costs is not available, preventing estimation of costs of a restriction to the sector for more than specific elements, even then limited to information from a few companies. The above listed issues provided by stakeholders through the consultation process demonstrate why companies continue to use fluoropolymers, despite the higher cost of purchase.

In the event of business closure, it may be possible to recoup some costs through the sale of assets. The businesses most likely to be affected are suppliers of seals, tubing, valve linings and so on whose entire business is currently dependent on PFAS (typically PTFE). The most likely market for these assets would be outside the EU, where controls on PFAS were not so stringent. Again, it is not possible to estimate the extent to which costs could be recouped, if at all.

Several stakeholders commented that the use of fluoropolymers increased productivity. This will feed through into prices for consumers, though it is not possible to estimate the size of

this impact.

Major food and drink producers operate in a competitive marketplace, though significant market power is held by a limited number of food companies and supermarkets (Van Dam et al., 2021). The power of the supermarkets reduces the margins of the producers, limiting the extent to which producers are able to pass costs onto consumers. This level of competition partly explains the importance of branding in the industry. For the smaller producers (noting that SMEs account for 99% of EU food and drink companies) competition is in many cases less related to price than it is to quality (ECSIP, 2016). Companies competing successfully on quality will be in a better position to pass costs onto retailers and/or consumers. The ECSIP Consortium report concludes that the European food and drink industry is able to compete internationally because of the high quality of produce. Across the industry as a whole in the EU, price competitiveness therefore varies from high to low, depending on the products and precise market segment targeted by producers.

Exports outside the EU account for 10% of the turnover of the food and drink sector (€120 billion out of a total turnover of €1.2 trillion/y) (FoodDrinkEurope, 2019). Increased costs for the sector because of reduced productivity linked to a PFAS restriction may have an impact on these sales.

In both cases, impacts of a restriction may not be long-term, given an inevitable increase in the research on alternatives to FP use. However, several stakeholders considered the likelihood of finding replacements for FPs that performed to a similar level to be low. There is evidence to support this view from the fact that FPs have a high price and hence tend to be used only when considered necessary. However, the current status of alternatives is in part a function of a market where there has not been a legislated barrier to FP use.

E.2.3.4.4. Economic impacts on consumers

It is not possible to estimate the change in consumer surplus from available data. However, it is useful to consider possible scenarios:

1. **Alternatives that match the performance of fluoropolymers are available by the time that the sector is affected by the restriction.** In this situation the impacts on consumers would likely be zero, bearing in mind the high price of the fluoropolymers that they would replace.
2. **Alternatives are available but do not quite match the performance of fluoropolymers.** This may lead to some increase in food prices arising from the need to increase the frequency of cleaning and maintenance. Food quality (from a hygiene perspective) would be unchanged given legislation on food safety. Impacts on those on moderate and high incomes would likely be small. Impacts for those on low incomes could be more significant, exacerbating inequalities, recognising that they will tend to spend a higher proportion of their income on food.
3. **Alternatives are available but their use significantly reduces capacity in the food and drink industry.** In this situation food prices could increase significantly leading to added financial costs for consumers. Food safety should again not be affected given existing legislation. Consumers may experience a reduction in food quality as they switch to alternatives that are cheaper than they would otherwise buy, leading to some welfare loss. There would of course again be higher impacts for those on low incomes. Imports to the EU from regions where fluoropolymers are not restricted would likely increase, leading to some distortion in trade.
4. **Alternatives are not available at all.** This situation is not considered realistic: alternatives are available at the moment but do not meet the performance of fluoropolymers. [3] is anticipated to represent the worst case.

According to this analysis there is some potential for significant impacts on consumers, including concern over affordability for those on low incomes. It is therefore appropriate to consider potential for mitigating such risk, for example by considering a derogation that would

give time for adaptation.

E.2.3.4.5. Other impacts on society

From the 2nd stakeholder consultation it was noted that several producers of equipment for the production of food and drink are very specialised in the use of fluoropolymers. In several cases, PFAS accounted for a large share of company production (up to 100%). These businesses consider themselves to be at significant risk of closure as a result of the restriction, leading to a loss in turnover for those companies that responded and provided data of between €11 and 320 million per year (Table E.51) and job losses of between 40 and 2 000 workers per company. The monetisation of the social costs due of unemployment follows the approach set out by [Dubourg \(2016\)](#). In this approach the loss of unemployment is estimated considering the following impacts:

- The value of output/wages lost during the period of unemployment
- The costs of job search, hiring and firing employees
- The scarring effect, i.e. the impact of being made unemployed of future employment and earnings
- The value of leisure time during the period of unemployment.

The discounted net present value (in 2014) of the social costs of losing one job in the EU-28 was estimated at €87 000, equal to 2.7 times the average annual gross wage. This ratio varies across different member states, mainly driven by the country specific average duration of unemployment. The supply chain is here assumed to be distributed across Europe, supporting the use of an EU-average ratio. The average duration of unemployment decreased from 18 to 16 months since the approach was published by Dubourg. The Dossier Submitters consider this change in unemployment duration not substantial enough to redo ECHA's assessment and takes the ratio of 2.7 as representative for the calculation of the societal costs of unemployment.

The EU-27 average annual gross wage for the manufacturing of chemicals is estimated at ~€47 000 in 2019/2020 prices based on Eurostat sector data (CfE). The NPV in 2020 of the social costs of losing one job in the manufacturing of chemicals sector is estimated at €130 000 by multiplying the average annual gross wage by 2.7. This figure is likely an upper bound, given higher wages in the chemical sector than the average across the economy, which would give a figure around €102 000.

The Dossier Submitters expect the proposed restriction to be implemented in 2025 with an entry into force in 2027. Therefore, the expected job losses do not take place before 2027, and depending on the position taken regarding derogations could be delayed a further 5 or 12 years. Table E.51 applies a discount rate of 3% to estimate the NPV (2020) of societal costs due to job losses of the proposed restriction for component manufacturers responding to the consultation for the food contact and packaging sector with a view that business closure was a likely response to the proposed restriction.

Table E.51. Estimated cost of job losses for some component manufacturers for the food and drink industry that consider themselves at risk of closure in response to a PFAS restriction (NPV, 2020 assuming that they are unable to introduce alternatives or otherwise adapt their businesses).

			Value (EUR million) for derogations of		
Company	Turnover (EUR million)	Jobs	0 years	5 years	12 years
A	120	750	79	68	56
B	75	360	38	33	27
C	320	2 000	211	182	148
D	15 - 20	40 - 50	5	4	3
E	11.5	400	42	36	30
Totals	544	3 555	376	324	264

Interpretation of these results is not straightforward. The following should be noted:

- The decline in NPV between the 0 and 12 year derogation periods only reflects the impact of discounting.
- The table assumes that companies are so dependent on the use of fluoropolymers that they are unable to develop and market alternatives or otherwise adapt: this position is increasingly unrealistic as the derogation period increases given the extra time available for R&D. Results for the 5 and 12 year derogations are therefore biased to overestimation. During consultation, questions were raised on the benefits to businesses of delaying the introduction of the restriction by 3 and 10 years. However, the question was widely misinterpreted, with respondents typically providing an estimate of lost turnover over 3 and 10 years respectively assuming closure at the start of the period, giving the impression that costs to industry would be higher if the introduction of the restriction was delayed. The extent to which impacts on business would be reduced by delayed implementation cannot therefore be estimated.
- The extent to which results reflect the impact for the whole sector is not known. Results are based only on information from companies that responded to the consultation process. This may bias to underestimation of impacts if other companies are similarly at risk.
- However, the component manufacturers are not limited to supplying the food and drink sector, but also work in fields such as transportation and medical devices. This biases to overestimation of impact for the food and drink sector.
- The likelihood of business closure may be exaggerated simply because there has been to date an absence of drivers to encourage research into alternatives.
- Food and drink production will not cease as a result of the restriction. Job losses at the companies providing fluoropolymer seals, tubing, etc. are therefore likely to be compensated by increased employment elsewhere, though this may be outside of the EU.

- Given their knowledge of the food and drink market the companies concerned have at least some competitive advantage over competitors for the development of alternatives.

Results are therefore intended only to be indicative, and it is not possible to quantify the magnitude of these impacts for the sector as a whole but it can be concluded that there is potential for significant impacts on component suppliers and their employees, particularly if a restriction was introduced on a short timescale. This could have consequences for the food drink producers downstream if alternatives matching the performance of fluoropolymers are not available, for example through reduced speed of production or increased rejection of product.

Wider Economic Impacts

Several stakeholders commented that the use of fluoropolymers increased productivity. This will feed through into prices for consumers, though it is not possible to estimate the size of this impact.

Major food and drink producers operate in a competitive marketplace, though significant market power is held by a limited number of food companies and supermarkets (Van Dam et al., 2021). The power of the supermarkets, reduces the margins of the producers, limiting the extent to which producers are able to pass costs onto consumers. This level of competition partly explains the importance of branding in the industry. For the smaller producers (noting that SMEs account for 99% of EU food and drink companies, Table E.48) competition is in many cases less related to price than it is to quality (ECSIP, 2016). Companies competing successfully on quality will be in a better position to pass costs onto retailers and/or consumers. The ECSIP Consortium report concludes that the European food and drink industry is able to compete internationally because of the high quality of produce. Across the industry as a whole in the EU, price competitiveness therefore varies from high to low, depending on the products and precise market segment targeted by producers.

Exports outside the EU account for 10% of the turnover of the food and drink sector (€120 billion out of a total turnover of €1.2 trillion/y) (FoodDrinkEurope, 2019). Increased costs for the sector because of reduced productivity linked to a PFAS restriction may have an impact on these sales.

In both cases, impacts may not be long-term, given an inevitable increase in the research on alternatives to FP use. However, several stakeholders considered the likelihood of finding replacements for FPs that performed to a similar level to be low. There is evidence to support this view from the fact that FPs have a high price and hence tend to be used only when considered necessary. However, the current status of alternatives is in part a function of a market where there has not been a legislated barrier to FP use.

E.2.3.5. Summary of cost and benefit assessment

The information described above has been brought together to consider the costs and benefits (in terms of changed emissions) of a general transition period of 18 months after Entry into Force of a restriction. Derogations are also considered for periods of 5 years and 12 years additional to the 18 month transition period. Information is presented for the following sub-sectors:

- Consumer cookware (Table E.52)
- Industrial food, drink and feed processing (Table E.53)
- Non-stick coatings in industrial and professional bakeware (Table E.54)
- Paper and board packaging (Table E.55)
- Plastic packaging (Table E.56)
- Other packaging applications (Table E.57)

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Table E.52. Consumer cookware and home kitchen appliances - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Health and environmental impact	Cost impact	Other aspects
Full ban	Not applicable	There is sufficiently strong evidence that technically and economically feasible alternative non-stick coatings are available for the domestic market, and already have significant market share.	Based on available evidence which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for PFAS and reasonable assumptions about environmental release), a full ban of PFAS use in food contact materials and packaging will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction under a full ban (RO1) equals around 96% of baseline emissions for a 30-year period (2025-2055). Note that this estimate may be an overestimation as emissions from the waste phase of products could not be included in the assessment.	Impacts will vary between companies depending on the extent to which they have adopted or researched the available alternatives to PFAS coatings for the non-stick market. Those that are already advanced in the transition to PFAS-free options are likely to see improved producer surplus, whilst those that are not could lose market share and producer surplus. [sufficiently strong evidence]. Manufacturers of fluoropolymer coated pans have claimed that alternative coatings do not last as long, leading to impacts on consumers. However, steady improvements in the quality of ceramic coatings have been noted. Also the fact that there are poor quality fluoropolymer coated pans on the market that have a short service life. There are also other alternatives on the market that are well suited to some applications. Impacts on consumer surplus are considered likely to be small. [sufficiently strong evidence]. Social impacts are unclear, given that there will be winners and losers in the market. Some companies may expand whilst others may shrink. Additional markets may open up in other countries as other regions move away from PFAS. The overall impact on jobs is uncertain, but considered likely to be small. [weak evidence].	
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion	A full ban after a derogation period of 18 months is concluded as feasible for the consumer non-stick coatings market. Some companies are likely to increase consumer surplus whilst others will lose out, depending on their readiness to move to the alternatives by the end of the transition period. Impacts on consumers are considered likely to be small given advances in recent years in the quality of the alternatives to fluoropolymers. The situation for the consumer appliances market is less certain and further information is desirable from the stakeholder consultation. However, no clear basis for delaying the restriction for this part of the market has been identified.				

The conclusions of the Dossier submitters are based on evidence/knowledge from the:

- Literature;
- A limited number of stakeholder interviews;
- Information from the CfE; and
- The 2nd stakeholder consultation.

The responses to the consultation exercises, whilst useful, are biased to the companies that are most dependent on PFAS. Little response was received from companies focused on alternatives.

It is concluded that the evidence is sufficiently strong that technically and economically feasible alternatives are available in the quantities required for use in the home cook- and bakeware markets and that the substitution potential is high under RO1, such that a derogation is not required. It is noted that a number of companies already provide non-fluoropolymer non-stick options either throughout their range or for part of it. Several stakeholders expressed concern over the durability of ceramic coatings, though there is evidence of improved durability well in excess of the figures cited by some stakeholders. At the same time, it is noted that the market for fluoropolymer coated goods shows significant variation in quality, with some products losing their non-stick property in a short time, and shedding fluoropolymer. Some manufacturers have started to produce appliances such as sandwich toasters with non-stick surfaces made from alternatives to fluoropolymers. Less information has been identified regarding fluoropolymers used in the mechanisms of kitchen appliances (for seals, gaskets, pipes, etc.), though again there are alternatives on the market. It is considered that the time between publication of this dossier and the date at which the provision of a restriction would come into effect provides time for companies to adapt to a restriction.

Evidence is considered sufficiently strong that the socio-economic benefits in terms of avoided emissions from the use phase will be in the region of 96% for the food contact materials and packaging sector overall. Information at the sub-sector level is not available. A large share of PFAS used in the sub-sector will not be emitted during use, but will be passed through to the waste phase.

With respect to costs, again, information to the CfE and 2nd stakeholder consultation was primarily from companies that work with fluoropolymers. For producers, there is sufficiently strong evidence that there will be winners and losers in the market, with those companies that are already marketing alternatives being likely to consolidate their market position, whilst those that have remained specialised in fluoropolymer use may lose ground. Impacts on consumer surplus are considered likely to be small, given observations on the price and performance of pans using and not using PFAS. It is acknowledged that there is variability in the quality of coatings, but this applies equally to the market for goods coated with fluoropolymers as it does to goods with ceramic coatings. There are then further alternatives, including uncoated kitchenware, that perform well. Social impacts via job losses are considered likely to be small at the level of the EU, noting that some companies are likely to do better after a restriction and may increase staffing levels, whilst those that are slower to adapt or unable to adapt will do worse potentially leading to job losses. Evidence on these social impacts is considered weak.

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Table E.53. Industrial food, drink and feed processing - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Alternatives exist for some uses of fluoropolymers but may not cover the full range of applications in the food, drink and feed sector. Further R&D will be needed to assess performance of alternative polymers under conditions varying in (e.g.) temperature, pressure and chemical environment (including cleaning agents) [sufficiently strong evidence] .	Based on available evidence which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for PFAS and reasonable assumptions about environmental release), a full ban of PFAS use in food contact materials and packaging will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for food contact materials equals around 96% of baseline emissions for a 30-year period (2025-2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Producer surplus losses as a result of business closures, particularly for companies that have specialised in the manufacture of fluoropolymer components (seals, pipes, etc) to supply the industry [sufficiently strong evidence]. Producer surplus losses could also arise for the companies buying machinery for food and drink production, for example through reduced throughput rates. Consumer surplus losses arise for customers for food, drink and feed products, in the event of price increases (with added costs being passed on to consumers) or a deterioration in quality. Producer and consumer losses from disruption to the food, drink and feed market is possible if a restriction was applied to the sector with only a limited transition period in place given the extent of R&D needed to introduce alternatives. [sufficiently strong evidence]. Potential for social costs through job losses especially in those companies that have specialised in working with fluoropolymers. [sufficiently strong evidence].	
Ban with use-specific derogations: Food contact materials for the purpose of industrial and professional food and feed production	5 years	An additional 5 years would enable companies manufacturing equipment for food, drink and feed production to evaluate existing alternatives and some new polymers and carry out the necessary R&D for associated modifications of existing equipment designs. [sufficiently strong evidence]	No evidence is available about the precise amount of additional emissions for this specific derogations. However, maximum additional emissions assuming a full derogation of fluoropolymers can be estimated and account of 2 822 t (30-year period, see Table E.41). In relation to this reference scenario, additional emissions of the proposed derogation are considered to be small.	An additional 5 years would enable a smoother transition from fluoropolymers to alternatives and provide opportunity for diversification for companies that are currently specialised in the use of fluoropolymers. It is therefore probable that producer, consumer and social impacts would be reduced compared to the position with no derogation beyond the 18-month transition period. However, it is unlikely that impacts would be eliminated altogether. [sufficiently strong evidence] .	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		strong evidence]			
	12 years	An additional 12 years provides greater opportunity for development of new polymers to meet the needs of the sector. [sufficiently strong evidence]	n/a	The additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses from use of less effective polymers. Performance to match fluoropolymers cannot, however, be guaranteed, leading to some risk, albeit reduced, of producer and consumer surplus losses. [sufficiently strong evidence]	
Conclusion	A full ban after a derogation period of 18 months would cause disruption to the food and drink market with the likelihood of some business closures and impacts on producers, consumers and workers. Risks are mitigated by introducing derogation periods. Given the reliance of the industry on fluoropolymers in recent years, the extent to which alternatives can be readily substituted to the market is unknown: detailed information on the performance of alternative polymers, and the consequences of using those polymers, has not been presented. There is therefore uncertainty over the period required for the industry to make a full transition away from the use of fluoropolymers, and the optimal derogation period taking account of both costs and benefits.				

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The conclusions of the DS expert team are based on evidence/knowledge from the:

- Literature;
- A limited number of stakeholder interviews;
- Information from the CfE; and
- The 2nd stakeholder consultation.

The responses to the consultation exercises, whilst useful, are biased to the companies that are most dependent on PFAS. Little response was received from companies focused on alternatives.

This sub-sector deals with a diverse range of components used in machinery for production of food, drink and feed, such as seals, O-rings gaskets, pipes and tubing. It is concluded that the evidence is sufficiently strong that technically and economically feasible alternatives are not available for all applications in sub-sector. Whilst it is possible that substitution potential is high for some components it is low for others that may be operating in harsh environments subject to significant temperature and pressure variation and the use of strong chemicals. A clear timeline for the development of alternatives has not been identified during the assessment. Progress could be made under a 5 year derogation though the chance of success, for example in developing new non-PFAS polymers would naturally increase with a longer derogation.

Evidence is considered sufficiently strong that the socio-economic benefits in terms of avoided emissions from the use phase will be in the region of 96% for the food contact materials and packaging sector overall. Information at the sub-sector level is not available. A large share of PFAS used in the sub-sector will not be emitted during use, but will be passed through to the waste phase.

With respect to costs, information to the CfE and 2nd Stakeholder Consultation was primarily from companies that work with fluoropolymers for example to produce components for the companies that manufacture machinery for the sub-sector. A number of these companies have specialised in fluoropolymers and there is sufficiently strong evidence that they could be at significant risk of closure if they are unable to adapt to the restriction. Closures would lead on to job losses with further cost impacts. Consumer surplus losses arise for customers for food, drink and feed products, in the event of price increases (with added costs being passed on to consumers) or a deterioration in quality.

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Table E.54. Non-stick coatings in industrial and professional bakeware - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Alternatives (e.g. silicone) are available and already used in the market. [strong evidence] . It is not clear that these are available for all relevant bakery products given variation in (e.g.) sugar and fat content, noting recommendations from one company for different options for different types of bread and cake. [weak evidence] .	Based on available evidence which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for PFAS and reasonable assumptions about environmental release), a full ban of PFAS use in food contact materials and packaging will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for food contact materials equals around 96% of baseline emissions for a 30-year period (2025-2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	The companies at most risk of producer surplus loss are those providing bakeware or recoating services who have specialised in use of fluoropolymers. These companies may be at risk of closure, with accompanying job losses, if they are unable to adapt to alternatives fast enough, for example if they cannot finance changes to their production lines (recognising that many re-coaters will be SMEs). [sufficiently strong evidence] . Such impacts would likely be partially offset by companies already working with alternatives. Manufacturers of baked products could be at risk of producer surplus loss if alternative coatings are not suitable for their specific product range. Added costs would feed through to a reduction in consumer surplus. [inconclusive evidence]	
Ban with use-specific derogation s: Potential derogation marked for reconsideration: Non-stick coatings in industrial and professional bakeware	5 years	Given that alternatives already have some market share it is considered that this would be sufficient time for alternatives to be developed for use across the range of bakery products. [sufficiently strong evidence]	No evidence is available about the precise amount of additional emissions for this specific derogations. However, maximum additional emissions assuming a full derogation of fluoropolymers can be estimated and account of 2 822 t (30-year period, see Table E.41). In relation to this reference scenario, additional emissions of the proposed derogation are considered to be small.	Impacts on producer and consumer surplus would fall relative to a full ban. [sufficiently strong evidence] .	
	12 years	n/a	n/a	n/a	n/a
Conclusion	A full ban after a derogation period of 18 months could cause disruption to the food market with the likelihood of some business closures and impacts on producers, consumers and workers. Given the existing availability of alternatives for some bakery products, it is concluded that a 5 year derogation may be appropriate for the sector, though this will mean that emissions to the environment during the use phase will increase. The derogation will also cause additional emissions during the waste phase of food contact materials, though given the finite life of coatings in industrial and professional use this is not expected to continue beyond a year or two				

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
	after the restriction becomes effective for the sector. In light of weak evidence regarding the potential for transitioning to alternatives for some businesses/product lines, such a derogation is not proposed at this point but marked for reconsideration. A derogation might be proposed at a later stage if additional information on alternatives becomes available, e.g. regarding performance of current coatings with different types of baked good and other barriers to alternatives.				

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The conclusions of the DS expert team are based on evidence/knowledge from the: Literature; Information from the CfE; and the 2nd stakeholder consultation. Whilst there was sufficiently strong evidence that technically and economically feasible alternatives are available for coatings for the production of a wide range of baked goods, there was also some (weak) evidence that they are not suitable for all. It was not clear if this reflected real differences in the suitability of different coatings or the ability of some companies to adapt to the restriction. However, it was noted that a producer of a range of different bakeware products that varied according to the coatings applied provided guidance as to what products were best suited to each pan type, suggesting that variation in baked goods according to criteria such as fat and sugar content or baking times could affect the preference for different coatings. Further information on this issue would be useful for deciding whether or not a derogation is appropriate for the sub-sector.

Evidence is considered sufficiently strong that the socio-economic benefits in terms of avoided emissions from the use phase will be in the region of 96% for the food contact materials and packaging sector overall. Information at the sub-sector level is not available. A large share of PFAS used in the sub-sector will not be emitted during use, but will be passed through to the waste phase.

There was sufficiently strong evidence that some companies could incur significant producer surplus losses in the event of a restriction, certainly in the short term but also possibly in the longer term given the extent to which they have specialised their services. This could lead to the closure of some businesses with associated job losses. On the other hand, some companies appear to have made the transition already and could increase their market share in the event of a restriction on the sector.

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Table E.55. Paper and board packaging - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	There is sufficiently strong evidence that technically and economically feasible alternatives to PFAS use are available for the paper and board packaging markets in the EU.	Based on available evidence which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for PFAS and reasonable assumptions about environmental release), a full ban of PFAS use in food contact materials and packaging will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for food contact materials equals around 96% of baseline emissions for a 30-year period (2025-2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Companies already selling alternatives will benefit from the restriction, whilst those currently dependent on PFAS may incur losses. However, reported transition times were typically short enough to be met even with only an 18 month transition, given the time taken for preparation of the Annex XV Dossier and its evaluation. Consumer surplus losses are therefore anticipated to be limited. [sufficiently strong evidence] There may be some loss of producer surplus due to price rises, for example of natural greaseproof paper, as this requires longer processing than PFAS treated paper. However, again, these are expected to be limited. [sufficiently strong evidence] . No evidence has been provided indicating that there may be job losses as a result of a restriction on PFAS use in paper and board packaging.	
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion	A full ban after a derogation period of 18 months is concluded as feasible for paper and board packaging. Some companies are likely to increase consumer surplus whilst others will lose out, depending on how advanced they are in moving away from PFAS, though evidence has been provided that transition times can be short. Impacts on consumers are considered likely to be small given the extent to which alternatives already have market share at competitive prices.				

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The conclusions of the DS expert team are based on evidence/knowledge from the:

- Literature;
- Information from the CfE; and
- The 2nd stakeholder consultation.

There was sufficiently strong evidence that technically and economically feasible alternatives are available to replace the use of PFAS in paper and board packaging. This is demonstrated by substantial research that has demonstrated not only are alternatives available but they also perform well.

Evidence is considered sufficiently strong that the socio-economic benefits in terms of avoided emissions from the use phase will be in the region of 96% for the food contact materials and packaging sector overall. Information at the sub-sector level is not available. A large share of PFAS used in the sub-sector will not be emitted during use, but will be passed through to the waste phase.

Overall impacts on businesses operating in the sector are considered likely to be low, based on sufficiently strong evidence. It is true that there would likely be a mix of winners and losers, with some companies in a better position to respond to a restriction than others. However there was no evidence that there were likely to be job losses as a result of a restriction on this sub-sector.

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Table E.56. Plastic packaging - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Sufficiently strong evidence that alternatives exist to replace polymeric PFASs used as processing aids in the production of plastic film to improve flow behaviour, speed up production rates, also enabling the production of thinner films. Several alternatives (e.g. boron nitride, polyethylene waxes) are available on the market. Conclusion: High substitution potential at EIF [sufficiently strong evidence]	Based on available evidence which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for PFAS and reasonable assumptions about environmental release), a full ban of PFAS use in food contact material use will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for food contact materials and packaging equals around 96% of baseline emissions for a 30-year period (2025-2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	The potential for cost impacts hinges on the extent to which alternatives are able to replicate the performance of fluoropolymers with respect to the speed and quality of production. Stakeholders have commented that fluoropolymers are expensive compared to alternatives and hence would not be used if they did not convey significant advantages for production or product performance. The occurrence of some functional losses is thus likely. Producer losses, e.g. as a result of costs associated with the need to adapt existing equipment, might occur but there is weak evidence on the extent to which existing systems using polymeric PFASs would need to be adapted.	
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion					

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The conclusions of the DS expert team are based on evidence/knowledge from the:

- Literature;
- Information from the CfE; and
- The 2nd stakeholder consultation.

There was sufficiently strong evidence that technically and economically feasible alternatives are available to replace the use of polymeric PFASs used as processing aids in the production of plastic film. The specific role of these additives in the plastic packaging market is to speed production and enable manufacture of very thin films whilst maintaining a high quality of film. However, it is not clear to what extent the alternatives are able to fully replicate the performance of PFAS, for example with respect to the thickness of plastic films.

Evidence is considered sufficiently strong that the socio-economic benefits in terms of avoided emissions from the use phase will be in the region of 96% for the food contact materials and packaging sector overall. Information at the sub-sector level is not available. A large share of PFAS used in the sub-sector will not be emitted during use, but will be passed through to the waste phase.

Stakeholders maintain that PFAS are used although they are more expensive than alternatives because they produce a higher quality product and avoid wastage, leading to improved producer surplus. The implication is that this would be eroded through the use of alternatives. However, detailed comparative data on the performance of alternatives and PFAS has not been provided. Evidence on this point is thus considered weak.

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Table E.57. Other packaging applications - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	There is sufficiently strong evidence of the availability of technically and economically feasible alternatives for: Packaging uses of f-HDPE (fluorinated high density polyethylene) Use of PTFE wax on the outer surface of drinks cans Temporary wrapping of new vehicles for delivery Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Based on available evidence which is considered to be sufficiently strong (i.e. based on verifiable tonnage estimates for PFAS and reasonable assumptions about environmental release), a full ban of PFAS use in food contact materials and packaging will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs) in comparison to the baseline. The expected emission reduction during the use phase for food contact materials equals around 96% of baseline emissions for a 30-year period (2025-2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Comparative cost data have not been identified to permit comparison of PFAS and non-PFAS alternatives.	
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion					

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The conclusions of the DS expert team are based on evidence/knowledge from the:

- Literature;
- Information from the CfE; and
- The 2nd stakeholder consultation.

Limited information was available from these sources. However it was concluded that there was sufficiently strong evidence that technically and economically feasible alternatives are available to replace the use of PFASs in a range of diverse packaging applications

Evidence is considered sufficiently strong that the socio-economic benefits in terms of avoided emissions from the use phase will be in the region of 96% for the food contact materials and packaging sector overall. Information at the sub-sector level is not available. A large share of PFAS used in the sub-sector will not be emitted during use, but will be passed through to the waste phase.

E.2.4. Metal plating and manufacture of metal products

Chrome plating, both functional and decorative, is the dominant application of PFAS in the plating market. PFAS are also used for plating substrates with other metals, such as nickel, copper and tin. However, only limited information is available on the use of fluorinated substances in metal plating processes, other than chrome plating.

The subcategory of 'metal products' is extremely broad. Fluoropolymers are used widely in the treatment of metal products used in construction, from roofing to door components, in various applications in transport, in the energy industries and so on.

The following applications are dealt with explicitly elsewhere in this proposal:

Coil coating of metals: Construction (E.2.13).

Cover gases for use in magnesium casting: fluorinated gases (E.2.8).

Oils and lubricants: Lubricants (E.2.14).

During primary aluminium production tetrafluoromethane (CF₄) and hexafluoroethane (C₂F₆) are formed and released to the environment. This results from the reaction of the carbon anode with the fluorine from the cryolite melt during a process upset condition. The "anode effect" occurs when the concentration of alumina in the electrolyte is too low to support the standard reaction (Marks J., 2006). These releases are outside the scope of this restriction as they are not associated with the deliberate manufacture, use and placing on the market of PFAS. They are addressed through the Industrial Emissions Directive (2010/75/EU) and the BAT Reference (BREF) note on Non-Ferrous Metals Industries (JRC, 2017), which describes PFC emissions from the aluminium industry as being regulated to a benchmark performance under the EU's Emissions Trading Scheme (ETS) for greenhouse gases.

E.2.4.1. Baseline

Information about market growth rates could not be retrieved. Therefore, for assessing the time path of PFAS use (tonnage) and emissions in metal plating a zero growth rate per year was assumed. Considering that economic growth in this sector is plausible in the medium and long-term, PFAS use and emission estimates may be largely underestimated.

The start year of the projection of tonnage and emission estimates is 2020 as presented in Table E.58. Note that tonnage estimates includes both chrome plating and the manufacture of metal products. Emission estimates denote emissions from hard chrome plating only. Information about emissions was provided by industry (no reference available). For the manufacture of metal products emission estimates are lacking.

Table E.58. Projected yearly PFAS use, emissions and waste in the metal plating sector of the EEA and use of PFAS for manufacture of metal products not covered elsewhere in this proposal between 2020 and 2070 in tonnes (mean values based on market data).

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	990	990	990	990	990	990	990	990	990
PFAS emissions	6	6	6	6	6	6	6	6	6
PFAS to waste	984	984	984	984	984	984	984	984	984

Emission estimates were provided by industry (i.e. not derived from use volumes using ERCs) and cover emissions from hard chrome plating only. Based on the assumptions set out in Table E.58 above, Figure E.6 shows PFAS use and emissions at sector level.

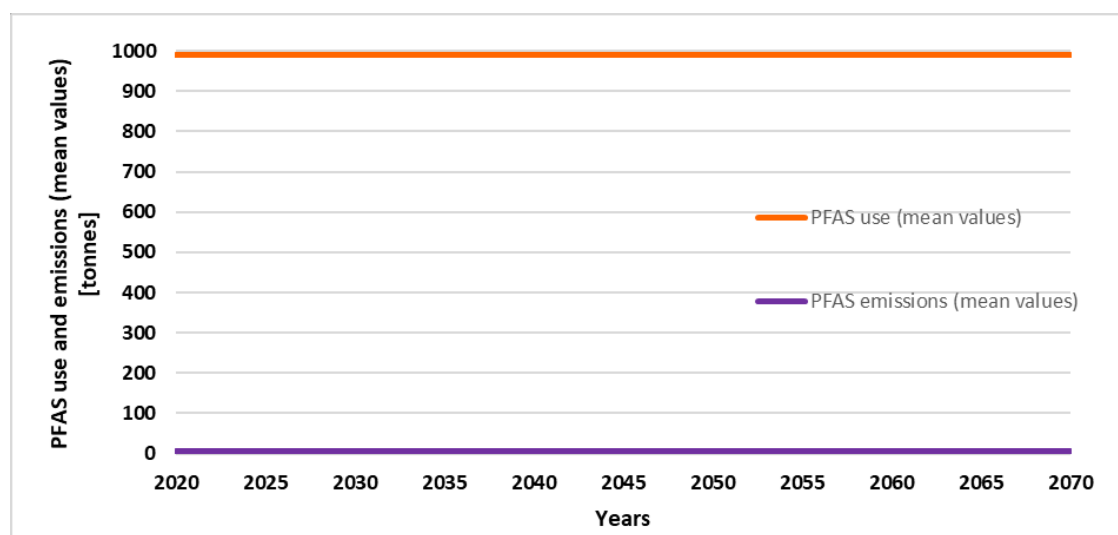


Figure E.6. Expected PFAS use and emissions in EEA under the baseline in the metal plating sector (mean values) [tonnes].

E.2.4.2. Alternatives

E.2.4.2.1. Metal Plating

Technical feasibility

Fluorine-free alternatives (substances as well as technologies) are available and already in use (Table E.59). Non-fluorinated surfactants seem feasible for functional (hard) as well as decorative chrome plating (UNEP, 2019b). However, they are not considered equally effective as fluorinated surfactants. Furthermore, additional risks connected to the use of non-fluorinated surfactants with respect to occupational safety, process stability and device preservation have been mentioned previously by the German electroplating industry association (UNEP, 2018a). Nevertheless, these substances have been used successfully in bright (decorative) chrome electrolytes (UBA, 2017). The use in functional chrome plating is also possible, but according to the current state of knowledge the substances should be used on a case-by-case basis. Furthermore, fluorine-free surfactants oxidatively decompose very rapidly in the process solutions and Cr(III) compounds are formed. This impairs the functional efficiency of the process solution (UBA, 2017). Information on health and environmental hazards of the alternatives is presented in Table E.59, and summarized in the next section.

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Table E.59. Information on non-fluorinated alternatives for chrome plating. Key: F = Functional or 'Hard' chrome plating, D = Decorative chrome plating, P= plastic etching. Sources: Blepp M. et al. (2017); Müller et al. (2020); UBA (2022); UNEP (2015b); UNEP (2018a); UNEP (2019b).

Alternative	F	D	P	Information on performance/feasibility
Alkane sulfonates	x	x		<u>Disadvantages</u> : not resistant to functional chrome plating; less effective in decorative chrome plating
Amines, C12-C14 alkyl, ethoxylated (CAS-No. 61791-14-8)	x	x		
Oleo amine ethoxylates (e.g. mixtures with (Z)-octadec-9-enylamine, ethoxylated CAS-No. 26635-93-8)	x	x	x	
3-[dodecyl(dimethyl) ammonio]propan-1-sulfonate (CAS-No. 14933-08-5) (mixture with 3-hydroxypropane-1-sulfonic acid (CAS-No. 15909-83-8) and amines, coco alkyldimethyl, N-oxides (CAS-No. 61788-90-7))		x		
paraffin oils, sulfochlorinated, saponified (CAS-No. 68188-18-1)	x	x		
Isodecanol, ethoxylated (CAS-No. 61827-42-7)			x	
Chromium (III) plating	(x)	x		<u>Advantages</u> : Problems with colour deviations have been largely solved <u>Disadvantages</u> : potential for conversion of Cr(III) to Cr(VI) during plating process is unclear; potential contamination with other metals; potential formation of complexing agent
Physical barriers e.g. mesh or blankets (composite mesh pads) placed on top of bath or add-on air pollution control devices (packed bed scrubbers)	x	x		<u>Advantage</u> : high efficiency in removing chromium (VI) aerosols (>98%) <u>Disadvantage</u> : PTFE coated balls will not reduce chromium emission from the bath (on the contrary: increasing chromium emission compared to using no mist suppressant); not fluorine-free
Add-on air pollution control devices, e.g. packed bed scrubbers	x	x		
Thermal spraying, e.g. HVOF (high velocity oxygen fuel) process	x	x		<u>Advantages</u> : process is globally available and is considered effective (high deposition efficiency and good quality finish); extremely thin layers with high corrosion resistance, wear resistance and high dimensional accuracy <u>Disadvantages</u> : requiring high temperature application; partly complex preparation of components; geometric restrictions (only rotationally symmetric parts can be coated); interior machining not possible
Physical vapour deposition (PVD)	x	(x)		<u>Advantages</u> : high wear-resistance

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Alternative	F	D	P	Information on performance/feasibility
				<u>Disadvantages</u> : limited areas of application because of application in vacuum chambers and therefore limitation to the size of the components and required relative hardness of the base materials; low corrosion resistance
Case hardening process, e.g. plasma nitriding ^[1]	x			In the field of automotive tools this process has already completely replaced functional chrome plating; closed system process.
Laser metal deposition (LMD), Extreme high-speed LMD	x			<u>Advantages</u> : no processing chemicals or solvents are used (only the applied metal alloys); process is more economical than functional chrome plating; Depending on material composition a higher corrosion and wear resistance than for chrome plating can be achieved (e.g. for off-shore applications); possible applications in automotive industry and mechanical engineering <u>Disadvantages</u> : productivity, process stability and automation have to be further optimized
Anhydrous ionic liquids based on Cr(III) salts	x			Still in development
Closed coating reactors	x	x		<u>Advantages</u> : no surfactants (either fluorine-free or fluorinated) are necessary; limited aerosol emission to room air. Due to highly diversified chrome plating processes it is impossible to describe a universal closed loop process technology for all of the various uses and process combinations
Nickel-based coatings	x			<u>Disadvantages</u> : possible nickel emission from the surface (not suitable for food and pharmaceutical industries)
Sulfonation of plastics with sulfur trioxide in the gas phase			x	<u>Advantages</u> : e.g. in terms of flexibility, energy costs or wastewater treatment
Acidic permanganate solutions, nitric acid and trichloroacetic acid mixtures.			x	<u>Disadvantages</u> : problems with wastewater treatment due to organohalogen compounds; problems when searching for suitable rack insulation; risk of formation of nitrous gases during the use of nitric acid; and problems with the formation of manganese dioxide and fire safety issues when using permanganate solutions

¹ Salt bath nitriding and nitrocarburising are other case hardening processes as technical alternatives for functional chrome plating (Müller et al. 2020) Because of a high risk for the professional user (i.e. physical hazards, use of acute toxic substances, use in open systems), these alternatives are not considered further.

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Fluorine-free wetting agents contain higher concentrations of active substances (fluorine-free 1 – 50%; 6:2 FTS 1 – 10%). Reasons for this are, for example:

- Higher dosage of the alternatives is needed to achieve comparable surface tensions
- Higher consumption of the alternatives occurs because of oxidation.

In contrast to fluorinated products the fluorine-free products often have to be diluted before adding and have to be applied more often throughout the day. Despite the need for higher dosage for these reasons, fluorine-free wetting agents are expected to have a lower impact on the aquatic environment than PFAS, due to rapid oxidation and biodegradation (UBA, 2022).

From a technical perspective there is no single solution for all cases. For some industrial applications closed reactors, which are used without surfactants, will be an option whereas others will have to switch to non-fluorinated wetting agents or mist suppressants. Some surface treatments will have to even switch to a completely different process such as laser metal deposition or plasma processes. This all requires further intensive research and development work, but approaches show that PFAS-free alternatives will be available for all applications which today require the use of PFAS.

One stakeholder reported that he is a developer of a hard-chrome Cr(III) plating processes. He reports that they assume that a wetting agent is also needed for Cr(III) based hard chrome plating. They are currently evaluating whether non-fluorinated wetting agents are technically feasible and have partial success with it, but have not found a 100% working alternative yet.

The following conclusions were reached on the availability of alternatives for chrome plating in the summary report for the sector:

- Hard Chrome Plating: within 5 years (medium uncertainty). Users will face very varying costs, mainly depending on characteristics of the current manufacturing sites (high uncertainty);
- Decorative plating: Regarding Cr(VI) the shift to Cr(III) is affordable (certain). For some applications the switch to Cr(III) is uncertain. Costs and availability of other alternatives are not clear (high uncertainty).
- Plastic Electroplating: Regarding Cr(VI) there is an ongoing substitution process to Cr(III) which suggests affordability.

Human health and environmental hazards of alternatives

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log K_{ow}) and bioconcentration factor (BCF) were assessed. Additionally, it is assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHA's dissemination site. Non-chemical alternatives are also listed in the table.

In relation to metal plating and manufacture of metal products, 4 of the alternatives were non-chemical in nature. The list of alternatives contained seven unique CAS numbers. All of the substances with unique CAS were classified according CLP (harmonised classification or self-classification). Three of the substances with unique CAS number did, according to their registration dossier, not fulfil the PBT or vPvB criteria and for the remaining substances no data was found or PBT/vPvB properties were not applicable, meaning that none of these substances were known to fulfil the PBT or vPvB criteria. No other hazard properties were mentioned.

The list contained an additional four substances with unique substance names for which no CAS numbers were available. For these substances, no information on classification or PBT and vPvB assessments were available. Appendix E.2. contains a table presenting this

information along with further data on alternatives for the various uses assessed in this dossier.

E.2.4.2.2. Manufacture of metal products

This sub-sector includes a wide range of metal products from mechanical components for vehicles and other machinery to construction materials. It is therefore to be expected that there will be significant variation within the sub-sector with respect to the availability of alternatives. It is noted that a key property of PFAS listed in Table E.59 for several applications was control of surface tension during production. To the extent that this is also key property for PFAS used in plating processes (Table E.58) it may be anticipated that alternatives are similarly available. However, there are other applications where other properties of PFAS are important, for example durability, resistance to chemical attack, thermal properties and sealing properties. Stakeholders did not identify alternatives that fulfil the performance of fluoropolymers e.g. for chemical and temperature resistance.

Alternatives such as polyester and silicone-modified polyester are available at a lower cost point and are already used in coatings. Galvanization and anodization are effective and cost-efficient alternatives for some applications. Based on literature review and feedback from stakeholders, however, it has not been possible to develop a comprehensive overview of the availability of alternatives for the subsector of manufacture of metal products.

E.2.4.3. Environmental impacts

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.2.3, assuming business-as-usual and, thus, on-going PFAS use and emissions. The analysis of environmental impacts focuses on two restriction options:

- **RO1**, adopting a ban of all PFAS used in the metal plating sector;
- **RO2**, adopting a ban on PFAS in combination with use-specific derogations. The potential derogation is marked for consideration for a 5-year period.

Environmental impacts of RO1 are analysed quantitatively. In contrast, for the potential use-specific derogation emission data were lacking. There is information about the PFAS composition of emissions (mainly PFAA precursors). Therefore, environmental impacts of RO2 are evaluated qualitatively in relation to a maximum additional emission scenario, i.e. a full derogation of the relevant PFAS group. Note that this maximum additional emission scenario does not represent a restriction option but is used for comparative purposes only. Table E.60 summarizes the characteristics of the restriction options in the metal plating sector, and the maximum additional emission scenarios.

Table E.60. Characteristics of restriction options and maximum additional emission scenario.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---
RO2	Ban with use-specific derogation	Potential derogation of PFAS use in hard chrome plating (mainly PFAA precursors, further possible PFAS: PFSA, PFPiAs see also Annex A)	18 months	5 years
Maximum additional emission scenario	Ban with full derogation of entire PFAS groups	PFAAs (incl. side-chain polymers)	18 months	5 years

For calculating the expected emission reduction of RO1 the assumed entry into force year of the restriction dossier is 2025. Assuming a standard transition period of 18 months, restriction options are expected to be implemented in 2027. Environmental impacts are expressed in relation to the baseline scenario discussed in section E.2.4.1. All emission estimates represent mean values. Table E.61 shows emissions and the expected emission reduction for time paths of 30 and 45 years (starting in 2025).

Table E.61. Total mean emissions and emission reduction of RO-1 and maximum additional emission scenario (metal plating sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	183	---	---
RO1	12	171	94
Maximum additional emission scenario '5-year derogation of all PFAAs incl. PFAA precursors' [*]	41	142	77
2025-2070			
Baseline	271	---	---
RO1	12	260	96
Maximum additional emission scenario '5-year derogation of all PFAAs incl. PFAA precursors' [*]	41	230	95

^{*}Maximum additional emission scenarios assuming a full derogation of a particular PFAS group against which emissions of proposed use-specific derogations are evaluated qualitatively. They do not represent restriction options.

The expected emission reduction is highest under RO1 (full ban of all PFAS after the transition period). RO1 achieves a total PFAS emission reduction of about 94% of baseline emissions. Moreover, RO1 is the only option leading to a full stop of emissions (arising during the use phase) after the 18-month transition period.

Environmental impacts of RO2 are discussed qualitatively below.

- *Potential derogation marked for consideration: Hard chrome plating*

The derogation is marked for consideration for a duration of until 5 years after EIF and covers mainly PFAA precursors, and further possible PFAS such as PFSA and PFPIAs. Since PFAAs used in the metal plating sector are predominantly used for hard chrome plating and considering the available **weak evidence on emissions from hard chrome plating**, expected additional emissions resulting from the derogation can be expected to be very close or even equivalent to emissions of the maximum additional emission scenario assuming a derogation (see Table E.61). The derogation can, therefore, be expected to reduce the effectiveness of the restriction to about 77%. There is **no evidence available with regard to emissions from the manufacture of metal products**. Hence, no indication about the fraction of additional emissions under RO2 in comparison to total emissions at sector level can be provided. Figure E.7, shows the time path of mean emissions (present values) for the baseline, RO1 and the relevant maximum additional emission scenario.

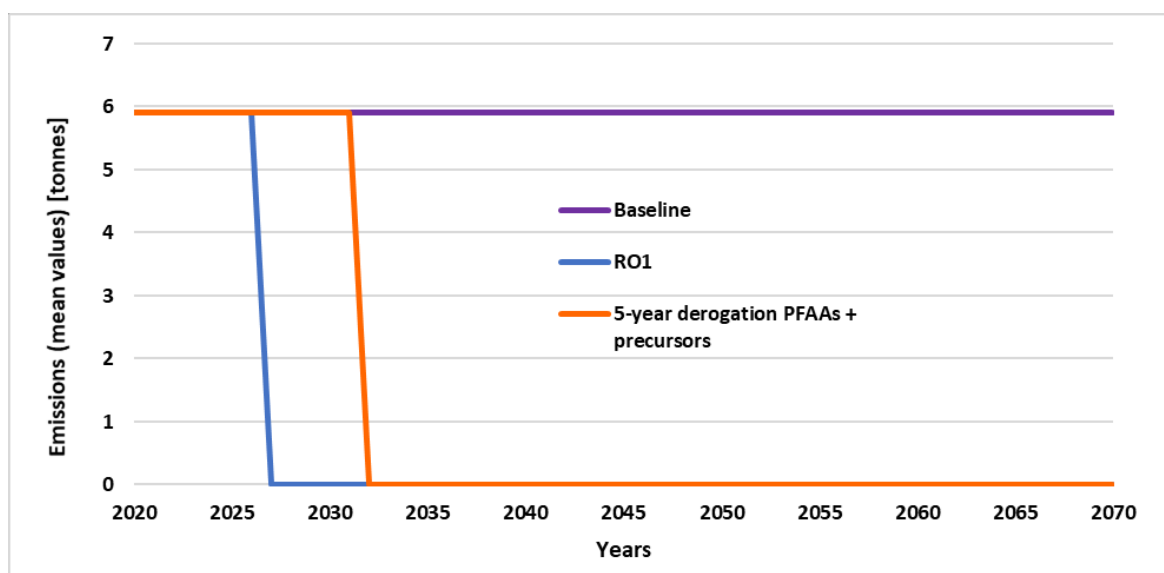


Figure E.7. Time path of mean emissions under the baseline, RO1, and the maximum additional emission scenario (metal plating sector, in tonnes).

E.2.4.4. Economic and other impacts

E.2.4.4.1. Metal plating sector

Economic impacts on industry

Size of the sector

Variable estimates have been identified for the size of the plating sector.

- As of 30/06/2022, ECHA reports that there are 1 724 total authorised uses for Cr(III), including 102 uses for which companies hold their own authorisation and 1 622 notified downstream uses. This includes companies of varying sizes, from small specialist platers to major manufacturers.
- According to the German central association for surface technology (Zentralverband Oberflächentechnik e.V. - ZVO), about 200 companies are working in the sector of functional chrome plating, about 800 in the sector of decorative chrome plating and about 30 in the sector of plastic products chrome plating in Germany alone (evaluation from 2018/2019 (UBA, 2022). Extrapolating the number of German companies to the EU, gives around 5 000 companies (extrapolation based on either population or GDP giving broadly similar figures). Boog and Kwaak (2016) indicated an average of 17 workers per plant in the Cr(VI) sector. Applying this to the 5 000 companies just estimated implies a total of 85 000 workers in the sector in the EU.
- Boog and Kwaak (2016) estimated a much higher number of companies (12 600) and workers (214 000) for Cr(VI) applicators in the EU. Figures increased to 42 000 companies and 736 000 workers when clients of the applicators were included.

The European automotive chromium finishing market was estimated to be worth more than USD 1 billion in 2020 (Graphical Research, 2021), with growth in the period 2021 to 2027 estimated at 2.9% annually. No information has been identified for the size of the chrome plating market for kitchens and bathrooms, expected to be another significant part of the market, or for sectors with smaller demand for chrome plating. Similarly, no information has been identified regarding the size of the market for plating with metals other than chromium. Boog and Kwaak (2016) indicates a much higher level of economic activity in the EU than identified by Graphical Research with annual turnover of €153 billion and value added of €47

billion.

It is to be noted that the data from ECHA, above, are for authorised Cr(III) users as of 2022, rather than Cr(VI) in 2013 as considered by Boog and Kwaak (2016), but the disparity between the two sets of data for chrome plating is extreme.

Uptake of alternatives given other regulatory drivers

For metal plating processes mainly C6 PFAS are used. There is little information available on the use of other PFAS for metal plating. Several C6 PFAS (e.g. 6:2 FTS) are already in the scope of the PFHxA restriction proposal and it is most likely that no other PFAS alternatives are available. Therefore, substitution will take place when the restriction on PFHxA and related substances enters into force within the next years and in that case no further economic impacts are expected to result from the PFAS restriction.

It is concluded that no additional transitional periods are needed for decorative chrome plating and plastic electroplating as alternatives are available. For hard chrome plating a longer transitional period seems necessary to limit risks to business and high economic costs.

Cost data

Despite the efforts taken to engage with stakeholders only limited and fragmentary data on costs has been obtained.

According to stakeholders the alternatives to PFAS are more expensive. Viewed as an individual process, costs may increase by several orders of magnitude. In relation to the manufactured product, cost increases in the low double-digit percentage range are to be expected. It is uncertain how customers react to price increases.

However, given the requirement for Authorisation for Cr(VI) use, and the potential impact of the PFHxA dossier, it is possible that the present proposed restriction would have no additional impact if introduced on the same timescale as the PFHxA dossier. On this basis the restriction would have no consequences for either businesses or consumers. This seemed to be confirmed by one stakeholder who commented that the ban on the use of Cr(VI) compounds by REACH forces his company to change the affected processes in the next few years. The stakeholder is working on replacing the pre-treatment process for plating on plastics. Then no Cr(VI) and consequently no PFAS is needed: this implies zero cost to the business concerned of the PFAS restriction. It is not, however, clear that this is the case for all plating operations, given limited data for specialist platers, and for plating with metals other than chromium.

Information from industry (Hauzenberger I., 2016) suggests that *'the costs of phasing-in alternatives varies per company. Tests with alternative products may cost a company €50 000 to €150 000 per test and a test cycle has a minimum length of at least 1 year. However, the representatives indicate that the costs are mainly related to the costs of phasing in the alternative in practice and not in the costs of testing. Most relevant for the cost is whether the alternative is a drop-in alternative or that new installations (tanks, baths, etc.) are required'*. If an alternative is used where the goods to be plated have to be dipped into the surfactant liquid, an additional bath has to be installed at the production facility. This means additional costs for the procurement of equipment as well as costs related to a reorganization of the production facilities for some companies. For decorative plating a shift to other electrolytes that are Cr(III), rather than Cr(VI) based is an available alternative. This would mean that the demand on surfactants and process fluids is considerably lower, and that PFAS are not required. The Norwegian association of electroplaters (NGLF) has estimated the cost of replacing Cr(VI) in plating baths with Cr(III) to be approximately NKR 100 000 (€10 000) per bath (UNEP, 2013). In the event that this change was made in response to the PFHxA restriction there is no cost attributable to the PFAS restriction. The cost estimate from the Norwegian association of electroplaters suggests that substitution of Cr(VI) with Cr(III) is

affordable. Substitution costs mainly consist of one-time replacement costs that amount to less than €1 000/y (€750-800/y/bath).

It is not possible to estimate overall costs given a lack of data on the number/size of chrome baths in EU/EEC, variance/distribution of size of manufacturing sites, uncertainty on the impact of earlier legislation and so on. It is not possible to define a 'typical' enterprise in the sector given that the chrome/metal plating industry is characterized by heterogeneity and a large share of small and medium enterprises. Large production facilities might use considerably more than 100 baths of different sizes. Small and medium enterprises might use single to double digit number of baths.

A study by the Danish Ministry of Environment from 2011 focussing on PFOS "*suggests that the price of the PFOS products used as mist suppressant for non-decorative hard chrome plating is around DKK 100 to 200 (€13 to 27) per kg/L. The price is dependent on the concentration of PFOS in the chemical. [...] The price [of alternatives] is not fully comparable as no information was received on the amounts to be used compared to a PFOS product. [...] Other information about the price of the non-PFOS alternatives was sparse. One supplier informed that their non-PFOS alternative is more expensive than PFOS (but not how much more expensive)*" (UNEP, 2013). The consultation process for the present dossier did not obtain further data on this issue.

In contrast to fluorinated products, the fluorine-free products often have to be added diluted and in smaller dosages throughout the day. To achieve comparable surface tensions, higher amounts of wetting agents are necessary (UBA, 2022). Therefore, it is possible that production processes need to be changed which may entail additional equipment and labour costs.

The potential for recouping losses from premature retirement of assets seems negligible, given the nature of the changes involved – i.e. there is no major asset to be disposed of, and if there was, it would be specific to the chromium plating industry.

It is likely that there would be recertification costs for substitution relating to production of some components, for example for the aviation industry. However, the extent of the need for recertification is unknown and will vary widely across the different products of the plating sector.

Overall, available information suggests general affordability, though it is possible that some manufacturing sites would face difficulties with regard to substitution.

Timelines

The association of the German plastic electroplating companies (FGK Fachverband galvanisierte Kunststoffe e.V.) reports that members "*plan the partly extensive modifications of the plating lines and to schedule them. This will take some years to complete depending on the company and the individual complexity and size of the machinery, but will be completed until 2024*". The restriction proposed here would not come into effect until after 2024, taking account of the time required for it to pass through the REACH Committees and European Commission, and a minimum 18 month transition period.

Answers provided by respondents to the stakeholder consultation for the proposed PFAS restriction were contradictory, with several citing substantially higher losses for introduction of a ban after 10 years than after 3 years (the same has been observed in responses in some other sectors also). This position is not accepted here, given that the 10 year period provides a much longer time horizon for development of alternatives.

The Boog and Kwaak (2016) report provided more coherent information on the impacts of authorisation for Cr(VI) plating operations over different timescales. An immediate ban at the time that their report was written was estimated to lead to a 60% reduction in turnover,

employment, etc. in the industry in the Netherlands. A ban after 4 years was estimated likely to lead to a 40% reduction, whilst a ban after 7 years was estimated as likely to lead to a 9% reduction. Results therefore indicate a significant decline in costs for longer transition periods for the plating sector. It is to be remembered that the Boog and Kwaak (2016) report addressed the situation leading up to 2016: legislation since then on Cr(VI) and use of PFHxA will cause some limiting of the specific impact of the proposed restriction on the sector.

Several stakeholders commented that approval by downstream users in some sectors is required and therefore extended transition periods are needed. Sometimes this approval is connected to industry and/or legal standards. No details are available but stakeholders claim that industry specific approval times can take months to several years (automotive, aviation, defence, food, medical equipment etc.). The extent of the need for recertification and associated costs is unknown.

The restriction would not affect demand for chrome plating as such, and where alternatives are available it is anticipated that few companies would stop operating. However, some industry stakeholders considered that a restriction could have significant impacts, specifically in the areas of hard chrome and black chrome plating, one claiming that it could lose 90% of its staff in the event of a restriction on a timeline of 3 years, with a large loss of turnover. Some others considered risks to business to be present, but of a much lower level, a few percent of turnover. Risks were dependent on the specific activities being carried out by companies. Also, those with a diverse portfolio of products and activities were naturally likely to be less affected overall as they had other work to fall back on. Table E.62 summarises the information collected for the chrome plating sector. No information is presented for plating with other metals.

Table E.62. Conclusions on total economic impacts on directly affected companies resulting from a PFAS restriction on the chrome plating sector.

		Decorative chrome plating	Hard chrome plating
NUMBER OF AFFECTED COMPANIES			
Number of companies estimated to be active in the sector		5 000 – 12 600	
Share of companies affected by the restriction due to using PFAS		Low	High
MOST LIKELY REACTION OF AFFECTED COMPANIES			
Most likely reaction	Based on information on impacts at company level from 2 nd stakeholder consultation	Substitution	Some substitution, some business closure.
	Based on information on technical feasibility of alternatives	Substitution	Dependent on transition period but with potential for business closure
Conclusion: Expected share of business closures		Negligible	Low, but dependent on transition period
COSTS AT COMPANY LEVEL			
Business closure: Cost per company active in the sector	Sales value per company	Likely negligible given availability of alternatives	Sales losses are deemed to range from nothing to a few million EUR per company
	Producer surplus losses	Low given availability of alternatives	Variable: response ranged from low impact to accounting for 90% of turnover.
	Costs for dismantling plants	Closure not considered likely	Unknown
Substitution: Cost per company active in the sector	Research & Development (R&D) costs	Undertaken in relation to other legislation (Cr(VI), PFHxA)	Significant given difficulties experienced so far in identifying satisfactory alternatives
	Capital costs	As above	Unknown
	Operating costs	As above	Unknown
	Certification costs	As above	Unknown
	Total cost	As above	Likely significant
ABILITY TO PASS ON COSTS TO CUSTOMERS			
Expected extent to which companies can pass on costs to customers		Variable depending on end-product and position of plater in the supply chain	
TOTAL ECONOMIC IMPACTS ON AFFECTED COMPANIES AT SECTOR LEVEL			
Conclusions on total economic impacts on affected companies in the sector	Total producer surplus loss: Company closures	Low, given impacts of other legislation and availability of alternatives	Potentially high if short transition period is adopted
	Total producer surplus loss:	Low, given impacts of other legislation and availability of alternatives	Potentially high if a short transition period is adopted

Economic impacts on consumers

Fluorine-free substances/products are not considered equally effective to fluorinated surfactants. Furthermore, additional risks with respect to safety, process stability and device preservation are mentioned by the German electroplating industry association (UNEP, 2018a). Nevertheless, these substances have been used successfully in bright (decorative) chrome electrolytes (UBA, 2017), indicating that in some areas there is no loss in quality. The use in hard chrome plating is also possible but still under development.

To the extent that PFAS are being phased out of the industry because of other regulatory action (Cr(VI) authorisation, PFHxA restriction), any impacts on consumers are a consequence of other legislation and are not relevant here.

No information has been gathered relevant to the impact on consumers of metal products where production currently involves use of PFAS (other than for plating operations).

Other impacts on society

One stakeholder reported that outside Europe the use of Cr(VI) will continue and there for there will be an unequal playing field. According to this stakeholder some Dutch companies already are moving their production to other countries, such as India. There are, however, many reasons why a company may choose to relocate operations, not least the differences in labour costs. No further information is available in this regard. But the Dossier Submitters assume that if there is an ongoing relocation of production facilities linked to increased regulation, it is mainly caused by the authorization requirement for Cr(VI) and not by anticipated future regulation of PFAS in mist suppressants.

Several respondents to the CfE considered job losses likely if a restriction was introduced within 3 years. It is not possible to make an accurate estimate of the impact given limited response in the CfE and the 2nd stakeholder consultation and the wide variation in the estimated numbers working in the sector (85 000 to 736 000 with clients of plating applicators included). Following from the conclusions of Boog and Kwaak (2016) in relation to authorisation requirements for Cr(VI), the implementation of a transition period of a few years could lead to a marked reduction in risk of business closure and risks to employment. The longer that period, the lower the risk.

E.2.4.4.2. Manufacture of metal products

As noted above, the sector 'manufacture of metal products' is extremely diverse, covering many activities including engineering, transport by all modes and industrial processing equipment. It is therefore not possible to provide a clear indication of the overall size of the sector beyond saying that it is broad and restriction has potential to affect many parts of the economy. Some specific applications are dealt with in other sections of this annex, for example, under E.2.13. Additional regulatory drivers ranging from building standards to energy efficiency and safety, for example in the aerospace industry will affect both the availability of alternatives and the speed with which they can be introduced, noting, for example, the need for recertification in some areas. Again, given the broad scope of the sector, detailed review is not possible. Data on costs for the sector was not obtained from the literature review, the CfE or the second stakeholder consultation at a scale that would permit provision of estimates giving an adequate overview of the impact of a restriction.

The complexity of the sector also prevents detailed consideration of the impacts of a restriction on consumers. Impacts in some areas will be small or non-existent, whilst in others the loss of functionality of metal products could be significant. Likewise, the potential for the closure of businesses and subsequent impacts on unemployment.

E.2.4.5. Summary of cost and benefit assessment

E.2.4.5.1. Hard chrome plating

Table E.63 summarises the outcomes of the assessment of costs and benefits for hard chrome plating. More detailed information can be found in the accompanying text following the table.

Table E.63. Hard chrome plating – Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Evidence on the availability of alternatives for the hard chrome plating sector is mixed, with some reporting satisfactory performance of alternatives and others not. Responses to the CfE and 2nd stakeholder consultation from industry are concluded to reflect the precise specifications of product lines provided by different companies, and these specifications causing some to be more advanced in transition than others. High substitution potential at EiF for the sector as a whole [sufficiently strong evidence] but low substitution potential at EiF in relation to some goods [weak evidence].	There is weak evidence provided by industry about emissions from hard chrome plating. No evidence is available about emissions from the manufacture of metal products. Based on available evidence about emissions from hard chrome plating, a ban can be expected to reduce emissions by about 94%. As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	High producer surplus losses due to a significant share of business closures [weak evidence]. Some producer surplus losses as a result of substitution, due to additional expenditure on R&D and additional capital costs [sufficiently strong evidence]. High socio-economic costs to customers [weak evidence] due to the unavailability of, or reduced quality of, hard chrome plating, though this may be negated by import of plated goods from outside of the EU where the restriction would not apply [weak evidence]. High employment losses as a result of significant share of business closures [weak evidence].	
Ban with use-specific derogations	5 years	Alternatives still being sought for example for hard- and black-chrome plating though there has been some success, indicating that a derogation beyond the 18-month transition period may be beneficial for the industry	Considering the available weak evidence on emissions arising from hard chrome plating, additional emissions resulting from the derogation can be expected to be very close or even equivalent to	A 5-year derogation would permit a longer period for R&D and would reduce costs for producers whilst maintaining production rates and quality. This would also limit potential impacts on	It is considered that the use of PFAS in the sector will shortly be legislated against through

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		[sufficiently strong evidence].	emissions of the maximum additional emission scenario (41 t). This reduces the effectiveness of the restriction for the metal plating sector to about 77%. As the environmental impact assessment does not cover the waste phase, additional emissions as a result of the derogation are likely underestimated.	consumers and the risk of job losses. [sufficiently strong evidence]	the PFHxA dossier. On this basis the proposed restriction would have no cost impact for the sector if conditions were similar to those of the PFHxA restriction [sufficiently strong evidence].
	12 years	n/a	n/a	n/a	n/a
Conclusion	It is concluded that there is evidence of problems for industry to substitute in the hard chrome sub-sector requiring further R&D for some manufacturers. It is unclear whether this is linked to specific product lines and associated technical parameters or other factors specific to individual companies. A derogation might be proposed at a later stage if additional information on alternatives becomes available. Given the REACH Committees conclusions on the PFHxA dossier it is concluded that there would be no additional economic impact of the proposed restriction if similar conditions on timing for the sub-sector apply. Still, a 5-year derogation in addition to the 18-month transition period for hard chrome plating coincides with significant additional emissions of PFAAs.				

The views of the Dossier Submitters are based on evidence from the CfE, 2nd Stakeholder Consultation, literature and the precedence provided by the PFHxA restriction. It is considered unlikely that the sample of businesses that responded to the CfE and 2nd stakeholder consultation are truly representative of the sector, given a greater tendency for those with concerns about potential regulation being more likely to respond than those that would be less affected or not affected at all.

It is concluded that the evidence is weak that technically feasible and economically feasible alternatives are available in the quantities required for use in hard/functional chrome plating where a number of consultees cited difficulty in transitioning away from the use of PFAS. This is recognised in the conclusions reached previously for a restriction on the use of PFHxA, where a time-limited derogation is proposed for hard chrome plating. This is highly relevant to the current proposal as the PFAS identified as being used for hard chrome plating at present are all covered already under the PFHxA proposal. However, it is also recognised that some operators have introduced alternatives already. On this basis it is concluded that the evidence is weak that it is technically and economically infeasible to introduce alternatives across the hard chrome plating sector under RO1 (restriction after an 18-month transition period after Entry into Force). If a derogation is to be investigated, it would be appropriate to consider the timelines of the PFHxA restriction.

Evidence on emissions is weak and focused on hard chrome plating. No data were found to enable quantification of emissions from manufacture of metal products.

It is concluded that there is sufficiently strong evidence for producer losses via added R&D costs through the need to carry out further research on alternatives on a short timescale for RO1. There are also potentially added capital costs for the same reason. Some respondents to the CfE and 2nd stakeholder consultation considered that there was a significant risk of business closures that would lead to high producer surplus loss and associated job losses. This is acknowledged as a risk, but evidence on the scale of losses is considered weak, given the progress made by some hard chrome platers it is concluded that the evidence is given variation in progress across the sector. The Dossier Submitters acknowledge that there is potential for impacts on consumers from a restriction that affects hard chrome plating, given that a number of businesses working in the sector have expressed difficulty in identifying alternatives that provide satisfactory performance.

E.2.4.5.2. Decorative chrome plating, plating on plastic and plating with other metals

Table E.64 summarises the outcomes of the assessment of costs and benefits for metal plating. More detailed information can be found in the accompanying text following the table.

Table E.64. Decorative chrome plating, plating on plastic and plating with other metals - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Technically feasible alternatives exist for decorative and plastic chrome plating and are already in commercial use [sufficiently strong evidence]. No information obtained on plating with other metals though there is some similarity with decorative plating in the mechanism of PFAS action via controls on surface tension. It is therefore concluded that alternatives exist for plating with other metals [weak evidence].	No evidence is available about emissions from the manufacture of metal products. Based on available evidence about emissions from hard chrome plating, a ban can be expected to reduce emissions by about 94%. As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated	Cost impacts for industry and consumers for the decorative chrome plating and plastics plating sectors are concluded to be negligible given the availability and take-up of alternatives that has already occurred. On this basis, it is not expected that there would be job losses in the sector linked to RO1. It is also concluded that there are no functional losses associated with this substitution [sufficiently strong evidence]. The situation for plating with other metals (primarily nickel, copper and tin) is less clear given a lack of information beyond the observation that the role of PFASs appears to be similar to decorative chrome plating for these metals. On this basis, it is expected that there will be negligible cost impacts for industry and consumers and negligible job losses [weak evidence].	
Ban with use-specific derogations	5 years	n/a	n/a	n/a	
	12 years	n/a	n/a	n/a	n/a
Conclusion	It is concluded that no derogation is required for decorative and plastic chrome plating. No information on plating with other metals was reported during the consultation process or identified in literature review, and so the position adopted is that no information is available to justify a derogation.				

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The views of the Dossier Submitters are based on evidence from the CfE, 2nd Stakeholder Consultation and the literature.

It is concluded that the evidence is strong that technically feasible and economically feasible alternatives are available in the quantities required for use in decorative chrome plating and plastic electroplating and that the substitution potential is high under RO1 (no derogation but an 18-month transition period after Entry into Force).

It is also concluded that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available in the quantities required for use in plating with other metals (nickel, copper, tin). The logic for this conclusion is that the required properties of PFAS for these activities appear similar to those for decorative chrome plating (control of surface tension), although available literature is limited and no substantive information was obtained from the CfE and 2nd stakeholder consultation. Following from the conclusion reached for decorative chrome plating it is concluded that the substitution potential is high under RO1 (no derogation but an 18-month transition period after Entry into Force).

No evidence was identified to permit quantification of emissions from the sub-sectors decorative chrome plating, plating on plastic and plating with other metals.

Given the availability of alternatives for decorative chrome plating and plating on plastic, the Dossier Submitters consider that there is sufficiently strong evidence that economic impacts of RO1 for the sector would be negligible. The Dossier Submitters also consider that economic effects on the part of the sector that deals with plating with other metals is also negligible, but evidence for this is weak.

E.2.4.5.3. Manufacture of metal products

Table E.65 summarises the outcomes of the assessment of costs manufacture of metal products. More detailed information can be found in the accompanying text following the table.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Table E.65. Manufacture of metal products - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Metal plating					
Full ban	Not applicable	It is not possible to provide a breakdown of areas where alternatives are available for the sector as a whole given the diversity of metal products that are likely to be affected. However, given similarity in the function of PFAS for a number of products it is anticipated that alternatives will be available for at least some applications immediately [weak evidence]	No data were obtained on emissions related to manufacture of metal products and their use, beyond information presented for other sectors. PFAS use is estimated at 960 t/y for the EU. [no evidence]	No evidence was obtained to demonstrate that RO1 would be problematic for the manufacture of metal products other than those addressed specifically under other sectors (e.g. transport and construction products).	There is overlap with other sectors covered in this restriction, for example transport and construction. Precedence should be given to conclusions reached on specific metal products from those other sectors where available, rather than the generalised conclusions provided here.
Ban with use-specific derogations	5 years	n/a		n/a	
	12 years	n/a		n/a	
Conclusion	Whilst some manufacturers of metal products are likely to be able to eliminate use of PFAS on a short time scale, it is not clear that this would apply in all areas, for example in the production of vehicles and other machinery, where significant additional research could be required, perhaps involving redesign of components. However, those uses are addressed elsewhere (transportation). Any risks would clearly be at least partially mitigated by allowing an additional derogation period. However, given limited feedback from stakeholders the need for and benefits of a derogation are unclear, so no derogation is proposed.				

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Very limited information was identified through literature review with respect to the use of PFAS in the manufacture of metal products. Information from the CfE and 2nd Stakeholder Consultation in this area addressed uses linked to other sectors described in this proposal (eg. construction and transportation) and so is not repeated here. It is concluded by reference to the plating sector that there is some (albeit weak) evidence that technically and economically feasible alternatives are available in the quantities required for use in the manufacture of metal products not covered elsewhere in this proposal and hence it is not possible to conclude that the substitution potential under RO1 would be problematic.

No evidence was provided or identified on costs or emissions.

E.2.5. Consumer mixtures (and musical instruments)

E.2.5.1. Baseline

For consumer mixtures information about market growth rates could not be retrieved. Therefore, a growth rate of 0% was applied in the assessment of the time path of PFAS use (tonnage) and emissions. No further information on historic tonnages and future (expected) tonnages is available. In the 2nd stakeholder consultation (during the preparation of this dossier) one company indicated that they were planning to phase out the use of PFAS from cleaning agents, polishes and waxes by 2025. Another company stated that the use of PFAS in cleaning agents, polishes and waxes will remain constant, and a third company estimated that the use of PFAS in cleaning agents will decrease but use in waxes will increase. No generalised trends could be derived from this information (see Table E.66). The start year of the projection is 2020.

Table E.66. Projected yearly PFAS use and emissions in the consumer mixtures sector of the EEA between 2020 and 2070 in tonnes (mean values based on market data).

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
PFAS emissions	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage).

It is assumed that PFAS use, consisting predominantly of non-polymeric PFAS, leads to an equivalent amount of emissions. Information about lower and higher bounds of use and emission estimates at sector level, or for specific PFAS applications, are not available. A graphical illustration of use and emission trends is therefore not possible.

E.2.5.2. Alternatives

E.2.5.2.1. Technical feasibility

Cleaners

It is not clear whether the drastic reduction of static surface tension which can be achieved by using PFAS is really necessary for consumer cleaning products or whether other surfactants (e.g. hydrocarbon or silicone based surfactants) could also be employed. For example, the surface energy of metal and glass is rather large; therefore, PFAS are not really necessary for use as a surfactant to achieve a drastic reduction in surface tension of the formulation. For example, the most recognised glass cleaner brand in the USA apparently does not use PFAS in their glass cleaners but claims to leave the treated surface streak free (S. C. Johnson & Son, 2020). Jensen et al. (2008) also states that fluorinated products do not seem to be used in ordinary glass cleaners. It is not known whether alternative substances can match the repellence for water and re-soiling of the PFAS-containing metal and ceramic cleaners.

Furthermore, extremely low surface tensions can also be achieved by siloxane Gemini surfactants that achieve a surface tension of 21 mN/m (stakeholder information). For carpet spot cleaners, caprylyl/myristyl glucoside (CAS 68515-73-1 and CAS 110615-47-9) has been used as alternative for PFAS (ECOS, 2021; Glüge et al., 2022). Alternatives for PFAS-containing surfactants in laundry detergents are e.g. C12–C16 pareth-7, potassium cocoate, decyl glucoside (Ecover, 2021a; Glüge et al., 2022).

Waxes

Regarding PFAS in waxes, a document of the Stockholm Convention (UNEP, 2012) describes that softer waxes (which are more or entirely biodegradable) may eliminate the need for fluorinated compounds. Instead, non-ionic or anionic surfactants can be used, which have good wetting properties.

Floor polishes

Alternatives to the use of fluorinated components in floor polishes are available in principle. One patent claims to have developed a non-fluorinated water-based floor wax, which maintains the same gloss and similar or even better levelling properties compared to C8-PFAS (Wang, 2008). Fluorinated wetting agents were replaced by silicone, alkynediol-based hydrocarbons, oleoalkylene oxide block copolymer wetting agents and others. Another patent (CN101293999) describes the use of a fluorine wetting agent (Glüge et al., 2022; Wang, 2008). It was also found that products are on the market that are based on Gemini structures using the substance (poly(oxy-1,2-ethanediyl), α,α'' -[1,4-dimethyl-1,4-bis(3-methylbutyl)-2-butyne-1,4-diyl]bis[ω -hydroxy-S3,(9CI,ACI)]) (CAS 169117-72-0) which is advertised as a cost-effective alternative to traditional fluorosurfactants with even better performance (Air Products, 2014; Glüge et al., 2022).

Aftermarket carpet care

Alternatives to PFAS employed in aftermarket carpet care to achieve stain and dirt resistance exist and are on the market. One chemical alternative for fabric protectors in general is based on silicon dioxide (Start Bio-Solutions, 2020; Washington State Department of Ecology, 2020). Another alternative is the use of proprietary anionic non-fluorinated polymers in the cleaning products (Bridgepoint Systems, 2020; Washington State Department of Ecology, 2020). Finally, the use of inherently stain-resistant fibres like wool, polypropylene, polyethyleneterephthalate, and polytrimethyleneterephthalate (Washington State Department of Ecology, 2020) is feasible.

Dry cleaning products for metals, glass, ceramics etc.

No information available.

Dishwashing products/rinse aid

For dishwashing products alternatives exist, for example sodium lauryl sulfate (CAS 151-21-3) and lauryl glucoside (CAS 27836-64-2) (Glüge et al., 2022), (Ecover, 2021c). Moreover, rinse aids for dishwasher products that do not contain PFAS in a functional role are on the market (Borg and Ivarsson, 2017). Alternatives are e.g. sophorolipids (Glüge et al., 2022), (Ecover, 2021b).

Windscreen treatments and windscreen wiper fluids

An alternative for PFAS in car windscreen treatments is on the market (e.g. (Ctra. Urnieta, 2020)). The company uses polydimethylsiloxanes in their products to achieve water and stain repellence. The non-polar methyl groups result in a similar hydrophobic surface as the one achieved by the fluorinated alkyl chain of fluoroalkylsilanes (Ctra. Urnieta, 2020; Justo, 2010). Since the silicones used in this product are not chemically bound to the glass surface, the effect is not as long-lasting and the product may have to be applied more frequently (Acton Media Inc., 2019).

Windscreen wiper fluids without fluorinated compounds are also available with alternatives such as silicone-based substances (e.g. non-ionic amino-modified silicone-polyalkyl copolymer (Patent US 7585828 B2) achieving similar results to PFAS. Non-fluorinated

surfactants which are also used for windscreen wiper fluids are well established (e.g. sodium dioctylsulfosuccinate). US patent US5922665A also covers the use of a branched or linear primary alcohol ethoxylate⁷⁵, a secondary alcohol ethoxylate, a branched decyltridecylalcohol ethoxylate, a branched or linear alkylphenol ethoxylate, a branched or linear alkylamine ethoxylate, an alkyletheramine ethoxylate, a linear alcohol alkoxylate, and a mixture thereof as non-ionic surfactants. Polyols including a fluorinated polyether diol can be added, but the addition of glycols is possible instead as well. (Patent US 7,585,828 B2). The additions of polyols increases the flash point and thus the safety of the product (Patent CA2216888C).

Car care

Alternatives for PTFE-containing polishes and waxes used for cars are also available on the market. In these products, carnauba wax (a natural wax obtained from carnauba palm trees, (CAS: 8015-86-9) is often used to achieve protection of the car's surface and water repellence. It achieves the same effect of closing pores in the car's varnish and is also stable under UV radiation (Krendlinger et al., 2015).

Musical instruments

Alternative materials for the fabrication of strings are readily available: a high number of strings is made from nylon or wound metal but strings from gut are available as well. The difference between those different materials is mostly in the sound produced by the resulting strings. One company supplied information that they are currently investigating one other alternative (confidential information) for coating guitar strings. However, it is not clear yet, whether this alternative will indeed turn out to be a feasible alternative. The company estimated that the cost of this work would be <€1 million per year for the next 3 - 5 years and could become four times as high in case the proposed alternative is found to be no suitable alternative and further research is required (confidential stakeholder information)

Most lubricants for guitar strings is based on mineral oil (for example white mineral oil (EC-number: 8042-47-5) is used (Thomann GmbH, 2020a)). As an alternative for PTFE micropowder or grease, graphite powder can also be used for minimising the friction between strings and the nut (Thomann GmbH, 2020b).

E.2.5.2.2. Human health and environmental hazards

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log Kow) and bioconcentration factor (BCF) was assessed. Additionally, it was assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHAs dissemination site.

In relation to consumer mixtures, the list of alternatives contained 14 unique CAS numbers. Seven (7) of the substances with unique CAS were classified according CLP (self-classification). Four (4) of the substances with unique CAS number did, according to their registration dossier, not fulfil the PBT or vPvB criteria and for the remaining substances no data was found or PBT/vPvB properties were not applicable, meaning that none of these substances were known to fulfil the PBT or vPvB criteria. No other hazard properties were mentioned.

The list contained an additional 20 substances with unique substance names for which no CAS numbers were available. For these substances, no information on classification or PBT and vPvB assessments were available. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

⁷⁵ Nonylphenol ethoxylate and octylphenol ethoxylate are heavily regulated.

E.2.5.3. Environmental impacts

The analysis of environmental impacts of restriction options adopted on PFAS use in consumer mixtures is conducted for restriction option RO1, i.e. a complete ban of all PFAS uses in this sector. No derogations are proposed.

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 is expected to be implemented in 2027. Environmental impacts of RO1 are expressed in relation to the baseline scenario discussed in section E.2.5.1. All emission estimates represent mean values. Table E.67 shows mean emissions and the expected mean emission reduction for time path of 30 years (starting in 2025).

Table E.67. Total mean emissions and emission reduction of RO1 (consumer mixtures sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	55	---	---
RO1	2	53	96

As illustrated in Table E.67, a ban on PFAS use in consumer mixtures leads to a mean emission reduction between of about 96% compared to the baseline. Emissions will fully cease after the 18 months transition period.

Figure E.8 shows the time path of mean emissions for the baseline scenario and for RO1.

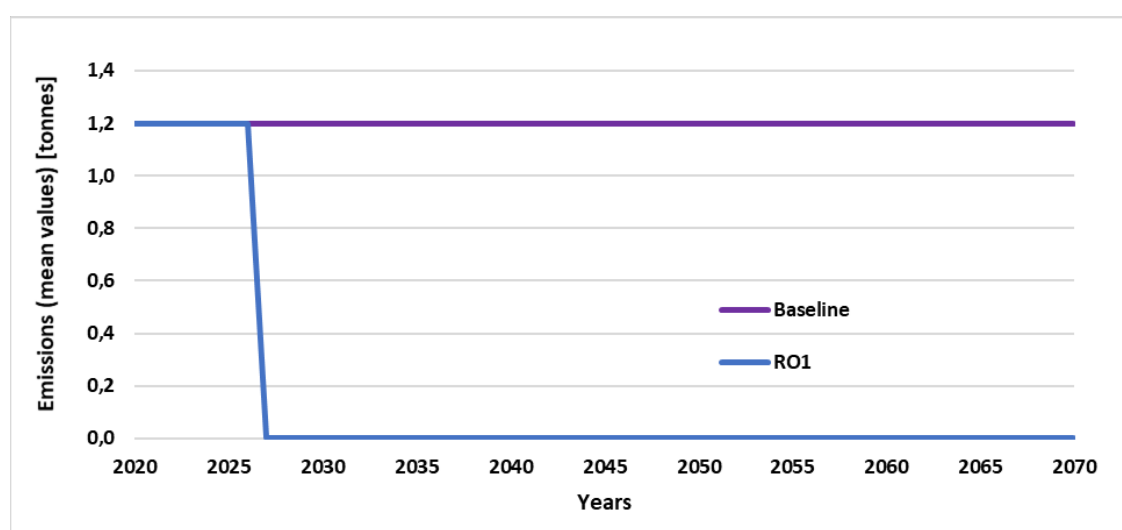


Figure E.8. Time path of mean emissions under the baseline and RO1 (consumer mixtures sector, in tonnes).

E.2.5.4. Economic and other impacts

No detailed information on economic impacts is available for consumer mixtures. No information in this regard has been submitted by stakeholders. The Dossier Submitters point out that also during the two Annex XV report consultations on the PFHxA restriction proposals and SEACs opinion no information was submitted on PFAS use in consumer mixtures by

stakeholders.

Regarding the global wax market, it is assumed to have valued 9.1 billion US-Dollar in 2019, with an annual growth rate of 4.2% between 2020-2026 (DataIntel, 2022). This information is very uncertain. Information on PFAS use in this market is unavailable.

For the 2nd stakeholder consultation during the preparation of this dossier, one company indicated that they were planning to phase out the use of PFAS from cleaning agents, polishes and waxes by 2025. Another company estimated that the use of PFAS in cleaning agents, polishes and waxes will remain constant, and a third company estimated that the use of PFAS in cleaning agents will decrease but use in waxes will increase. No generalised trends could be derived from this information. No information on costs associated with substitution was submitted.

One supplier of guitar strings estimated that the annual average market value for guitar strings containing PFAS is €10 – 30 million, and that the market would grow in proportion to the general market for musical instruments with a compound annual growth rate of 1.6%

Stakeholder organization The International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.) is not aware of market estimates for their membership as a whole. PFAS are used only in niche professional applications and available data are limited. One member company (manufacturer of professional cleaning solutions) indicated annual usage of less than 1 t, of which 60% is in commercial laundry (impregnation of protective clothing/equipment) and the remainder in long-life floor polish and floor strippers/cleaners. This is associated with a high value (€1 – €10 million turnover) due to highly specialised applications. Extrapolation would suggest usage of no more than a few tonnes per year across the entire A.I.S.E. membership. Very low quantities are required, e.g. 0.01% or less in a concentrated solution, to achieve a significant effect. Comparable information for consumer uses is not available.

Regarding the global wax market, it is assumed to have valued 9.1 billion US-Dollar in 2019, with an annual growth rate of 4.2% between 2020-2026 (DataIntel, 2022). This information is very uncertain.

For the 2nd stakeholder consultation, it was explicitly stated in the accompanying information that the Dossier Submitters interpret the available information as indication that alternatives are available and technically and economically feasible for all uses.

The only input in relation to this statement came from a stakeholder organization representing the manufacturers of soaps, detergents and maintenance products. This stakeholder pointed out that functional losses might be associated with the use of the alternatives in some of the products. They also stated that in their view costs are not an issue when considering possible impacts from a restriction on all PFAS.

This mirrors the situation faced by Dossier Submitter Germany and the RAC and SEAC rapporteurs in regard to the restriction proposal for PFHxA, where no manufacturers or other relevant stakeholders commented on the background document or the SEAC-opinion. Therefore, no further information, e.g. on market price, market development and manufacture for PFAS-containing mixtures/articles in this sector, is available.

SEAC concluded in its opinion on the restriction proposal for PFHxA: 'Whilst SEAC notes a lack of information on the magnitude of emissions/emission reduction (benefits), information on restriction-related costs and ongoing substitution activities indicate somewhat limited socio-economic impacts. SEAC concludes that restricting this use is likely not disproportionate (...) SEAC finds that sufficient information to demonstrate the necessity of a derogation was not provided.' The Dossier Submitters are not aware of any additional products or product groups that can be classified as consumer mixtures that were not already within the scope of the

PFHxA restriction proposal.

One company considers that the use of fluorosurfactants can lower the total amount of surfactants necessary in consumer mixtures and therefore lower the costs for surfactants three- to tenfold (Chemours, 2017). It is not known whether this significantly alters overall production costs or not. In general, alternatives exist, and until now no information has been submitted to convincingly show a substantial extent of increasing costs, or lowered quality, or reduced lifetime for these alternatives. On the basis of the available information and the fact that the available PFAS-free products seem to be generally available, the Dossier Submitters infer that a complete ban of PFAS in consumer mixtures will have no significant economic effects.

No additional information is available in regard to the impact of a restriction on small and medium companies. However, the stakeholder organization representing the manufacturers of soaps, detergents and maintenance products indicated that it asked its members for information for the 2nd stakeholder consultation. More than 800 members of this industry association are small and medium-sized enterprises.

The Dossier Submitters in general have insufficient information to judge the overall economic impact of a PFAS restriction proposal regarding musical instruments. For many applications alternatives exist, but the extent of increasing costs or lowered quality or reduced lifetime (if existent at all) cannot be concluded on. No information has been submitted to convincingly show a substantial extent of increasing costs, or lowered quality, or reduced lifetime for these alternatives.

E.2.5.5. Summary of cost and benefit assessment

Table E.68 summarises the outcomes of the assessment of costs and benefits for consumer mixtures and musical instruments.

Table E.68. Consumer mixtures (and musical instruments) - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Cleaners (for glass, metal, ceramic, carpet and upholstery): Sufficiently strong evidence that technically feasible alternatives exist, i.e. silicones, as well as sufficiently strong evidence (in the form of practical examples of completed substitution for glass cleaners) pointing to the economic feasibility of alternative. Waxes and polishes (for e.g. furniture, floors and cars): Sufficiently strong evidence that technically feasible alternatives exist (e.g. carnauba wax for car polishing), i.e. in the form of patent information, as well as sufficiently strong evidence (in the form of practical examples of completed substitution) pointing to the economic feasibility of alternative. Dishwashing products (as rinse aid): Sufficiently strong evidence that technically feasible alternatives exist, i.e. silicones, as well as sufficiently strong evidence (in the form of practical examples of completed substitution for rinse aids) pointing to the economic feasibility of alternative. Windscreen treatments for automobiles and also windscreen wiper fluids: Sufficiently strong evidence that technically feasible	Compared to the baseline, a full ban of PFAS use in consumer mixtures and musical instruments will contribute to reducing emissions (PFAAs and PFAA precursors, fluoropolymers and PFPEs). The expected emission reduction for all sub-sectors together equals around 96% of baseline emissions. As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Consumer mixtures: No further evidence available. Musical Instruments: Moderate producer surplus losses as a result of substitution, due to cost for research on additional alternatives (weak evidence, information on guitar strings based on confidential information from one stakeholder). No further information available.	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		alternatives exist, i.e. patents, as well as sufficiently strong evidence (in the form of practical examples of completed substitution for windscreen treatments) pointing to the economic feasibility of alternative. Guitar strings: Sufficiently strong evidence that technically feasible alternatives exist, i.e. strings from nylon, gut, metal, lubricants based on mineral oil, as well as sufficiently strong evidence (in the form of practical examples of completed substitution) pointing to the economic feasibility of alternatives. Use in pianos: No information available, including no evidence to the contrary on technically and economic feasibility of alternatives.			
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion	No evidence available for PFAS use in pianos [no evidence]. High substitution potential at EiF for all other uses in consumer mixtures and musical instruments [sufficiently strong evidence]. Given the sufficiently strong evidence pointing to the existence of technically and economically feasible alternatives at EiF, no derogation is proposed.				

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No information has been provided on the impact of different transitional periods. Considering that alternatives for all uses seem to be available the Dossier Submitters assume that substitution is technically and economically feasible within 18 months.

E.2.6. Cosmetics

E.2.6.1. Baseline

A 0% growth rate was assumed for assessing the time path of PFAS use (tonnage) and emissions. This is in line with market data indicating no growth in cosmetic retail value for a three-year period ending in 2019 (KEMI, 2021). The start year of the projection is 2020. Note that information about lower and higher bounds of use and emission estimates at sector level, or for specific PFAS applications, was not available for the cosmetics sector, see Table E.69.

Table E.69. Projected yearly PFAS use and emissions in the cosmetics sector of the EEA between 2020 and 2070 in tonnes (mean values based on market data).

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	32	32	32	32	32	32	32	32	32
PFAS emissions	32	32	32	32	32	32	32	32	32

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage).

As discussed in section E.2.6.2, several companies had declared their PFAS phase out in cosmetic products in 2021. However, information about the implications on PFAS use volumes in the cosmetics sector, and emissions, have not become available. Furthermore, the precise timing of the planned phase-out is unclear. The projected time path for PFAS use and corresponding emissions, therefore, does not incorporate reductions of PFAS use and emissions due to the voluntary phase-out measures.

E.2.6.2. Alternatives

E.2.6.2.1. Technical and economic feasibility

For further details and references related to this section, see KEMI (2021).

For this report, we applied information from several databases or platforms, of which three are European cosmetic databases based on consumer data collected via smartphone applications (apps), i.e. CosmEthics (Finnish), Kemiluppen (Danish), ToxFox (German). With these apps, consumers scan cosmetic product barcodes and receive information on ingredients and their potential hazards to make conscious purchase choices or submit new products and product information to the databases. Of these databases, the Dossier Submitters consider CosmEthics to be the one most representative of the EEA market, given the wide geographical spread of their data and the large number of products included. The same conclusion was reached in the REACH restriction proposal for D4, D5 and D6 (ECHA, 2019).

The share of PFAS containing cosmetic products is below 10% in all the 108 cosmetic product subcategories included in the the CosmEthics database (extracted in August 2020)⁷⁶. In absence of new information to the contrary, our assumption is that PFAS can be replaced by other ingredients and do not have critical functions in cosmetics. To this conclusion comes also the POPFREE stage two project and it was also confirmed in an interview with a cosmetics producer.

Experience from the cosmetic product sampling conducted as part of the dossier preparation

⁷⁶ The highest share of PFAS containing products were reported in shaving foam, shaving gel followed by various subcategories of make-up (e.g. pressed powder and foundation).

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showed that several products that in the databases (mentioned above) were indicated as containing PFAS did not list any PFAS as an ingredient in the declaration of content on the product packaging. The Dossier Submitters assume that a substitution of PFAS or reformulation of the product has happened in these cases. Additionally, we noticed at least for these products that companies did not change the product name after reformulation.

By September 2021, at least 57 different brands (54 global) of nine different companies had declared their PFAS phase out in cosmetic products. PFAS phase out declaration of companies/brands might indicate that at least some have already actively found new formulations without PFAS that still work for the functionality of their products.

All the above indicates that PFASs can be replaced by other ingredients and do not have critical functions in cosmetic products.

Since the share of PFAS containing cosmetic products is low (less than 10 percent) in all the 108 cosmetic product subcategories included in the CosmEthics database, the Dossier Submitters assume that there are economically feasible alternatives available for all uses of PFAS in cosmetic products.

The Dossier Submitters conclude that the evidence is sufficiently strong that technically and economically feasible alternatives are available for the quantities required for use in cosmetic products and that the substitution potential is high.

E.2.6.2.2. Human health and environmental hazards

A few specific alternatives to PFAS in cosmetics have been identified (see Table E.70).

Table E.70. Examples of non-PFAS used in cosmetics.

Substance	CAS number	EC number	Sub-category use	Reference
Synthetic waxes (e.g. magnesium stearate)	91031-63-9	292-967-2	For pressed powders (PTFE)	https://echa.europa.eu/substance-information/-/substanceinfo/100.084.484
(Perfluorononyl dimethicone) silicones	259725-95-6		For lip pencils	(EPA-DK, 2018)
Fats			For lip pencils	
Synthetic waxes (e.g. sodium myristate)	822-12-8	212-487-9	For pressed powders (PTFE)	https://echa.europa.eu/substance-information/-/substanceinfo/100.011.352

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log Kow) and bioconcentration factor (BCF) was assessed. Additionally, it was assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHAs dissemination site.

In relation to cosmetics, the list of alternatives contained 2 unique CAS numbers. Both substances were not classified. No data on PBT/vPvB properties were found.

One substance without CAS number was listed. For this substance, no information on classification or PBT and vPvB assessments were available. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses

assessed in this dossier.

E.2.6.3. Environmental impacts

The analysis of environmental impacts of restriction options adopted on PFAS use in cosmetics is conducted for restriction option RO1, i.e. a complete ban of all PFAS uses in this sector. Since no derogations are proposed, an analysis of further restriction options is redundant.

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 is expected to be implemented in 2027. Environmental impacts of RO1 are expressed in relation to the baseline scenario discussed in section E.2.6.1. All emission estimates represent mean values. Table E.71 shows emissions and the expected emission reduction for time paths of 30 and 45 years (starting in 2025).

Table E.71. Total mean emissions and emission reduction of RO1 (cosmetics sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	995	---	---
RO1	64	931	94
2025-2070			
Baseline	1 467	---	---
RO1	64	1 412	96

As illustrated in Table E.71, a ban on PFAS use in cosmetics leads to a mean emission reduction of at least 94% compared to the baseline. Figure E.9 shows the time path of mean emissions for the baseline and for RO1. Under RO1, emissions are expected fully cease after the transition period of 18 months.

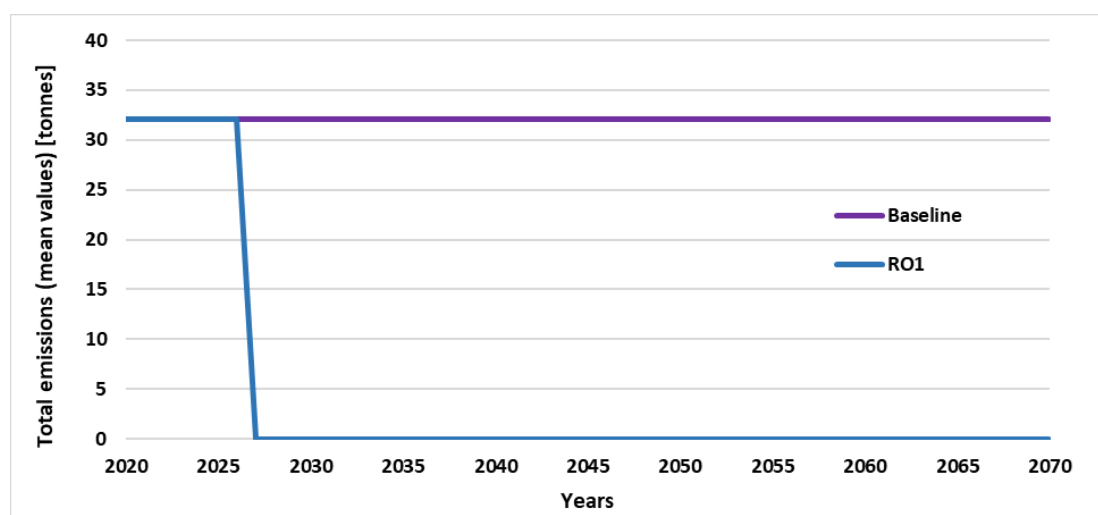


Figure E.9. Time path of mean emissions under the baseline scenario and RO1 (cosmetics sector, in tonnes).

E.2.6.4. Economic and other impacts

E.2.6.4.1. Market overview

In 2019, the EEA market for cosmetics had a revenue at retail sales prices of about €67 billion. The market shares and EEA market value per cosmetic product category is presented in Table E.72.

Table E.72. EEA cosmetic products market 2019, Retail Sales Prices (RSP including VAT) and market share by product category (Cosmetics Europe, 2020).

	Product category	Percent (%)	Retail Sales Price (bn Euro)
Market share 2019 by product category	Skin Care	27.1	18.22
	Toiletries	24.8	16.67
	Hair Care	18.7	12.57
	Perfumes and Fragrances	15.4	10.35
	Decorative Cosmetics	14.0	9.41
Total EEA market*	all product categories	100.0	67.22

*EU27 and Norway (EEA without Lichtenstein and Iceland)

There was no growth in market value in real terms in three-year period ending in 2019. There are some regional differences, with growth in market value in some Eastern European countries and declining market value in some Western European countries. The Dossier Submitters assume that this trend will continue, at least in the short term, and that there will be no growth in real terms in the next few years.

The market for the manufacture of cosmetic products is a high margin business. According to Eurostat the value added at factor costs is around 30% of production value⁷⁷.

The European Commission impact assessment on simplification of the Cosmetics Directive in 2008 estimated that there were 300 000 cosmetic product formulations on the EEA market (EC, 2008). This estimate has been updated for the purposes of this assessment based on information from Cosmetics Europe⁷⁸ and results in an estimate of 520 000 formulations⁷⁹. Only a small share of these formulations contains PFAS. The share of PFAS containing products, i.e. the percentage of total cosmetic products that contain PFAS in the CosmEthics database was 1.4% (extracted in August 2020)⁸⁰.

According to Eurostat there are around 10 000 enterprises involved in the manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations⁸¹. Cosmetics Europe states that there are 7 000 SMEs involved in manufacturing of cosmetic products⁷⁸. The Dossier Submitters have no information on the number of companies that currently have cosmetic products containing PFAS. However, as indicated above, PFAS is present in a fraction of the cosmetic products on the market, and it is therefore likely that only a limited share of all the companies active in the manufacture of cosmetic products have

⁷⁷ The production value and value added at factor cost for 'Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations' (C.20.4 in NACE Rev. 2) were €58 billion and €17 billion, respectively, in 2017 (the latest year with non-confidential data available, at the time of writing). Eurostat, Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) (sbs_na_ind_r2), extracted 2022-06-26.

⁷⁸ <https://cosmeticseurope.eu/cosmetics-industry/>, date of access: 2023-01-13.

⁷⁹ Assuming 100 000 formulations from 'larger companies', 60 formulations per 'SME' and 7000 'SMEs'.

⁸⁰ This is a slight overestimate, since it also includes products containing the non-PFAS F-gas HFC-152a.

⁸¹ C.20.4 in NACE Rev. 2. Eurostat, Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) (sbs_na_ind_r2), extracted 2022-06-29.

products that include PFAS.

E.2.6.4.2. Impacts on users of cosmetic products

Consumer costs associated with performance loss

In the alternatives section above, the Dossier Submitters concluded that PFASs can be replaced by other ingredients and do not have critical functions in cosmetic products. Substitution away from PFAS could still – in theory – lead to some loss product performance, even if this performance loss would not be critical. The Dossier Submitters have no information available indicating that any such losses will occur as a result of a restriction of PFAS in cosmetic products, and therefore assumes that the associated consumer losses are non-existent or negligible.

E.2.6.4.3. Impacts on producers of cosmetic products

Substance substitution costs

Substitution costs have not been quantified in this study. The Dossier Submitters have no information that indicates that these costs would be a barrier to implementation of the proposed restriction. The Dossier Submitters assume that these costs are negligible. The assumption is primarily based on the information that the share of PFAS containing cosmetic products is very low (less than 10%) in all the 108 cosmetic product subcategories included in the CosmEthics database, which indicates that there are economically feasible alternatives available for all uses of PFAS in cosmetics.

Product reformulation costs

The proposed restriction prevents the use of PFAS in cosmetic products. Companies producing PFAS containing cosmetics will have to reformulate their products to remove PFAS if they want to continue placing them on the market. The key assumptions for reformulation costs are described below. The method and assumptions for the estimation largely follows the approach taken for the D4, D5 and D6 restriction proposal (ECHA, 2019)⁸², which has already been considered and agreed by SEAC.

Total number of cosmetic formulations on the EEA market

The European Commission impact assessment on simplification of the Cosmetics Directive in estimated that there were 300 000 cosmetic product formulations on the EEA market in 2008 (EC, 2008). This estimate has been updated for the purposes of this assessment based on information from Cosmetics Europe⁷⁸ and results in an estimate of 520 000 formulations, of which 100 000 from large companies and 420 000 from small and medium sized enterprises (SMEs)⁸³.

Number of cosmetic formulations on the EEA market containing PFAS

For this report, we applied information from several databases or platforms, of which three are European cosmetic databases based on consumer data collected via smartphone applications (apps), i.e. CosmEthics (Finish), Kemiluppen (Danish), ToxFox (German). With these apps, consumers scan cosmetic product barcodes and receive information on ingredients and their potential hazards to make conscious purchase choices or submit new products and product information to the databases. Of these databases, the Dossier Submitters consider CosmEthics to be the one most representative of the EEA market, given

⁸² Also, the approach taken for the D4, D5 and D6 proposal closely followed the approach for the preceding D4 and D5 restriction proposal.

⁸³ Assuming 60 formulations per 'SME' and 7000 'SMEs'.

the wide geographical spread of their data and the large number of products included.

The market share of PFAS containing products, i.e. the percentage of total cosmetic products that contain PFAS in the CosmEthics database was 1.4% (extracted in August 2020)⁸⁴.

The Dossier Submitters note that a substantial share of the PFAS-containing products in the three cosmetic product databases consulted for this study contain PFASs that are or are about to be restricted⁸⁵. In the CosmEthics database this share was 33% (550 out of 1 658 products with PFAS)⁸⁶. These cosmetic products need to be reformulated in the baseline scenario, i.e. even in the absence of the restriction proposed in this report.

The number of cosmetic formulations on the EEA market containing PFAS by the time the restriction will be implemented is estimated to be 4 878 ($520\,000 \times 1.4\% \times (100-33\%)$), of which 938 are in large companies and 3 940 in SMEs.

Number of reformulations expected due to a restriction of PFAS in cosmetics

The Dossier Submitters assume that 5% of the relevant products are reformulated.

The assumption follows on the restriction proposal for D4, D5 and D6 which argued that for subcategories where products containing the substances proposed to be restricted represent less than 30% of the market, the alternatives are expected to take over their market share and very few of these products are expected to be reformulated (assumed 5%).

The reasoning behind this assumption is that the lower the proportion of products that contain the substances to be restricted within a subcategory, the lower the proportion of products within a subcategory that will actually be reformulated in the event of a restriction. If there are many products within a category that do not contain PFAS then it is likely that these already offer comparable product performance to products that contain PFAS. In this scenario companies (particularly large ones, which are also likely to produce alternative formulations within the same category) will accept that customers will switch to an existing alternative product rather than invest in reformulation.

The Dossier Submitters note that the assumption that 5% of the PFAS-containing products will be reformulated could be considered an overestimation, since the assumption in the restriction proposal for D4, D5 and D6 was based on shares below 30% while the share of formulations with PFAS is substantially lower than that for all subcategories of cosmetics in the CosmEthics database.

The number of reformulations expected as a result of this restriction proposal are ($5\% \times 4\,878 =$) 244, of which 47 belong to large companies and 197 to SMEs.

The expected number of reformulations per cosmetic product category is presented in Table E.73.

⁸⁴ This estimate includes cosmetic products containing the non-PFAS F-gas HFC-152a, which implies that it is a slight overestimation. The calculations of the number of reformulations required and, consequentially, the expected reformulated costs, does not take this into account and can therefore also be considered to be slightly overestimated.

⁸⁵ Primarily C9-15 fluoroalcohol phosphate, Perfluorooctyl triethoxysilane and Perfluorononyl dimethicone.

⁸⁶ This does not consider the pending restriction on intended use of microplastics. PTFE is the most common PFAS in all three of the cosmetic product databases consulted. In the CosmEthics database PTFE was present in 33 % of the products. If PTFE is in both particulate and solid form (<5 µmm particle size) it is covered by the proposed microplastics restriction. This includes if it is present as a coating around another 'inorganic material'. Liquid particles (colloids) would be excluded.

Table E.73. Summary of estimated number of formulations containing PFAS and expected number of reformulations due to the proposed restriction, per cosmetic product category

Product category	Estimated number of formulations containing PFAS	Expected number of reformulations due to restriction
Decorative	3 297	165
Hair care	430	21
Perfumes & Fragrances	10	1
Skin Care	959	48
Toiletries	181	9
Total	4 878	244

Number of reformulations per year

The assumed share of formulations per year over the assessment period 2025-2055 is presented in Table E.74.

Table E.74. Assumed share of reformulations per year in the baseline scenario and in the restriction scenario.

Year	Baseline	Restriction
2025	5%	67%
2026	5%	33%
2027-2044	5%	0%
2045	5%	67%
2046	5%	33%
2047-2055	5%	0%

As in the D4, D5, D6 proposal the Dossier Submitters assume that, in the baseline scenario, 5% of the cosmetic products undergo a major reformulation every year.

The implication of the proposed restriction is that the 244 expected reformulations instead will need to occur during the 18-month transition period. The expected year of the adoption of the restriction proposal is 2025. The Dossier Submitters assume that two thirds of the reformulations take place in 2025 and the remaining third in 2026. These formulations are assumed to require a new round reformulation after 20 years, i.e. two thirds in 2045 and one third in 2046.

Cost per reformulation

In the D4, D5, D6 restriction proposal the cost (in 2017) per major reformulation done by large companies in the cosmetics industry was assumed to be €365 000, while a major reformulation by an SME was assumed to cost €42 000. Adjusting these costs for inflation to 2021 values implies that a major reformulation costs €391 000 for large companies and €45 000 for SMEs.

The Dossier Submitters assume that all reformulation required due to this restriction proposal can be considered as major reformulations. The Dossier Submitters note that this could imply an overestimation of the true reformulation costs since all expected reformulations might not be major.

Total net product reformulation costs

Based on the assumptions described above, the proposed restriction leads to major

reformulations of 244 cosmetic products, of which 47 belong to large companies and 197 to SMEs. These reformulations are expected to cost (undiscounted) €27.2 million (of which €18.4 million affect large companies and €8.9 million SMEs) in 2025 and 2026. Over the assessment period of 2025-2055 these products are expected to go through another round of major reformulations in 2045 and 2046. The present value (in 2023, 3% discount rate) of the costs of these two rounds of reformulations is estimated at €39.5 million.

In the baseline scenario, 5% of these products are assumed to go through a major reformulation per year. The present value (in 2023, 3% discount rate) of these reformulation costs over the assessment period of 2025-2055 is estimated to be €26.4 million.

Consequently, the present value of the net reformulation costs due to the proposed restriction is estimated to be €13.1 million. The costs per cosmetic product category is presented in Table E.75.

Table E.75. Estimated net reformulation costs due to restriction over the period 2025-2055 (million €, present value 2023, 3% discount rate).

Product category	Reformulation costs in baseline scenario (million €, 2023)	Reformulation costs in restriction scenario (million €, 2023)	Net reformulation costs due to restriction (million €, 2023)
Decorative	17.9	26.7	8.8
Hair care	2.3	3.5	1.2
Perfumes & Fragrances	0.1	0.1	0.0
Skin Care	5.2	7.8	2.6
Toiletries	1.0	1.5	0.5
Total	26.4	39.5	13.1

Over the extended assessment period of 2025-2070, the present value of the net reformulation costs is estimated to be €14.5 million.

The Dossier Submitters note that the estimated cost assumes that it is feasible to complete all the required reformulations in 18 months. One argument for the feasibility of this is that the R&D resources required for the product reformulations due to the proposed restriction is a small fraction of the annual R&D budget of the cosmetics industry. Cosmetics Europe assumes that the total expenditure on R&D in Europe was approximately €2.35 billion in 2017⁷⁸.

Since the profit margins in the market for manufacture of cosmetic products are relatively high, the Dossier Submitters assume that the product reformulation costs primarily will be borne by the cosmetics producers in the form of lower producer surplus.

E.2.6.5. Summary of cost and benefit assessment

Table E.76 summarises the outcomes of the assessment of costs and benefits for cosmetic products.

Table E.76. Cosmetics - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives are available. No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. As a result, the evidence is sufficiently strong that the substitution potential is high.	Emissions of PFAS to the environment is estimated to be reduced by 931 t (94% compared to the baseline, 30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Net product reformulation costs of €13.1 million over the time period 2025-2055. Over the extended assessment period 2025-2070 the net reformulation costs are estimated to be €14.5 million. Substance substitution costs have not been quantified, but the Dossier Submitters have no information that indicates that these costs would be a barrier to implementation of the proposed restriction. The Dossier Submitters assume that these costs are negligible. Substitution away from PFAS could – in theory – lead to some loss product performance. The Dossier Submitters have no information available indicating that any such losses will occur as a result of a ban, and therefore assume that the associated consumer losses are non-existent or negligible.	Assuming that all other costs than those associated with product reformulation are negligible, the cost per emission reduction is approximately 14 000 €/t over the period 2025-2055. Over the extended assessment period of 2025-2070 the estimated cost per expected emission reduction is 10 300 €/t.
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion	A full ban of PFASs in cosmetics with a transition period of 18 months is proposed.				

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

The net reformulation costs over the assessment period 2025-2055 is estimated at €13.1 million. Other costs are assumed to be negligible. The expected emission reduction over the assessment period is 931 t. Consequently, the cost per emission reduction is approximately 14 000 €/t. Over the extended assessment period of 2025- 2070 the estimated cost per expected emission reduction is 10 300 €/t. These cost-effectiveness estimates are close to the lower end of equivalent estimates of other recent REACH restrictions (Table E.77). Therefore, a full ban on the use of PFAS in cosmetics can be considered cost-effective and proportionate.

Table E.77. Cost-effectiveness of recent REACH restrictions.

Restriction under REACH	€/kg, central value
Lead in shot in wetlands	9
D4, D5 in wash-off cosmetics	415
DecaBDE	464
Phenylmercury compounds	649
PFOA-related substances	734
PFOA	1 649

The annual retail value of the cosmetics sector is €67 billion (see E.2.6.4.1). The estimated costs from a full ban on PFAS is less than 1/10 000 of the retail value, which implies that a ban is affordable.

E.2.7. Ski wax

E.2.7.1. Baseline

The forecasted market growth of ski wax in general indicates growth in the coming years due to the expected increase of the number of skiers and snowboarders, and of the expected increasing number of ski resorts. In contrast, based on existing market data, a negative real growth rate of -8%/y until 2030, and of -1%/y until 2040 was applied for assessing the time path of PFAS use (tonnage) and emissions. After 2040, the market for PFAS containing ski waxes is assumed not to decline any further. The start year of the projection is 2020 (Table E.78).

Table E.78. Projected yearly PFAS use and emissions in the ski wax sector of the EEA between 2020 and 2070 in tonnes (mean values based market data).

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	1.64	1.08	0.71	0.7	0.64	0.64	0.64	0.64	0.64
PFAS emissions	0.95	0.62	0.41	0.39	0.37	0.37	0.37	0.37	0.37

Source: Own calculations based on market data provided by NEA (2021b) assuming a PFAS content of 7.6% in ski wax products.

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage).

PFAS emissions arising from ski wax use consist of polymeric and non-polymeric PFAS. Due to the shrinking of the market for PFAS containing ski wax, both PFAS use, and emissions are expected to decline in the coming years. However, without a restriction, emissions may stabilize at a constant level, and being a source of on-going PFAS release to the environment (see also Figure E.10).

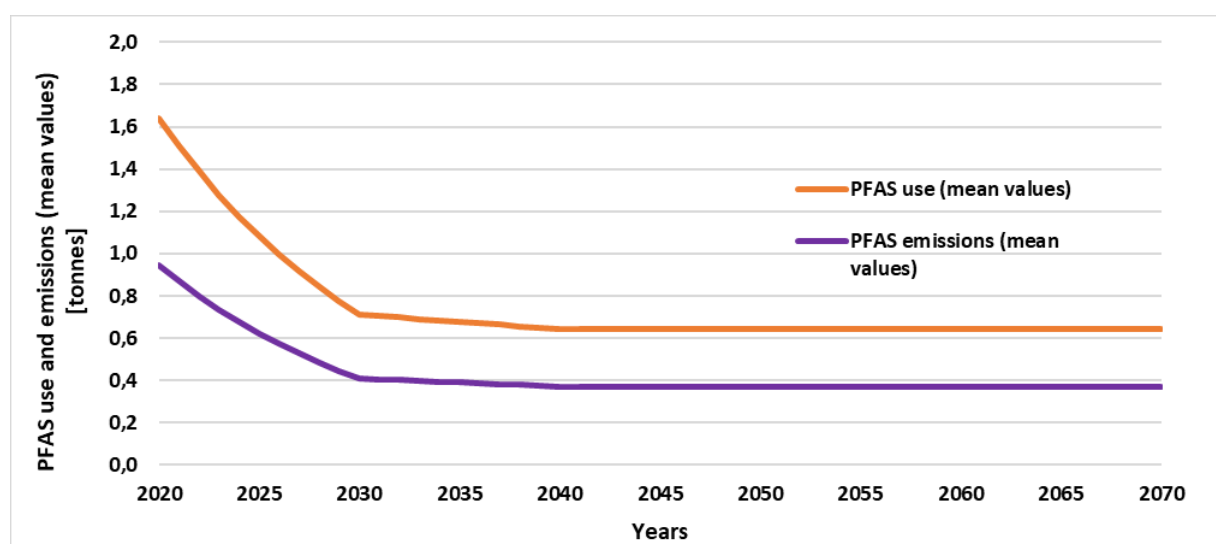


Figure E.10. Expected PFAS use and emissions in EEA under the baseline in the ski wax sector (mean values) [tonnes].

E.2.7.2. Alternatives

E.2.7.2.1. Technical feasibility

Due to increasing concern and publicity regarding the potential human health and

environmental effects caused using PFAS in ski wax treatments, there is a concerted move within this sector towards phasing out the use of PFAS and moving towards safer alternatives. Most users of ski waxes already use fluorine-free ski waxes, in particular amateur skiers and to some degree athletes during training. However, there is a segment of active amateurs training to and participating in non-FIS events where fluorine waxes have been frequently used. It is estimated that fluorine-free ski waxes account for 70% of the market, the remaining 30% is divided between products that are completely and partially fluorinated.

The following alternatives have been identified:

- **Fluorine-free ski waxes** have always been in use and widely commercially available⁸⁷. A number of companies⁸⁸ have developed alternative fluorine-free ski wax products. In almost all cases a mixture of substances is used in various percentage combinations for each of the fluorine-free alternatives to attain the necessary functions of the wax. The available alternatives are mainly based on hydrocarbons and paraffins, where paraffin waxes make up the majority. Siloxanes are another option, but they are subject to environmental concerns. New nanoparticles are also being developed as alternatives (Table E.79). A non-exhaustive list of fluorine free ski waxes is included in Appendix A.3.8.
- **Alterations to the ski itself** can also be used to improve the performance of the ski and therefore “replace” some of the functionality of the wax. These include:
 - Modifying the microstructure of the ski base⁸⁹. The thin layer of water that forms between the ski base and the snow must be monomolecular, as too much water would cause too much friction. Researchers are currently looking for an optimal microstructure of the ski that helps limit the amount of water under the ski.
 - Fluorinated ski base⁸⁹. There are already ski bases which include side chain fluorinated polymers. It is important to note that the effect of having a thin layer of PFAS-based wax on the ski is bigger than having it in the plastic base of the ski⁹⁰.
 - Improve the performance of the polyethylene of the ski⁹¹. Research is ongoing through a collaboration between polyethylene producers.
 - Heating the base to obtain a better glide which requires energy⁸⁷.
 - Methods to minimise friction by controlling the vibrations of the ski are also being researched. It is estimated that 5-10 years or longer will be required for such products to be developed and available⁸⁷.

Table E.79 provides an overview of the technical feasibility (i.e., ability to provide the required functionality) and economic feasibility (e.g. unit and operational costs associated with its use) of the possible alternatives compared with the PFAS-based waxes.

Table E.79. Non-fluorinated ski wax alternatives. Broad assessment of technical and economic feasibility.

Product type	Hydrocarbon and paraffin waxes
Manufacturer	Multiple – including Swix, DPS, Mountain Flow, Nordic Waxes, Holmenkol, Green Ice Wax, Purl, Wend, Dominator, Start, Maplus, Toko, Rode, Rex, Vauhti, Star, Fast Wax and Ulla.

⁸⁷ Interview with Swix.

⁸⁸ Manufacturers that offer fluorine-free products include Swix, DPS, Mountain Flow, Nordic Waxes, Holmenkol, Green Ice Wax, Purl, Wend, Dominator, Start, Maplus, Toko, Rode, Rex, Vauhti, Star, Fast Wax and Ulla.

⁸⁹ Interview with NILU.

⁹⁰ Interview with FIS.

⁹¹ Interview with Rodewax.

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Product type		Hydrocarbon and paraffin waxes
Chemical composition		Substances listed in safety data sheets: Hydrocarbon and paraffin waxes
Technical feasibility	Application areas (as specified in technical specification)	Multiple ski waxes are available for all the different application types and temperature/weather conditions
	Compliance with international performance standards	N/A
	Examples of use experience and performance compared to PFAS-containing waxes	The key property that PFASs provide in this application is a high-water repellence (hydrophobicity) thus allowing a suitably low surface tension for the skis on snow. The relative performance (speed) of the alternatives is slightly lower especially in weather conditions with high temperatures and humidity. It has been shown that the use of high fluorinated waxes can result, on average, in a 4% increase in performance of the skis (Breitschädel et al., 2014).
	Critical uses/applications where product do not meet (fully or partially) the required performance standard and why	None
	Need for changes in equipment	No change necessary. Same equipment can be used in manufacture of waxes and application to the skis
Economic feasibility:	Unit price	Often less expensive to buy than PFAS waxes
	Unit price as compared with PFAS-containing wax for same application	Often less expensive to buy than PFAS waxes
	Relative volume required to achieve comparable/best possible performance	Depends on product type and application method but similar to PFAS waxes. For hot wax – 10-15 g per set. For liquid wax – 0.5 g per set
	Storage, shelf-life	~3 years
	Frequency of wax replacement	No different to PFAS waxes. Depends on the amount of skiing performed by the user.
Availability:	Volume manufactured, sold and used in the EU	Data on volume considered confidential by manufacturers. No issues with supply identified
	Production capacity in the EU	No data but no issues with supply identified
Risks:	CMR properties	Substances not classified with CMR properties
	Other potential human health concern	No data
	PBT of vPvB properties	Substances in the product do not meet the PBT/vPvB

Product type		Hydrocarbon and paraffin waxes
		criteria
	Other environmental risk concern	No data
	Conclusion on risks	As the constituents are not classified with CMR properties and do not meet the PBT/vPvB criteria, the overall risks with hydrocarbon and paraffin waxes are considered lower than the risks of PFAS-based products.

The Dossier Submitters conclude that the evidence is sufficiently strong that technically and economically feasible alternatives are available for the quantities required for use in ski wax and that the substitution potential is high.

E.2.7.2.2. Human health and environmental hazards

For the alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log Kow) and bioconcentration factor (BCF) was assessed.

No information was available on the classification of these substance or whether or not these substances fulfil the PBT or vPvB criteria. No other concerns were mentioned. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.7.3. Environmental impacts

The analysis of environmental impacts of restriction options adopted on PFAS use in ski wax is conducted for restriction option RO1, i.e. a complete ban of all PFAS uses in this sector. Since no derogations are proposed, an analysis of further restriction options is redundant.

For calculating the expected emission reduction the assumed entry into force year of the restriction is 2025. Assuming in this case a transition period of 18 months, RO1 is expected to be implemented in 2025. Environmental impacts of RO1 are expressed in relation to the baseline scenario discussed in section E.2.7.1. Emission estimates represent mean values derived from available market data. Table E.80 shows emissions and the expected emission reduction for time paths of 30 years (starting in 2025).

Table E.80. Total mean emissions and emission reduction of RO1 (ski wax sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	13	---	---
RO1 (18 months transition period)	1,2	11.8	91

As illustrated in Table E.80, a ban on PFAS use in ski wax leads to an emission reduction of 90%. Figure E.11, showing the time path of emissions for the baseline scenario and for RO1, illustrates that emissions from PFAS use in ski wax are expected to decline due to the negative market growth rate for PFAS in this sector, which, in turn, results from an increasing substitution of PFAS in ski waxes. Considering that the available evidence on (avoided)

emissions in this sector can be considered sufficiently strong it can be concluded that RO1 will lead to a full cessation of emissions by the end of 2027.

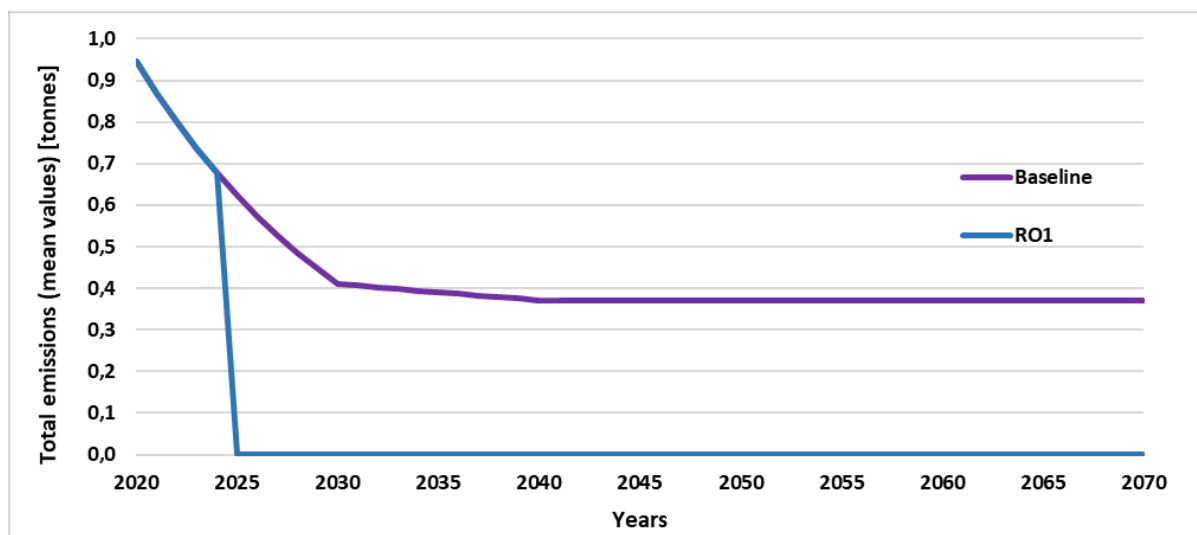


Figure E.11. Time path of mean emissions under the baseline and RO1 (ski wax sector, in tonnes).

E.2.7.4. Economic and other impacts

E.2.7.4.1. Market overview

Information obtained from stakeholders suggests that the total ski wax market is split approximately 50/50 between consumer and professional sales. Fluorinated waxes tend to be used primarily during competitions, and first of all by elite athletes, who may also use fluorine free waxes during training. However, there is also a segment of active amateurs training to and participating in non-FIS events where fluorine waxes have been frequently used in the past.

Lists of PFAS-based ski waxes and fluorine free alternatives and their prices are included in Appendix A.3.8. The price data is based on reviews of literature and retailers' websites as well as information submitted in the CfE. Descriptive price data of these articles are presented in Table E.81 below. The price of PFAS-based ski waxes is in most cases higher than prices of fluorine-free alternatives.

Table E.81. Price ranges and averages of ski waxes reviewed in 2020.

	Average	Minimum	Maximum
PFAS-based ski waxes	2.35 €/g	0.23 €/g	6.33 €/g
Fluorine-free alternatives	0.23 €/g	0.07 €/g	1.13 €/g

Note: The average values are simply an average across all of the listed products; the values are not weighted according to market share (due to lack of data).

Based on the average prices (see Table E.81) for PFAS-based and fluorine-free alternatives respectively, and the tonnage estimates provided in A.3.8.2., the market value of ski wax used in the EEA is approximately €62 million per year (Table E.82). Note that this is an uncertain estimate since the prices vary considerably, and the averages used are not weighted

according to market share⁹².

Table E.82. Estimated market value of ski wax used in the EEA.

	Annual tonnage	Average retail price (€/g)	Market value (m€/y)
PFAS products	22	2.35	51
Non-PFAS products	50	0.23	12
Total	72		62

E.2.7.4.2. Impacts on users of ski wax

As mentioned above, stakeholder interviews indicate that PFAS-based ski waxes are mainly used for competitions, while recreational skiers and athletes during training already mostly use fluorine-free alternatives.

A phase out of PFAS-based waxes in the top tier of competitive skiing is ongoing. In 2019 the International Ski Federation (FIS) set to introduce a full ban on all PFAS in waxes in all competitive ski disciplines from their 2020-2021 season, a move that follows national-level bans imposed, for example by the Norwegian Ski Association in 2017. However, enforcement of the FIS ban has been postponed until they have successfully developed a Fluorine Tracker, an instrument that would instantly detect the presence of PFAS on the ski, that would make the competitions fair. This ongoing phase-out in the top tier of competitive skiing suggests that a substantial share of the use of PFAS-based ski waxes will likely be eliminated regardless of the proposed restriction. A REACH restriction on the manufacture and placing on the market of PFAS-based ski wax would also increase the chances that such ski wax is phased out completely and not used illegally in competitions. It is, however, important to note that there are non-FIS events with thousands of participants where the FIS-ban would not apply (e.g. Vasaloppet in Sweden).

In stakeholder interviews, Rodewax and NILU suggested that the cost of alternatives is lower than PFAS-based waxes, while Swix suggested that the prices are similar. It was also suggested by Swix that the cost of ski waxes has never been closely linked to cost of raw materials, but rather wax performance, as there are many options available at a wide range of prices, despite similar raw materials. To further elaborate on the potential magnitude of the price difference a review of prices from manufacturers websites for a wide range of ski waxes has been undertaken. The ranges of prices per gram of PFAS-based ski waxes and fluorine-free alternatives are very wide and overlap, but the average price of the fluorine-free ski waxes in this review was significantly lower (by a factor of 10) than the average price of the PFAS-based ski waxes (see Table E.81). This clearly suggests that fluorine-free alternatives are typically (but not necessarily always) cheaper than PFAS-based ski waxes, which is consistent with the suggestions from interviewed ski wax manufacturers. A phase-out of PFAS-based ski waxes would therefore imply lower consumer expenditure on ski wax.

The alternatives can provide the required functionality, but in certain situations the use of alternatives can result in slightly lower performance. The importance of such functionality loss depends among other things on the type of ski sport and on the snow condition. According to stakeholder information, the loss could be up to 4% reduction of speed/glide. The Dossier Submitters make the following assumptions on the impacts of this reduction in performance

⁹² The Dossier Submitters note that a market research report by Industry Growth Insights estimates that the global market for ski waxes is substantially larger, around USD 800 million annually and growing at 4.5%/y. The Dossier Submitters have not assessed the credibility of this estimate as to whether it covers the same range of articles, or whether it also includes the value of other associated articles and services (Industry Growth Insights, 2021).

on consumer surplus:

- In FIS-based competitive skiing, the Dossier Submitters assume that creating a level playing field and equal competition is most important. The impact on consumer surplus would therefore be negligible as long as all competitors are treated equally.
- For ordinary amateurs, the Dossier Submitters assume that the difference in performance will barely be noticeable, thus they will probably not experience a loss of consumer surplus.
- For the subset of active amateurs participating in non-FIS events and using PFAS-based waxes, the loss in performance can be assumed to have a negative impact on consumer surplus. The extent of this loss is not obvious. Some active amateurs have a revealed preference for PFAS based ski waxes, even though it comes at an additional cost. This implies that these users would suffer a net loss in consumer surplus if PFAS-based waxes were no longer available. However, it can also be argued that this is primarily a case of conspicuous consumption or a case of buying the highest performing product available even if the actual relative benefits of using the product are small compared to the alternatives, and that the consumer losses resulting from a restriction are negligible also for this group of users.

Overall, the Dossier Submitters assume that the net loss in consumer surplus due to a ban on PFAS-based ski waxes is negligible.

E.2.7.4.3. Exposure to PFAS

A restriction of PFAS in ski wax would eliminate the direct human exposure, and the related health risks, associated with its use.

Direct human exposure to PFAS can occur when applying ski wax treatments, as the application often includes heating, melting, brushing and sanding of mixtures containing PFAS close to the airways, meaning users can be exposed to high concentrations of PFAS. PFAS-based ski wax may contain up to 100% PFAS, although the concentrations depend on the formulation. Personal protective equipment is recommended, but not always used, especially among amateur skiers.

No specific information was provided regarding PFAS exposure during production of ski waxes, but producers suggested that the main potential for exposure is during application of the wax to the ski.

Prior to application, the sole of the skis is usually cleaned with a liquid non-fluorinated base cleaner and a cloth. The traditional high-end ski wax is then placed on the sole of the ski as a powder, melted with an iron and distributed evenly on the ski sole. Upon cooling the wax becomes solid again and much of the wax is removed from the ski base by scraping, and brushing, leaving a thin layer of wax on the ski sole. This has led to several concerns:

- The range between melting point and boiling point of the compound is very narrow, so fumes can be released even when the boiling point is not reached. As a result PFAS has been found in the blood of people applying ski wax. It should be noted however that emissions of fumes from the application of fluorine-free alternatives may also have health concerns.
- A proportion of the wax applied will fall to the floor.
- Scraping and brushing can lead to formation of dust that could be inhaled.
- Professional ski technicians use protection equipment to shield themselves from potential exposure, including gas masks, fume hoods, gloves and protective clothing. However, this is not as common for non-professionals.
- Often, especially with non-professionals, the contained wax is disposed of in general waste or even in the snow/outside, but some ski wax producers and EEA countries (e.g. Norway) have recommendations in place for waste wax to be disposed of by waste handling companies (e.g. through incineration).

Another formulation of PFAS-containing ski wax is as a liquid with the fluorinated ingredients as a suspension. Applications of these will result in much lower exposure as they do not require melting with an iron or the same level of scraping and brushing. The waste generated is also considerably less. However, the performance of liquid wax during skiing does not match the best powder waxes.

There have been studies which document a direct correlation between years exposed as a ski waxer and concentration of several different perfluoroalkyl carboxylate (PFCA) compounds in blood, with one study showing that Swedish wax technicians' median blood level of PFOA is 112 ng/mL compared to 2.5 ng/mL in the general population (Freberg et al., 2010; Nilsson et al., 2010).

Nowadays, professional ski technicians are usually using proper personal protective equipment. However, amateurs that are using fluorine-based waxes for recreational skiing or for 'hobby competitions' may suffer considerable exposure during application of wax due to insufficient protection against exposure.

The total number of people involved in the waxing of skis with PFAS-based ski waxes is highly uncertain, because at lower or amateur level skiing competitions, skiers will likely manage their equipment themselves (or their parents will, in the case of junior competitors). In some cases, sports shops offer to wax skis, but it is assumed that a minor part of skis is prepared in this way. For higher level competitions, the number of professionals involved in applying PFAS based ski waxes can be estimated, based on interviews with ski wax manufacturers, to be around a few hundreds.

The Dossier Submitters conclude that human exposure to PFAS during application when preparing skis, may be very high, possibly the highest human exposure level that is documented for any consumer use of PFAS.

E.2.7.4.4. Impacts on manufacturers of ski wax

According to interviews with some of the main ski wax producers, around 100-200 people are employed by at least 20-25 ski wax producers (many of which are small companies) in the EEA⁹³. This includes the production of both PFAS-based and fluorine-free ski waxes. Fluorine-free ski waxes account for some 70% of the market (by tonnage), the remaining 30% is PFAS-based waxes (see Annex A.3.8.2). Considering that most producers offer both, it is not possible to distinguish workers relating to only PFAS-based ski waxes. Despite the niche nature of this use, stakeholder interviews suggested that some small ski wax manufacturers exist that only offer PFAS-based ski waxes and are likely not yet ready to transition to fluorine-free alternatives. For these manufacturers the impact of a restriction will be considerable and could potentially lead to business closures.

PFAS-based waxes have a substantially higher retail price than the alternative waxes. On average, the prices differ by a factor of 10 (Table E.81). A phase-out of PFAS-based ski waxes would therefore imply lower revenues for manufacturers of ski wax. Input from one major manufacturer (Swix) indicate that the prices of ski waxes are not closely linked to the cost of the raw materials. The producer surplus from sales of PFAS-based ski waxes could therefore be higher than the surplus from sales of alternative waxes and a restriction of PFAS could therefore lead to an overall reduction in producer surplus. To some extent the producers could compensate for this loss by increased sales (and potentially higher margins) of the highest performing alternative waxes. This is dependent on the consumers price elasticity. Considering the large variety in prices, it is likely that a large fraction of consumers, professionals and enthusiastic amateurs, have an inelastic demand, and thus creates room for the producers to have reasonable margins. In conclusion, a ban on PFAS in ski waxes is likely to lead to a reduction in total consumer expenditure on ski waxes and could lead to a

⁹³ Interviews with Rodewax and Swix.

reduction in producer surplus, the extent of the latter is however unclear.

E.2.7.4.5. Costs relating to testing, equipment, occupational safety measures and product development

Most suppliers, professional users (service providers offering ski waxing) and end users (skiers) already offer/use fluorine-free alternatives. Therefore, no additional testing, new equipment or training in occupational safety measures would be required to enable the use of alternatives. Costs to regulators to enforce the restriction on this niche use would likely be small. It is therefore expected that the rest of the supply chain (i.e. distributors and service providers offering waxing of skis) would also simply switch to fluorine-free alternatives.

There is ongoing research and development to further improve the performance of skis without PFAS-based waxes. However, it is not clear that the associated cost could be considered a necessary cost of the proposed restriction, given that most skiers already use fluorine-free alternatives and athletes in competitions would all be subject to the same potential ban on PFAS-based waxes.

Given the potential advantage athletes would have in illegally using PFAS-based waxes, it is necessary to develop a testing methodology to verify the presence of PFAS before the competition, which would come as a development cost. However, testing for ensuring a fair competition is the responsibility of the sports organisations, and development costs would not be a direct cost of a REACH restriction. While waiting for the testing technology, FIS, the main international ski federation, has already decided to ban fluorinated waxes from competitions. For enforcement of the REACH PFAS restriction, authorities may rely on collection on ski wax samples and sending them to an analytical laboratory for the quantification of PFAS.

E.2.7.5. Summary of cost and benefit assessment

Table E.83 summarises the outcomes of the assessment of costs and benefits for ski wax.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Table E.83. Ski wax - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban - 18 month transition period	Not applicable	Sufficiently strong evidence technically and economically feasible alternatives are available. No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. As a result, the evidence is sufficiently strong that the substitution potential is high.	Emissions of PFAS to the environment would be reduced by 11 t over the assessment period 2025-2055. As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	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. Loss in consumer surplus expected to be negligible. No evidence of costs relating to testing, equipment, occupational safety measures and product development available to the Dossier Submitters.	A full ban would eliminate the direct human PFAS exposure and the associated health risks. Human exposure to PFAS during application when preparing skis, may be very high, possibly the highest human exposure level that is documented for any consumer use of PFAS.
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion	A full ban of PFASs in ski wax with an 18 month transition period is proposed.				

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Based on evidence gathered in the CfE, stakeholder interviews and reviews of literature and market data, the Dossier submitters note:

- that human exposure to PFAS during application when preparing skis, may be very high, possibly the highest human exposure level that is documented for any consumer use of PFAS,
- that a phase-out of PFAS-based ski waxes is already on-going,
- that the fluorine-free alternatives generally come at a lower cost than the PFAS-based ski waxes, and
- that any losses of functionality will primarily affect competitive skiing but there would still be a level playing field because all athletes would equally be forced to use fluorine-free alternatives therefore limiting potential consumer surplus losses.

The Dossier Submitters conclude that there is sufficiently strong evidence that a restriction on PFAS in ski waxes is very likely to have negligible socioeconomic costs.

E.2.8. Applications of fluorinated gases

The term fluorinated gases are in this dossier understood to cover any gaseous substance that meets the definition of PFAS according to section 1.1.1. of the main report. It is not limited to those gases legislated under the F-gas Regulation of the EU (517/2014).

A description of the different applications of fluorinated gases may be found in Annex A.3.9.

Industry stakeholders underlined the importance of HFO and fluoroketone (FK) alternatives during the development of this dossier via the CfE and 2nd stakeholder consultation. These substances can substitute the function provided by other fluorinated gases alone or in blends, whilst at the same time having significantly lower global warming potentials (GWP), one of the objectives of the F-Gas Regulation. However, the F-Gas Regulation does not address the problem of persistence.

The use of fluorinated gases in transportation systems for mobile air conditioning (MAC) and refrigeration, and in military applications are addressed separately in Annex E.2.10.

E.2.8.1. Baseline

For specific applications of fluorinated gases, the market is assumed to grow considerably in the coming 30 years. For instance, for commercial refrigeration a yearly real growth rate of 3% is assumed. Furthermore, the EU market for air conditioning has seen strong growth over the last 25 years, originally in the commercial sector but now also in the domestic sector. Demand is forecast to roughly double in Europe in both the residential and commercial sectors over the next 30 years (IEA, 2018). Improved efficiency at data centres has prevented significant growth in cooling demand for the sector. It is, however, unclear for how long efficiency will continue to offset increased internet traffic. Market data for fire suppressing agents (Research and Markets, 2019) suggest a strong growth over the period 2018 to 2025 at a compound annual growth rate of 5.9%, with the fire detection and suppression market valued at USD3.27 billion in 2018. Growth is anticipated to be driven by increased safety measures including tighter building codes. However, these figures reflect growth across the whole market, and are not specific to sectors that use fluorinated gases as opposed to other fire suppressants. 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 start year of the projection (2020), emission estimates during the use phase comprise emissions from manufacture of fluorinated gases, and from gases in technical stocks. Tonnage (use) data and emission for these two applications are also accounted for in the environmental impact assessment of the transportation sector (Table E.84).

Table E.84. Projected yearly PFAS use and emissions in the fluorinated gases sector of the EEA in tonnes (mean values based on market data).

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	542 194	598 626	660 931	729 722	805 672	889 527	982 109	1 197 186	1 459 363
PFAS emissions	41 511	45 841	50 602	55 868	61 683	68 103	75 191	91 658	111 731

¹ Tonnage and emission estimates also include applications of fluorinated gases in mobile air conditioning and in transport refrigeration. The EIA of derogations proposed for these applications are also analysed in the transportation sector.

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage).

Two approaches were considered for either generating or identifying emission estimates:

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

1) REACH Guidance (R.16) default methodology (ECHA, 2016)

2) United Nations (UN) methodology.

The first methodology is that most often used in REACH restrictions that are concerned with PFAS and is set out in ECHA's R.16 Guidance (ECHA, 2016). This allows for the generation of emissions from market quantity data but is generic and applied to any use sector.

The second approach is that used by EU/EEA Governments (EEA, 2022) for the purposes of providing information annually to the United Nations Framework Convention on Climate Change (UNFCCC) according to the methodology and guidance set out by the Intergovernmental Panel on Climate Change (IPCC). The European Environment Agency, together with various EU institutions and the EU Member States, prepares an annual inventory of greenhouse gas emissions, trends and the underpinning drivers in the European Union. The European Environment Agency refers to the inventory as the 'EU Greenhouse Gas (GHG) Inventory' and it is reported to the UNFCCC annually. After detailed consideration, the UN Methodology was chosen because the emissions have already been calculated and these are done so using a well-established and use-specific approach.

The geographical scope of the EU GHG Inventory data for 2018 is EU-28 plus Iceland (IS). Norway (NO) reports separately to the UNFCCC process, so for the purposes of this project the Norwegian data has been added to the EU GHG Inventory data to provide a geographical coverage of EU-28 & IS & NO geographical scope. No data was available for Liechtenstein.

The European Environment Agency also collects and publishes data reported by industry according to the obligations under the F-Gas Regulation. The most recent report referred to in this project, the 'F-Gas Report' (EU, 2020c), provides EU-28 data up to and including 2019 and covers fluorinated gas activity (production, reclamation, imports, exports, destruction and feedstock use), supply of gases (trends in supply) and progress of phasing down the use of HFCs. It is updated annually and is a source of data that industry stakeholders have consistently pointed to as a 'definitive reference' during the 2nd stakeholder consultation for this project. Importantly though, the data presented do not include emissions data but conversely data are included for unsaturated hydro(chloro)fluorocarbons (although aggregated for confidentiality reasons), these are primarily HFOs, because FKs are not required to be reported according to the list of substances in Annex II of the F-Gas Regulation. For these reasons the use of the F-Gas Report data was limited to trend information and information on HFOs for the purposes of the current report.

The use of fluorinated gases, and emissions during the use phase at sector level, are shown in Figure E.12. Considering the assumptions about the expected market growth as discussed above, emissions are expected to increase continuously. The precise amount of this increase is difficult to project with sufficient reliability due to lacking information about the market growth in the different areas of applications of fluorinated gases. Projections of long-term emissions must, therefore, be treated with care. Under current market conditions, emissions of fluorinated gases originate particularly from applications in the HVACR sector (heating, ventilation, air conditioning and refrigeration), in particular from commercial and industrial refrigeration, and from existing technical stocks of stationary air conditioning and heat pumps, see also Annex A).

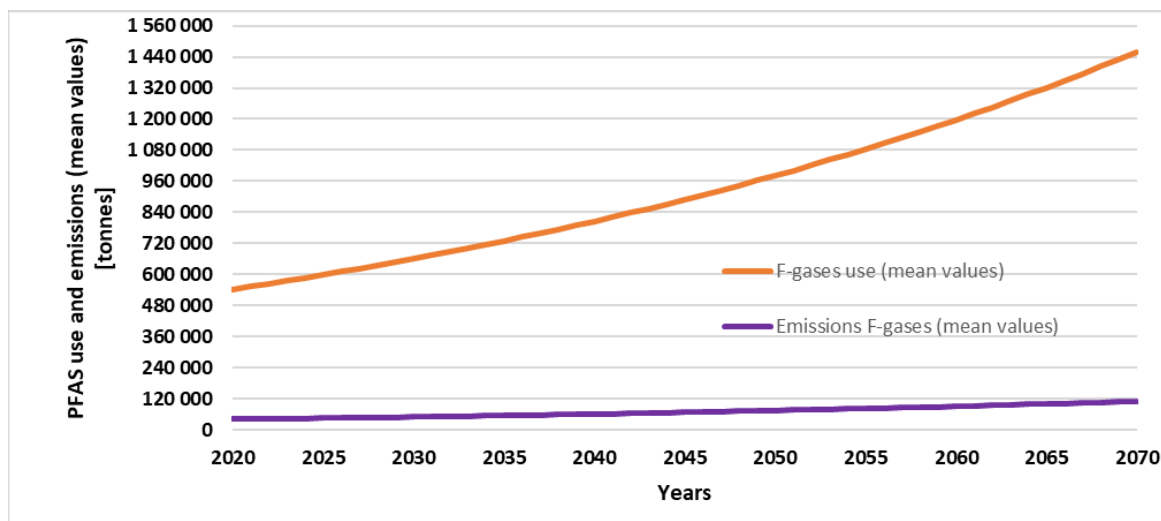


Figure E.12. Expected PFAS use and emissions in EEA under the baseline in the fluorinated gas sector (mean values) [tonnes].

E.2.8.2. Alternatives

E.2.8.2.1. General consideration of the availability of alternatives

Alternatives need to be identified at the specific application level. In some cases more or less the exact same performance may be provided with an alternative non-PFAS substance, or a different technical solution. In other cases a slightly different functionality may be provided, which is still sufficient to cover the needs. It is more about seeing the possibilities rather than the ghosts when selecting the optimal refrigerant for the project or a product. No single fluorinated gas can cover all applications, and the same applies for the different non-PFAS alternatives. Some parts of the market have already switched away from the use of fluorinated gases to alternative substances or solutions. However, in certain specific cases, finding alternatives may be more challenging.

Information gathering via stakeholder input shows that there are often strong opinions with different views on the suitability and availability of non-PFAS alternatives for the current applications of fluorinated gases. Stakeholders often argue either that fluorine-free alternatives are available for essentially every application, or that fluorine-free alternatives are generally unsuitable due to the properties like high flammability (hydrocarbons), toxicity (ammonia) or the requirement for high operating pressures (CO₂). However, in many cases the technical and safety issues may be solved in the design of equipment. In the present assessment the evaluation of availability of alternatives has been performed at the specific subapplication level, while weight has been put on the demonstrated availability of alternative solutions.

The introduction of a certification scheme for personnel and companies that work with HFO and natural refrigerants has been suggested to secure competence to work safely with these substances, in the same way as what applies in the F-gas regulation for technicians handling HFCs. This appears to be an important step forward to reduce emissions during service and secure safe handling.

Under the Montreal Protocol the Technology and Economic Assessment Panel (TEAP) is regularly assessing the availability of alternatives to HFCs in various applications. Their latest working group report (UNEP, 2022) contains valuable, detailed information on the availability of non-HFC alternatives for specific applications divided into the following main uses: foam blowing agents, fire suppressing agents, medical and chemical uses, as well as refrigeration,

air conditioning and heat pumps. However, TEAP primarily considers global warming and ozone depleting potential for the potential alternatives, and not e.g. the degradation to persistent TFA in the atmosphere and the environmental impacts that follow from that. Hence, HFOs are in the report considered viable alternatives to HFCs (which is not in line with the assessment in this dossier).

Some stakeholders have noted that the use of fluorinated gases within military applications, like refrigeration, fire suppression and air conditioning, is important as the different alternatives are not viable options in military applications due to safety considerations. Refrigeration in military 'transport' equipment (ships, submarines) faces several barriers to substitution due to some strong operating and safety conditions: sizing, compactness (and impact on armament equipment), sea motions, shocks, vibrations, noise, closed compartments, pressure conditions, toxicity issues of some natural fluids (NH₃ cannot be used on a Navy ship; CO₂ comes with limits such as toxicity and compactness). However, for many of these applications alternatives are available, just like for the same applications within a civil setting.

Several stakeholders have pointed at HFC-32 (CH₂F₂) as a viable alternative for multiple applications. HFC-32 is an F-gas according to the F-gas regulation, but it is not a PFAS according to the scope definition of this restriction proposal. Its GWP is 675, and as such it has a considerable contribution to climate effects. HFC-32 has an atmospheric lifetime of 5.4 years and forms CO₂ and HF as degradation products.

Importantly, HFO-1234ze has been found to be a highly flammable gas in combustion experiments, and CO₂ and HF together with toxic carbonyl fluoride were identified as combustion products (Schwabedissen et al., 2020). This will need to be taken into consideration when the flammability of hydrocarbon alternatives is evaluated.

Elasto-caloric cooling is a completely different technique to refrigeration that has developed fast over the last years. An elasto-caloric cooling system uses the shape memory effect of certain metals to induce a reversible temperature change through the application of force. In elasto-caloric materials, mechanical pressure causes a crystalline phase transformation, which heats up the material from the initial temperature T₀ to T₀+ΔT. The heat generated is transferred to a heat sink and the temperature of the material drops back to the initial temperature T₀. When the mechanical stress is removed, the material cools to a temperature below the initial level (T₀-ΔT)⁹⁴. Elasto-caloric cooling is considered completely harmless to people and the environment and regarded as one of the most promising alternatives to vapour compression cooling (Kabirifar et al., 2019).

In the following, the availability of alternatives for the different sub-applications of fluorinated gases is examined.

E.2.8.2.2. HVACR applications

Several stakeholders have pointed out that natural refrigerants have always been considered as alternatives to the use of fluorinated gases. They are effective, energy efficient and safe in all segments and sub-sectors of HVACR industries. Natural refrigerants are substances that exist naturally in the environment (hydrocarbons, ammonia, CO₂, air, water etc.), whose properties and drawbacks are clear and well-understood. Given the progress in technology and engineering processes, natural refrigerants are technically feasible in all applications. When higher loads of hydrocarbons are needed in the equipment (up to 1.2 kg), dissipating air flows are required in the premises. Price parity has already been achieved for natural refrigerants in the commercial and industrial sector, and it will be achieved within a decade

⁹⁴ <https://www.ipm.fraunhofer.de/content/dam/ipm/en/PDFs/product-information/TE/KAS/Elastocaloric-Systems-cooling-refrigerant-free.pdf>, date of access: 2023-01-13.

in the heat pumps and air conditioning.

According to one stakeholder research demonstrates that hydrocarbons can be used safely in a much wider range of refrigeration and heat pump applications than what is normally expected today. The thermodynamic properties of hydrocarbons are very good and they often outperform fluorinated gases in terms of energy efficiency. Equipment with very low refrigerant charges of hydrocarbons has been developed by component miniaturization (reducing the refrigerant loading).

For HVACR applications, Hafner and Ciconkowi (2021) investigated the current state and market trends in technologies with natural refrigerants and concluded that all temperature levels and most applications can be cooled by applying natural refrigerants. There is no technical barrier to replace currently used synthetic fluorinated gas refrigerants with natural working fluids. None of the fluorinated gases can go as low in temperature or as high as the natural refrigerants, they only cover the most profitable markets in the middle temperature range. Several stakeholders confirm that natural refrigerants are available for domestic/commercial/industrial applications.

The 2018 UNEP assessment report of the refrigeration, air conditioning and heat pumps technical options committee explores the options for different refrigerants within the different sectors (UNEP, 2019a). The availability of both fluorinated gases and fluorine-free alternatives are assessed.

For refrigerants, the "Pathway to net-zero cooling product list"⁹⁵ provides an overview of the availability of energy efficient and ultra-low GWP (<5) natural refrigerants that are used for various refrigeration purposes as alternatives to fluorinated gases.

The domestic refrigeration sector has moved from near total reliance on fluorinated gases at the time that the Montreal Protocol came into effect to almost total reliance on hydrocarbon alternatives now. There are signs that a similar approach is also being taken in the clothes dryer heat pump market, with many manufacturers opting for hydrocarbon refrigerants in preference to fluorinated gases. However, there is also strong resistance in other areas: the mobile air conditioning market seems particularly averse to a switch to non-PFAS alternatives, citing concerns on the grounds of safety (for hydrocarbons) and cost (for CO₂).

In the EU project Life Front, it was looked at barriers that established regulations and standards impose on the introduction of flammable refrigerants (A3 classified)⁹⁶. The authors concluded that current application of safety standards limits on flammable refrigerants charges are too restrictive for the application of propane (R-290) in most HVACR applications. Furthermore, it was suggested that the safe application of higher charge limits is possible, and that future applications of safety measures will result in charge limits that enable a far greater and wider application of hydrocarbon refrigerants without resulting in a significant risk increase for users.

In certain countries building codes prohibit the use of flammable refrigerants in public buildings (e.g. Italy). This could limit the use of hydrocarbons as non-PFAS alternatives in HVACR applications in these countries. However, a relaxation in the limitations would be in line with the development of equipment over the last years as modern technology offers safer solutions as compared to some years ago.

Water and air are additional non-PFAS alternative refrigerants that are currently being developed for several applications. The energy efficiency of air systems at higher temperatures is quite poor, and the refrigerant is not suitable for all applications. However, water/air are used for certain niche applications, e.g. air in very low temperature rheumatism

⁹⁵ <https://cooltechnologies.org/pathway-to-net-zero/>, date of access: 2023-01-13.

⁹⁶ <http://lifefront.eu/portfolio-posts/impact-standards-hydrocarbon-refrigerants-europe-report-2/>, date of access: 2023-01-13.

chambers.

Domestic refrigeration

Cost effective non-PFAS alternatives are already widely used.

Domestic air conditioning and heat pumps

Hydrocarbon based alternatives are already on the market for smaller systems. Calls for relaxation of the limits on charge size have been made. Specific situations may continue to be more challenging, e.g. use in high rise buildings, where the risks of accidents may be considered to exceed the risks from emissions of fluorinated gases. For domestic and commercial air conditioning and heat pumps, the refrigeration circuit can be put outside. It is claimed that the widespread use of natural refrigerants as an alternative in heat pumps cannot currently replace the use of HFOs for technical reasons due to safety (including flammability) requirements and the desired efficiency requirements.

The availability of natural refrigerants for heat pumps was assessed by Infinitus Energy Solutions and Entropy Cooling Solutions on behalf of the Netherlands Enterprise Agency for the Energy Top Sector⁹⁷. It was concluded that suitable natural refrigerants are available for many heat pump applications. These refrigerants have a low environmental impact and perform comparably to or better than synthetic alternatives, with acceptable and stable costs. The three most common natural refrigerants are hydrocarbons, carbon dioxide and ammonia. Hydrocarbons are particularly suitable for smaller heat pumps, monoblocks and single-split ACs. They are suitable for collective systems (blocks of houses and apartment buildings) and industrial applications, if adequate risk management measures can be put in place. Hydrocarbons are less suitable for larger multi-split and VRF systems due to the high costs and the constraints of the required safety measures. Carbon dioxide is particularly suitable for higher supply temperatures in both small and large heat pumps. Ammonia is mainly suitable for industrial heat pumps. In the future it may be used in high-tech hybrid domestic heat pumps fueled with natural gas. Existing heat pumps generally cannot be converted for use with natural refrigerants.

David et al. (2017) explored the availability of natural refrigerants for use in large-scale electrical heat pumps in district heating. Ammonia was found to be a viable option in large scale systems and is also used already in several cases. However, safety precautions are required as ammonia is moderately flammable and toxic. CO₂ is also a suitable alternative, although high pressures are required, making it less suitable for systems larger than 1–2 MW.

Today HFC-32 (CH₂F₂) is frequently used in stationary airconditioning and chillers, while the heat pump segment is introducing CO₂. It is also already used in split air conditioners in small data centres and in domestic heat pumps. However, one stakeholder claimed that fluorinated gas solutions are unavoidable for domestic air conditioning and for heat pumps with higher heating capacities where more than 5 kg of propane are needed.

One stakeholder indicated that elastocaloric cooling could be commercialised within 5 years for heat pumps and mobile air conditioning.

Industrial heat pumps

Heat pumps will have to produce steam at a temperature of about 160 °C or higher if fossil steam boilers are to be phased out as this is a kind of standard in current steam systems. Even 250 °C is used in some drying processes where dry saturated steam is needed because of its hygroscopicity. No universal non-PFAS refrigerant is suitable for all applications up to about 230 °C. However, the hydrocarbons butane (R600), iso-butane (R600a), pentane

⁹⁷ <http://infinitus-energy.com/>, date of access: 2023-01-11.

(R601) and heptane (R603) are applicable solutions. For temperatures in the range 230 to 250 °C, steam (R718) is an option⁹⁸.

Domestic clothes dryers

Cost effective non-PFAS alternatives are already widely used.

Commercial and industrial refrigeration

There is growing acceptance of the use of alternatives, particularly CO₂ or hydrocarbons, in the commercial sector. However, the sector is still dominated using fluorinated gases, and the assumption that the sector is fully ready to replace them with alternatives may be premature. Further research is being conducted in several areas. In some cases of commercial refrigeration, a secondary/indirect loop (glycol or water) can be used to reduce risk with flammable alternatives – however this will be less energy efficient and more expensive. For commercial refrigeration isobutane and propane is currently only used for very small equipment due to its A3 high flammability, as safety laws say 150 g is the limitation. Alternatively, the safety laws may be relaxed if the technical state allows. For CO₂ high working pressures and poor performance in hot climates makes its uses in small/mid-size commercial chillers/refrigerators less efficient. However, CO₂ multipack or rack systems have become more common.

CO₂ has gained a lot of attention as a refrigerant over the recent years and currently the 4th generation of supermarket CO₂ units are entering the stage. CO₂ is also used in cascade systems with other natural working fluids, such as ammonia. Cascade systems are widely used in warehouses and for industrial refrigeration and heat pump systems (Hafner and Ciconkow, 2021). However, it has been noted by stakeholders that drawbacks with CO₂ as a refrigerant include high working pressures that require solid equipment design and lower energy efficiency in warm climate.

Efficient systems based on ammonia have been in place for many years in industrial refrigeration. Other alternatives to fluorinated gases are also practicable for some applications. For industrial heat pumps the main market is using fluorinated gases, but this could easily be replaced with natural refrigerant alternatives that provide higher efficiency. There may potentially be situations or processes, however, where the continued use of fluorinated gases is required.

It is claimed that for new installations within commercial and industrial refrigeration, a complete transition to natural refrigerants is already taking place. Training is the only barrier to transition to natural alternatives in commercial refrigeration. It is foreseen that within the next decade the same will apply to the air conditioning and heat-pump sector. Air and water-based systems will also develop.

According to stakeholder information it is technically possible to remove fluorinated gases today within domestic and commercial refrigeration and heat pumps. Commercial and industrial applications using CO₂ as refrigerant is already available and in use. However, flammability when using hydrocarbons and costs may be barriers for full substitution of fluorinated gases. Within commercial and industrial refrigeration, low temperature refrigeration below -50 °C in large capacities is expected to still depend on fluorinated gases in 10 years. Such low temperatures are often required to store material for medical (e.g. vaccines) or biochemical use.

One stakeholder noted that atmospheric air can be used in a special loop to create temperatures from -40 °C down to -130 °C, but even -160 °C is possible to reach. Hydrocarbons (e.g. ethane (R- 170) and ethylene (R- 1270)) are used in ultra-low temperature

⁹⁸ <https://ntnuopen.ntnu.no/ntnu-xmlui/handle/11250/2827404>, date of access: 2023-01-13.

applications, including in processing plants at temperatures as low as -80 to -100 °C.

In refrigerated equipment within industrial and laboratory/medical uses, as well as test and measurements, fluorinated gases offer a highly dynamic and precise temperature control in the whole range of -100 °C to +300 °C. Although the whole temperature range may be achieved with non-PFAS alternatives, no single non-PFAS refrigerant seem to have the same broad operating interval. Hence, fluorinated gases may have an advantage in equipment where temperatures are frequently changed over the entire temperature range. Such equipment may be designed with hermetically sealed systems verified to not leak in normal use.

Refrigerated centrifuges are critical in medical laboratories and e.g. sample separation (e.g. blood separation for transfusion centers) and cannot, on a larger system utilize hydrocarbons or high-pressure system (CO₂) as a rotor failure (classified by EN 61010-2-020 as a maximum credible accident) may result in a ruptured refrigerant system and therefore a hazard to the area where flammable refrigerants or high-pressure systems are used.

VFR systems in commercial air conditioning and heat pumps may be challenging to build with natural refrigerants due to flammability. The option is to use chillers which normally have a somewhat higher energy consumption. Larger propane chillers for industrial applications are readily available in Europe.

Wineries, greenhouses, food processing factories and life sciences industries currently rely on fluorinated gases for refrigeration. However, it is possible to use non-PFAS alternatives in most but not all of those applications according to stakeholder input.

Transport refrigeration

Some non-PFAS alternatives are already in use in trucks, in trawlers and in reefer containers. However, they are not currently widespread. Alternatives may have lower energy efficiency, and safety is of concern as people are carried together with the goods to be cooled. Specific barriers affect the sector, for example, size limitations are problematic for the use of active CO₂ systems given the layout of existing trucks. Further design work would be needed to provide viable alternatives that are widely applicable across the market.

Refrigeration systems used under transport especially need high energy efficiency to travel long distances. Trucks drive from the Arctic Circle to southern Spain and are exposed to great fluctuations in outside temperature, while safety of the refrigeration system is also crucial as it carries people and various materials. There is no non-PFAS alternatives yet available to meet the required performance, energy efficiency and safety. CO₂ systems are currently not reliable systems due to restrictions in available space and increase in energy consumption. Therefore, continued need for fluorinated gases is expected in the transport of refrigerated goods over long distances and variable operating conditions between warm and cold climate. However, the 'Pathway to net-zero cooling product list' contains a range of examples of natural refrigerant-based equipment already in use in transport refrigeration and suggests that focus in this sector is now focused on natural alternatives including CO₂, ammonia, liquid nitrogen and hydrocarbons⁹⁹.

The main barriers that need to be overcome in order to allow for an increased uptake of natural refrigerant alternatives to fluorinated gases in the sector is proper training and competence, high costs (CO₂), safety standards (propane), production and availability of parts (compressors) and technology/design development for some applications. Transport over long distances and variable operating conditions between warm and cold climate represent a special challenge that need to be addressed for transport refrigeration. Time to address those barriers is estimated to 5-10 years by some stakeholders.

⁹⁹ <https://cooltechnologies.org/pathway-to-net-zero/>, date of access: 2023-01-13.

One stakeholder noted that the applicability of alternatives in transport refrigeration is limited due to safety concerns, for example in ferries or tunnels.

For marine applications, due to safety, care must be taken with equipment with flammable refrigerants. However, ammonia and CO₂ refrigerants are often used either alone or in cascade systems in new ships.

Mobile air conditioning (MAC)

In mobile air conditioning CO₂ can be used in place of fluorinated gases in electric vehicles and combustion engine vehicles with electric compressors (hybrid and plug-in hybrid cars). CO₂ is unsuitable for combustion engine vehicles with mechanical compressors, as the compressor's leak resistance durability is challenging due to high pressures. CO₂ can also be used for buses under the same conditions as described for passenger cars. For trucks CO₂ reliability/durability has not yet been proven. Extensive field testing covering different aspects of operation should be fulfilled prior to introduction. Volkswagen has developed a car with CO₂-based air conditioning, which is used by e.g. the German Environmental Protection Agency, UBA¹⁰⁰. The CO₂ system cools the vehicle interior very fast and is energy-efficient. The new mobile air conditioning system with CO₂ uses even less energy than the serially produced system with the fluorinated gas HFC-134a. However, in the future due to best energy efficiency, propane should be used according to stakeholder input, although research and development is still needed for implementation.

An estimate has been provided of an additional cost of €300/vehicle for adoption of CO₂ MAC systems. The motor industry regards this as too expensive for adoption other than as an option. Assuming leakage of the full quantity of fluorinated gas used in a system over its lifetime, a restriction would cost less than €1 000/kg gas which is the lower indicative benchmark of proportionality derived by Oosterhuis et al. (2017).

Secondary loop systems (SL-MAC) based on HFC-152a as refrigerant have been shown to be efficient and safe, see Section A.3.8. HFC-152a (CHF₂-CH₃) is not a PFAS and is outside of the scope of the restriction proposal. Its GWP is 138 (Chen et al., 2020). SL-MAC systems with propane (HC-290) as an efficient refrigerant are also currently being explored.

Air is already in use as refrigerant in air conditioning in trains and aircraft (Hafner and Ciconkow, 2021).

One stakeholder indicated that elastocaloric cooling could be commercialised within 5 years for heat pumps and mobile air conditioning.

Electronics cooling, heat exchanger part with fluorinated gases or other refrigerants

Large, isolated data centres may be able to use alternative refrigerants such as ammonia without problems for cooling. Small systems may be cooled using basic ventilation or small-scale AC systems for which hydrocarbon charge size would not be problematic. Water is also an alternative refrigerant for the safe and efficient cooling of data centres.

E.2.8.2.3. Foam blowing agents

The availability of natural foam blowing agents as alternatives to fluorinated gases is described in detail in the report "Natural Foam Blowing Agents - Sustainable Ozone- and Climate-Friendly Alternatives to HCFCs" by Deutsche Gesellschaft für Internationale

¹⁰⁰ <https://www.umweltbundesamt.de/en/topics/climate-energy/fluorinated-greenhouse-gases-fully-halogenated-cfcs/application-domains-emission-reduction/mobile-air-conditioning-in-cars-buses-railway/mobile-air-conditioning-climate-friendly>, date of access: 2023-01-13.

Zusammenarbeit (GIZ), 2009¹⁰¹. In the report it is explained that hydrocarbons are the preferred blowing agent in the manufacturing of refrigeration appliances in many regions and are entering other applications as well. Pentane offers long-term environmental benefits (no ODP and very low GWP) at comparably low costs; it has good ageing characteristics and thermal insulation properties and is readily available in most regions. Safety risks associated with pentane, such as flammability, have been successfully controlled by implementing safety procedures and installing sound safety systems within companies. CO₂ is also used as a blowing agent in many applications. Already in 2009 it was stressed that pentane or CO₂ can be used as blowing agents in all types of rigid XPS foam, rigid PUR foams and flexible PUR foams, and the technology has been successfully used by several large manufacturers for many years to produce high-quality products. Isobutane (with co-blowing agents) is also a major alternative to blowing agent for XPS. Cyclopentane is a viable alternative blowing agent for materials used in domestic appliances.

However, several stakeholders have claimed that non-PFAS alternatives to fluorinated gas blowing agents are unsuitable due to fire performance, energy efficiency and durability.

HFOs/HCFOS have been estimated by stakeholders to provide best-in-class insulation improving by up to 20% the values achieved by hydrocarbons. In applications with space constraints, having excellent insulation values is a must to achieve the required levels of insulation. Another stakeholder claimed that non-PFAS blowing agents exist, but they do not provide the same level of thermal performance and can therefore be detrimental to energy saving goals within the built environment.

It may be argued that the insulating properties of foam blown with natural gases are slightly reduced, and therefore that in order to reach the same insulating effect, a thicker layer of foam will need to be used with the alternatives. In certain cases with volume or area limitations, this may be a relevant factor. Proper insulation of buildings is one of the most effective ways to reduce CO₂ emissions and is considered an important means to achieving more energy-efficient design for commercial and domestic buildings in the future.

One-component caulking foam cannot expand on release from the can without a blowing agent. However, the blowing agent does not support the insulating effect of the foam. Most of it is emitted during application. The propellant gas in canned PU foam, which was previously often fluorinated gases, has now been replaced by hydrocarbons.

For PU spray foam the major challenge relates to the safe processing of these systems under in-situ conditions within a building. The potential for the accumulation of blowing agent in 'pockets' creates the risk of fire or explosion if flammable materials are used. Water-blown foam is also used, but there are challenges with dimensional stability (including density which increases costs) and insulating capability (UNEP, 2018a). On this basis some stakeholders claim that low-pressure spray polyurethane foams in self-contained cylinders is a niche reliant on fluorinated gases as blowing agents in a 10 years' perspective.

Galden SV110 is also a PFAS used as foam blowing agent in PU insulation foam, however, this is a perfluoropolyether (PFPE) substance and is not considered a fluorinated gas.

E.2.8.2.4. Solvents

Some of the fluorinated gas type substances exist in the liquid form at ambient conditions – at least long enough for use as solvents. The applications of fluorinated solvents are very diverse as solvents are used widely due to their specific properties. Alternatives will need to be assessed on a case-by-case basis. In general, there are many potential non-PFAS alternatives to fluorinated solvents. Solvent selection is based on effectiveness, compatibility, stability, toxicity, environmental properties and physical properties. No single solvent is likely

¹⁰¹ <https://www.ctc-n.org/resources/natural-foam-blowing-agents-sustainable-ozone-and-climate-friendly-alternatives-hcfc>, date of access: 2023-01-12.

to fit all uses, but for a given application often a suitable alternative can be found. In some cases a completely different solution/technology can be used that provides the service that the fluorinated solvent delivers.

In the present assessment no alternatives have been identified for the use of fluorinated gases/solvents as industrial precision cleaning fluids and cleaning fluids for use in oxygen-enriched environments, or for the use of such substances in solvent-based debinding systems in 3D printing, and as a smoothing agents for polymer 3D printing applications. Information about potential alternatives for such uses is in general difficult to find without first-hand knowledge of the specific applications.

E.2.8.2.5. Propellants

In general, non-PFAS alternatives to fluorinated gas propellants are widely available. However, no single alternative will work for all applications and different solutions may need to be selected for different applications. Nitrous oxide is used in some food applications (spray cream) but its use as a propellant is limited because of potential for misuse as a recreational drug with serious side effects. The compressed gases generally have lower capacity per can than other options. The liquefied gases that have been identified are all hydrocarbons with flammability risks. Despite these risks they are used widely and safely in the domestic market. Not-in-kind alternatives such as trigger sprays are also widely used but typically have an inferior quality of spray (inconsistent particle size and spray rate) which is limiting for some applications. Bag-on-valve alternatives overcome a number of these issues (the propellant has the properties of the compressed gases but remains inside the can). However, they are not appropriate for applications where the propellant also acts as a solvent for the payload (for example, products where the can needs to be shaken before use), or the propellant is the payload (e.g. air dusters).

E.2.8.2.6. Cover gases

Alternatives to fluorinated gases used as cover gases include sulphur dioxide and argon, as well as salt fluxes and powdered sulphur as a not-in-kind alternative. The most likely option is SO₂ for which there is a long history of successful use in the magnesium casting industry. SO₂ is toxic and corrosive, but systems have been developed to cope with these risks.

E.2.8.2.7. Fire suppressants

There are several alternatives that may be used for different applications within the sector when considering technical function. However, with several of the alternatives there are certain drawbacks, so the fire suppressant must be selected carefully for a given application. For example, for blends containing CO₂, there is a risk of serious human health effects of progressive severity as CO₂ concentration increases above 4%. Water mist technologies may not be used where water-sensitive equipment requires protection. For some parts of the market there appears to be a lack of alternatives to the use of fluorinated gases that are clean (not leaving residues), of limited toxicity and fast acting. For example, for total flooding agents, stakeholders claim that there are no drop in alternatives available that are considered clean. There is also no indication that a non-PFAS solution will be available in the near future.

E.2.8.2.8. Other

Insulation gas in electrical equipment

Clean air technology has been introduced to replace both SF₆ and fluorinated gases as insulating gas in electrical equipment, together with dry air (mix of nitrogen and oxygen) and vacuum. However, for high voltage switchgear the technology is still in development. A full fluorinated gas free portfolio up to 145 kV is already available and in operation. Some products e.g. instrument transformers up to 420 kV are also available. By 2026 high-voltage electricity products up to 420 kV may start to be replaced with non-PFAS alternatives. However, it is

expected that some time beyond 2026 will be needed before a full transition to clean air technology for high voltage applications is applicable.

Semiconductor manufacture

No substitutes for the use of fluorinated gases for plasma etching and chamber cleaning in semiconductor manufacturing processes has been identified. However, information about potential alternatives for such uses is in general difficult to find without first-hand knowledge of the specific applications.

IT hardware immersion cooling

Alternatives to immersion cooling of electronics include different not-in-kind technical solutions that have been in use for many years.

Preservation of cultural paper-based materials

Alternatives to the technologies for preservation cultural heritage materials based on fluorinated solvents must be completely chemically inert to protect sensitive objects. However, no such alternative approach has been identified.

E.2.8.2.9. Human health and environmental hazards

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log Kow) and bioconcentration factor (BCF) was assessed. Additionally, it was assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHAs dissemination site. Non-chemical alternatives are also listed in the table.

In relation to fluorinated gases, various alternatives were non-chemical in nature. The list of alternatives contained 29 unique CAS numbers. Twenty-seven (27) of the substances with unique CAS were classified according to CLP (harmonised classification or self-classification). Twenty-two of the substances with unique CAS number did, according to their registration dossier, not fulfil the PBT or vPvB criteria and for 3 of them, no data was found or PBT/vPvB properties were not applicable, meaning that none of these substances were known to fulfil the PBT or vPvB criteria. No other hazard properties were mentioned.

The list contained an additional 2 substances for which no CAS numbers were available. For these substances, no information on classification or PBT and vPvB assessments were available. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.8.3. Environmental impacts

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.8.1, assuming business-as-usual and, consequently, on-going PFAS use and emissions. The analysis of environmental impacts focuses on two restriction options:

- **RO1**, adopting a ban of all PFASs used in HVACR and other fluorinated gas applications;
- **RO2**, adopting a ban on PFAS in combination with use-specific derogations. Regarding the duration of the derogations two variants are distinguished, i.e. a 5-year derogation and a 12-year derogation.

Environmental impacts of RO1 are analysed quantitatively. In contrast, for the use-specific derogations emission data were lacking except for two derogations. There is, however,

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information which PFASs are covered by a particular derogation. Where use-specific emission data are lacking, environmental impacts of RO2 are, therefore, evaluated qualitatively in relation to maximum additional emission scenario assuming a full derogation of all fluorinated gases. Note that this maximum additional emission worst-case scenario does not represent a restriction option but is used for better anchoring a proposed derogation. Table E.85 below summarizes the characteristics of the restriction options, and of the maximum additional emission scenarios.

Table E.85 Characteristics of restriction options benchmark scenarios.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---
RO2 (5 years)	Ban with use-specific derogations	Derogations for defined uses of fluorinated gases	18 months	5 years
RO2 (12 years)	Ban with use-specific derogations		18 months	12 years
Maximum additional emission scenario	Ban with full derogation of entire PFAS groups	All fluorinated gases	18 months	5 years
Maximum additional emission scenario	Ban with full derogation of entire PFAS groups	All fluorinated gases	18 months	12 years

Note that the assessment of environmental impacts excludes environmental impacts arising from fluorinated gases used in mobile air conditioning and transport refrigeration as they are assessed in the transportation sector. 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, restriction options are expected to be implemented in 2027. All emission estimates represent mean values.

Assuming a standard transition period of 18 months, restriction options are expected to be implemented in 2027. All emission estimates represent mean values. Table E.86 shows mean emissions and the expected mean emission reduction for time paths of 30 and 45 years (starting in 2025).

Table E.86. Total mean emissions and emission RO1 and of maximum additional emission scenarios (fluorinated gas sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	1 942 313	---	---
RO1	92 580	1 849 734	95
Maximum additional emission scenario '5-year derogation of all fluorinated gases'*	340 724	1 601 589	83
Maximum additional emission scenario '12-year derogation of all fluorinated gases'*	732 110	1 210 204	62

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Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2070			
Baseline	3 406 681	---	---
RO1	92 580	3 314 102	97
Maximum additional emission scenario '5-year derogation of all fluorinated gases'*	340 724	3 065 957	90
Maximum additional emission scenario '12-year derogation of all fluorinated gases'*	732 110	2 674 572	79

*Maximum additional emission scenarios denote worst-case emission scenarios (assuming a full derogation of a particular PFAS group) against which emissions of proposed use-specific derogations are evaluated qualitatively. They do not represent restriction options.

Refrigeration:

(i) Proposed derogation: Refrigerants in low temperature refrigeration below -50°C

The derogation is proposed for a time period of 5 years after EiF of the restriction and the 18 months transition period. Alternatives for the use are available and technically feasible. However, according to stakeholder input alternatives may be less flexible with regards to operating temperature ranges. Compared to a ban (RO1), a derogation will cause additional emissions. A 5-year derogation of all fluorinated gases use for industrial refrigeration causes additional emissions of 111 705 t. There is **no evidence available** about the precise amount of additional fluorinated gases emissions from this specific derogation, or the precise fraction of emissions compared to a full derogation of fluorinated gases use for industrial refrigeration. However, they can be expected to be small compared to a derogation of fluorinated gases uses for industrial refrigeration (about 10% as a worst case estimate) as only a limited number of industrial and commercial applications exist (e.g. storage of material for medical or biochemical use, such as vaccine preservation). Compared to a maximum additional emission scenario (i.e. a derogation of all fluorinated gases use, see Table E.86), additional emissions from the proposed derogation would account of <1%.

(ii) Proposed derogation: Refrigerants in laboratory test and measurement equipment

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. Alternatives for the use are available and technically feasible. However, according to stakeholder input alternatives may be less flexible with regards to operating temperature ranges. Compared to a ban (RO1), a derogation will cause additional emissions. A 12-year derogation of all fluorinated gases use for industrial refrigeration causes additional emissions of 136 680 t. There is **no evidence available** about the precise amount of additional **fluorinated gases** emissions from this specific derogation, or the precise fraction of emissions compared to a full derogation of fluorinated gases use for industrial refrigeration. However, additional **fluorinated gases** emissions from this derogation can be expected to be very small (<10% compared to a derogation of all fluorinated gases use for industrial refrigeration) as the use of fluorinated gases is limited to laboratories only and comprises very small volumes compared to the other applications, in particular fluorinated refrigerants. Compared to a maximum additional emission scenario (i.e. a derogation of all fluorinated gases use, see Table E.86), additional emissions from the proposed derogation would account of <1%.

(iii) Proposed derogation: Refrigerants in refrigerated centrifuges

The derogation is proposed for a duration of 12 years after EiF of the restriction and the 18

months transition period as no alternatives have become known so far that may be operated safely. The availability of non-PFAS alternatives is limited as a rotor failure would risk a ruptured refrigerant system and a hazard to the area where flammable refrigerants or high-pressure systems are used. However, safe alternatives may be developed over time. A derogation of all fluorinated gases use for industrial refrigeration causes additional emissions of 136 680 t. There is **no evidence available** about the precise amount of additional **fluorinated gases** emissions from this specific derogation, or the precise fraction of emissions compared to a full derogation of fluorinated gases use for industrial refrigeration. However, emissions can be expected to be small (about 1% as a worst case estimate) as the application is limited to uses in laboratories and small-scale preparations. Compared to a maximum additional emission scenario (i.e. a derogation of all fluorinated gases use, see Table E.86), additional emissions from the proposed derogation are considered to be marginal (<0.01%).

Air conditioning and heat pumps:

(iv) Proposed derogation: Maintenance and refilling of existing HVACR equipment put on the market before [18 months after EoF] and for which no drop-in alternatives exist

The derogation is proposed for a time period of 12 years after EoF of the restriction and the 18 months transition period. HVACR equipment based on fluorinated gases is widespread nowadays and comprises both professional and consumer applications (e.g. domestic, commercial and industrial refrigeration, mobile and stationary air conditioning, and heat pumps). Therefore, a derogation of the use of fluorinated gases in existing HVACR equipment can be expected to cause additional emissions which are **substantial** compared to a full ban (RO1). As a starting point reference, a 12-year derogation of all fluorinated gases use in commercial and industrial refrigeration (the relevant use category for this derogation), mobile and stationary air conditioning will lead to additional emissions of 349 889 t, which is more than 3 times higher than emissions under a ban of fluorinated gases (RO1) and would be about 50% of a maximum additional emission scenario (i.e. a derogation of all fluorinated gases use, see Table E.86). **No evidence is available** about the precise amount of additional **fluorinated gases** emissions from this specific derogation. It is, however, plausible to assume that **fluorinated gases** emissions will gradually decrease over time as new equipment based on non-PFAS refrigerants will be introduced, which will make refilling redundant. The time period required to achieve a significant substitution is not known. If the gradual replacement occurs to be slow, high additional emissions can be expected for several years or even decades to come. At the same time, terminating current HVACR equipment with many years of service life left will likely also cause environmental impacts, as energy and other resources would be needed to replace functional equipment.

(v) Proposed derogation: refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives

A time-unlimited derogation is proposed which is justified by existing national safety standards which limit the use of hydrocarbons, ammonia or CO₂ as alternatives. So far, national safety standards and codes limiting the use of non-PFAS alternative refrigerants still apply to some EU countries, but there is progress to amend the standards and allow for the use of some flammable alternative refrigerants. Therefore, it is expected that equipment based on alternatives become safer and more widely used. The time period required to achieve a significant substitution is, however, not known. A time-unlimited derogation of the use of fluorinated gases for refrigerants in HVACR equipment can be expected to cause additional emissions which are **substantial** compared to a full ban (RO1). As a starting point reference, and based on available data, a 30-year derogation of all fluorinated gases use in stationary air conditioning and heat pumps (the relevant use category for this derogation) will lead to additional emissions of 429 022 t, which is more than 4 times higher than emissions under a ban of fluorinated gases (RO1) and would be about 60% of a maximum additional emission scenario (see Table E.86). **No evidence** is available for evaluating the precise

amount of emissions of this derogation. It can, however, be assumed that, additional **fluorinated gases** emissions are **medium** (50% as worst-case estimate) **and will decline overtime**. The latter depends on the speed of substitution. If the gradual replacement occurs to be slow, additional emissions can be expected for several years or even decades to come.

Foam blowing agents:

- (vi) *Potential derogation marked for reconsideration: Foam blowing agents in expanded foam sprayed on site for building insulation*

The derogation is considered for derogation for a time period of 5-years. While, technically, non-PFAS alternatives exist, further development is needed in order to identify practical and safe operation conditions. 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. Spray foam represents a minor part of the emissions from the foam blowing agent segment. Most of the quantified emission should be for factory production of boardstock and insulation for specific products given that this dominates the market. For the latter emission estimates are available, which account of approximately 10% of total emissions of **fluorinated gases** (all applications). A derogation of the use of fluorinated gases in foam blowing agents can be expected to cause additional emissions compared to a full ban (RO1). As a starting point reference, a 5-year derogation of all fluorinated gases use in closed cell foam blowing will lead to additional emissions of 108 047 t, which is slightly higher than emissions under a ban of fluorinated gases (RO1). Though **evidence** on the precise amount of emissions resulting from this use-specific derogation **is lacking**, it is expected that additional emissions of the derogation correspond to approximately 10% compared to the maximum additional emission scenario (i.e. a full derogation of fluorinated gases use).

Solvents

- (vii) *Proposed derogation: Industrial precision cleaning fluids*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. According to limited information available no suitable alternatives are known as yet. The applications of fluorinated gases as solvents are very diverse as the gases are used widely due to their specific properties. Alternatives will need to be assessed on a case-by-case basis, and the necessary information is not yet available. A derogation of the use of fluorinated gases in solvents can be expected to cause additional emissions compared to a full ban (RO1). As a starting point reference, a 12-year derogation of all fluorinated gases use in solvents will lead to additional emissions of 92 730 t, which is slightly higher than emissions under a ban of fluorinated gases (RO1). **Evidence** for a qualitative evaluation of expected additional **fluorinated gases** emissions in this application **is lacking**, but they are expected to be small compared to the maximum additional emission scenario (i.e. a full derogation of fluorinated gases use).

- (viii) *Proposed derogation: Cleaning fluids for use in oxygen-enriched environments*

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. According to limited information available no suitable alternatives are known as yet. The applications of fluorinated gases as solvents are very diverse as the gases are used widely due to their specific properties. Alternatives will need to be assessed on a case-by-case basis, and the necessary information is not yet available. A derogation of the use of fluorinated gases in solvents can be expected to cause additional emissions compared to a full ban (RO1). As a starting point reference, a 12-year derogation of all fluorinated gases use in solvents will lead to additional emissions of 92 730 t, which is slightly higher than emissions under a ban of fluorinated gases (RO1). **Evidence** for a precise evaluation of expected additional **fluorinated gases** emissions in this application **is lacking**,

but they are expected to be small.

(ix) Potential derogation marked for reconsideration: Industrial and professional use of solvent-based debinding systems in 3D printing= 12 years

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. According to limited information available no suitable alternatives are known as yet. A derogation of the use of fluorinated gases in solvents can be expected to cause additional emissions compared to a full ban (RO1). As a starting point reference, a 12-year derogation of all fluorinated gases use in solvents will lead to additional emissions of 92 730 t, which is slightly higher than emissions under a ban of fluorinated gases (RO1). **Evidence** for a precise evaluation of expected additional **fluorinated gases** emissions in this application **is lacking**, but they are expected to be small.

(x) Potential derogation marked for reconsideration: Industrial and professional use of smoothing agents for polymer 3D printing applications

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. According to limited information available no suitable alternatives are known as yet. A derogation of the use of fluorinated gases in solvents can be expected to cause additional emissions compared to a full ban (RO1). As a starting point reference, a 12-year derogation of all fluorinated gases use in solvents will lead to additional emissions of 92 730 t, which is slightly higher than emissions under a ban of fluorinated gases (RO1). **Evidence** for a precise evaluation of expected additional **fluorinated gases** emissions in this application **is lacking**, but they are expected to be small.

Propellants

(xi) Potential derogation marked for reconsideration: Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required

A derogation of the use of fluorinated gases in propellants will cause additional emissions compared to a full ban (RO1). As a starting point reference, a 12-year derogation of all fluorinated gases use in propellants will lead to additional emissions of 102 142 t, which is slightly higher than emissions under a ban of fluorinated gases (RO1). **Evidence** for a precise evaluation of expected additional **fluorinated gases** emissions in this application **is lacking**, but they are expected to be small.

Fire suppressants

(xii) Proposed derogation: Clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. Potential alternatives are available, however, there are drawbacks (e.g. they can cause health effects, or may destroy equipment, or are not considered clean) and therefore fluorinated gases used as fire suppressants are not easily replaceable in the short-term. For this application emission data are available. There is therefore **sufficiently strong evidence** to evaluate expected emissions in case of a derogation. A 12-year derogation of all fluorinated gases use in fire suppressants will lead to additional emissions of 102 183 t, which is slightly higher than emissions under a ban of fluorinated gases (RO1). Given this evidence it can be concluded that additional emissions of the proposed derogation will account of about 14% of emissions under the maximum additional emission scenario (i.e. a derogation of all fluorinated gases, see Table E.86).

Preservation of cultural paper-based materials

(xiii) Potential derogation marked for reconsideration: Preservation of cultural paper-based materials

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period. Potential alternatives need to be chemically inert in order to protect the sensitive objects. No such alternatives are known as yet. The application covers very low amounts, for which only limited information is available. **Evidence** for a qualitative evaluation of expected additional emissions **is lacking**. Still, considering the marginal use of PFAS in this application, additional emissions are likely very small to marginal.

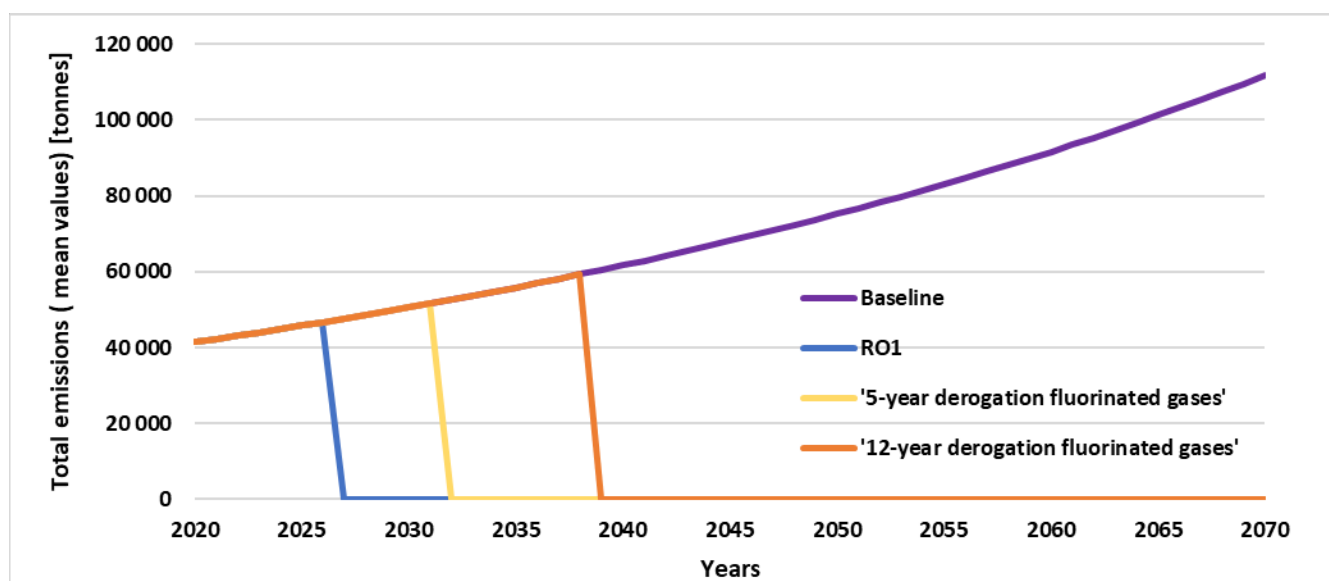
Insulated gas in electrical equipment:

(xiv) Proposed derogation: Insulating gases in high-voltage switchgear (above 145kV)

The derogation is proposed for a time period of 5 years after EiF of the restriction and the 18 months transition period. The main reason is that alternatives are considered not yet ready for all voltage ranges but are in the process of being developed. Fluorinated gases were introduced to replace SF₆ as insulating gas in electrical switchgear due to their high climate impact. Recently, alternatives to fluorinated gases in these applications have been introduced and are in development for the full voltage range. Hence, even fluorinated gases may be replaced when technology is ready. Specifically, clean air technology has been introduced to replace both SF₆ 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. The amount of fluorinated gases in this application is considered significant use but small in comparison to other main applications such as refrigeration and foam blowing agents. **Evidence** for a qualitative evaluation of additional emissions is, however, **not available**. It can be expected that a derogation will cause limited emissions due to low leakage rates.

Figure E.13 displays the time path of mean emissions for the different calculated scenarios.

Figure E.13. Time path of mean emissions under the baseline, R01, and maximum additional emission scenario (fluorinated gases sector, in tonnes).



Source: Own calculations based on data collated by the Dossier Submitters.

E.2.8.4. Economic impacts

E.2.8.4.1. HVACR in the domestic sector

Refrigeration

No economic (or other) impact is expected as a result of a restriction on the use of fluorinated gases in the domestic refrigeration sector given that the market has switched away from fluorinated gases already. Models of all sizes up to larger 'American-style' refrigerators were identified that operate with hydrocarbons as alternatives to F-gases.

Air Conditioning and Heat Pumps

The use of air conditioning and heat pumps are both significant to meeting European carbon reduction objectives though for different reasons. The use of heat pumps reduces demand on fossil fuels and their widespread adoption is seen as an essential measure for moving to net zero emissions of greenhouse gases. The growing use of air conditioning, however, linked to increased affluence and a warming climate, places additional demands on the energy system. The most likely alternatives for domestic air conditioning and heat pumps are hydrocarbons such as pentane.

However, several stakeholders that responded to the consultation expressed concern over the safety implications of using hydrocarbons for air conditioning and heat pumps in the domestic sector. Concern has also been raised in relation to the sale of split air conditioning systems using propane refrigerant for installation by non-professionals some of whom will inevitably lack the appropriate tools, skills and knowledge to ensure safe fitting of the equipment¹⁰². The European Commission has investigated barriers arising from codes, standards and legislation to using climate-friendly technologies in the refrigeration, air conditioning, heat pump and foam sectors (EC, 2016b) indicating the need for update of standards, improved data collection on risk management for flammable refrigerants and review by Member States of restrictive national codes, standards or other legislation¹⁰². The later report (EC, 2020b) concluded that standards and codes were unnecessarily restrictive to the use of A3 refrigerants for new single split ACs (air conditioners) with a cooling capacity <7 kW. The report concluded that it was still necessary to use fluorinated gases in single split ACs with a cooling capacity >7 kW, but this conclusion seems to reflect the limited availability of propane based ACs of this size on the market. It was, however, noted that at a global level there is some adoption of systems with larger charge sizes, indicating that they can compete on the market with equipment using fluorinated gases.

There is strong aversion from some stakeholders to the use of systems charged with propane in some situations, particularly in high rise buildings, and indeed this may be prevented by national or local building codes. Some stakeholders went so far as to say that there is no alternative to HFOs (specifically R-1234yf) for the heat pump market because of concerns over the safety of using hydrocarbons (referred to both in the CfE and 2nd stakeholder consultation, though this position is not supported by the European Commission's conclusions on use of hydrocarbons in AC systems (EC, 2020b).

It is noted that there is clear overlap in the analysis of alternatives in this area between the review of the F-gas regulation and the development of the universal PFAS restriction.

Domestic Use of Heat Pumps in Clothes Dryers

Many models of clothes dryer are already using hydrocarbons rather than fluorinated gases

¹⁰² <https://www.coolingpost.com/uk-news/sales-of-r290-splits-to-diyers-is-irresponsible/> and <https://www.coolingpost.com/world-news/ec-report-creates-f-gas-confusion/>, date of access for both: 2023-01-13.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Review of price data online indicated that heat pump tumble dryers tended to be more expensive, though this would be mitigated through lower energy costs when in use. Available information suggests that there is no clear economic impact of a restriction on producers of heat pump clothes dryers or consumers. Some manufacturers may need to adapt to the use of hydrocarbons, and could incur R&D and retooling costs, but many have already made this switch. Similarly, there are unlikely to be significant environmental, health or social consequences of a restriction, given that it would have little impact on the market.

A summary of information on the cost elements identified at the start of this section is provided in Table E.87.

Table E.87. Summary of Information on the Costs of Alternative Options for Refrigeration, AC, Heat Pumps for Space and Water Heating and Heat Pumps for Clothes Drying for the Domestic Sector Relative to the Costs of Continued Use of fluorinated gases.

Cost element	Commentary
1. R&D costs of designing equipment to utilise alternative refrigerants.	R&D costs for using hydrocarbons have already been incurred by manufacturers of heat pump clothes dryers and refrigerators, and some manufacturers of AC systems.
2. Costs for certification of new product in some markets.	Unknown, but costs would be spread across bulk sales in the domestic marketplace.
3. Difference in the cost of equipment using fluorinated gases and equipment using alternatives.	Based on information regarding the costs of ACs using different refrigerants, there may be an increase in equipment costs (6-10%), but data may simply reflect the current state of the market, before economies of scale come into play. There would be no effect on the cost of refrigerators as these are already almost entirely reliant on the use of propane. Review of market data on the cost of heat pump clothes dryers indicated no systematic difference in price between propane and fluorinated gas models.
4. Variation in the costs of alternative refrigerants.	Propane is cheaper than the fluorinated gases that it would replace, offsetting any price differences.
5. Variation in running costs.	Running costs appear similar for fluorinated gas and propane options.
6. In the event of increased energy losses through the use of technologies that are less energy efficient, additional costs of abatement for greenhouse gas emissions elsewhere in the economy to ensure that climate goals and targets are met.	Efficiency data suggest similar energy usage.
7. Potential for PFAS-dependent operations to cease leading to reduced market share and possible closure of businesses.	Manufacturers of refrigerators and European heat pump clothes dryers are unlikely to be affected given their current models. Manufacturers of AC and heat pumps for space and water heating may be less prepared for change and could be exposed.

E.2.8.4.2. HVACR in the commercial sector

The commercial sector ranges in scale from small venues, such as individual shops, to large shopping malls and office buildings.

Refrigeration

Commercial refrigeration utilises different systems according to situation. Where there is limited need for refrigeration, small units similar to domestic refrigerators and freezers may be used, with hydrocarbons a typical and growing choice as refrigerant and also CO₂. Hydrocarbon charge is typically around half of the fluorinated gas charge (UNEP, 2019a).

Medium-sized systems with refrigerating capacities between 1 kW and 20 kW can use condensing units, featuring several display cases linked to a small machine room. Fluorinated gases are commonly used as the refrigerant. The transition from high GWP refrigerants in this part of the sector is mainly towards low GWP HFCs, HFC/HFO blends and HFOs. Use of propane is growing more slowly, but safety standards are improving, with better leak protection and technical improvements that reduce charge size. There is research on the use of CO₂ but so far these have not extended beyond the trial stage. (UNEP, 2019a).

Larger centralised and distributed systems are used in supermarkets, operating with racks of compressors either in a machine room or on the rooftop linked to cooling coils in the display cabinets or cold rooms. Refrigerant charges of these systems can be large, between 100 kg and 3 t depending on the size of the supermarket. All parts of the system are linked, leading to the potential for very high loss through leakage. Since 2000 there has been increased interest in using propane, propene, ammonia and CO₂ in this part of the commercial refrigeration sector, and they have started to penetrate the market. CO₂ based systems have been installed in supermarkets up to 7 000 m² in size (sheccoBase, 2020). Trans-critical CO₂ systems have been built in most European countries including countries with hotter climates previously considered unsuitable for the technology. Another option, 'indirect' centralised systems is available featuring cascading systems that transfer heat from circuit to circuit, providing an optimised system by combining the use of different refrigerants such as CO₂ or glycol inside stores with refrigerants such as hydrocarbons, ammonia, or HFO/HFO blends in the outer machine room loop (the 'primary refrigeration circuit') (EC, 2017). Targeted legislation in Luxembourg and Sweden has particularly favoured their introduction.

Trans-critical CO₂ (Ma et al., 2013) and small stand-alone systems are cited by the European Commission as being cost-competitive with conventional fluorinated gas systems. In Spain, stand-alone systems based on hydrocarbons and CO₂ have demonstrated energy savings of 20% compared to stand alone systems using HFCs (EC, 2017). It should, however, be noted that comparisons of different systems are not always reliable, for example comparing the latest technology for one refrigerant with yesterday's technology for an alternative.

From the stakeholder consultation information was gathered to indicate that the lifetime of medium and large equipment is in the order of 15 to 25 years, and that it would take 10 to 12 years to develop new products and take them to market. On this basis, there is a significant lifetime remaining, in the order of decades, for equipment that is already in place.

Commercial Air Conditioning and Heat Pumps

Smaller systems, stand-alone ACs and single split ACs, were discussed above under the domestic sector. This section considers larger systems (UNEP, 2019a), acknowledging that some may also be used outside of the commercial sector:

- Multi-split ACs with capacities of 10 kW to 150 kW and typical charge levels of fluorinated gases of 0.30 to 0.70 kg/kW of cooling
- Split ducted ACs with capacities of 7 kW to 1 100 kW and typical charge levels of fluorinated gases of 0.26 to 0.35 kg/kW of cooling
- Ducted commercial packaged ACs with capacities of 7 kW to >700 kW and typical charge levels of fluorinated gases of 0.30 to 0.50 kg/kW of cooling

Most systems are based on fluorinated gases. Propane is currently mostly restricted to small applications because building codes and other regulations limit charge size. It is used in some bigger systems including split and rooftop ducted systems (UNEP, 2019a). Air cooled CO₂ AC systems are available in capacities from 3 kW to 300 kW, though systems become inefficient at high ambient temperatures. Available data, and information gained through the CfE and the 2nd stakeholder consultation, indicate limited options for commercial AC systems at the present time, though research on the use of CO₂, especially in cooler climates, is continuing.

Another category of AC systems is chillers, that provide indirect cooling by using a primary

coolant that chills a secondary coolant, which is then distributed and used to cool air or another substance. These chillers are used in a wide range of applications from schools and commercial buildings to pharmaceuticals and mining to data centre cooling. Chillers tend to operate for many years and have been reported to last worldwide ‘not uncommonly for over 40 years’ (UNEP, 2019a). Most applications use fluorinated gases though there are some ‘less common’ cases where propane, ammonia, CO₂ and water are used as the coolant. Across Europe there is some penetration of options into the chillers market using alternatives to F-gases. UNEP (2019a) refers to a number of applications of ammonia, hydrocarbons and CO₂ in Europe, though these do not extend to the full range of chiller sizes, and other ‘emerging’ refrigerants include HFOs, HCFOs and lower GWP HFCs. The use of water as a refrigerant involves niche markets, for example, desalination plants, deep mines and ice and snow making.

For heat pumps, as in other sectors, the main alternatives to fluorinated gases are propane and CO₂. Propane is identified for water heaters and space heaters using air source and water/ground source heat pumps, whilst CO₂ is listed for water heaters and combined water and space heaters using air source and water/ground source heat pumps (UNEP, 2019a). Ammonia is a further possibility for large systems. Barriers to deployment in the commercial sector as elsewhere are flammability for propane, the high pressure of CO₂ systems and the toxicity of ammonia. These factors become increasingly important as the size of equipment increases. However, the presence of alternatives on the market indicates that they are available at a price that is competing with equipment based around the use of fluorinated gases.

Summary for HVACR Use in the Commercial Market

A summary of information on the cost elements identified at the start of this section is provided in Table E.88.

Table E.88. Summary of Information on the Costs of Alternative Options for Refrigeration, AC, Heat Pumps for Space and Water Heating and Heat Pumps for Clothes Drying for the Commercial Sector Relative to the Costs of Continued Use of F-gases.

Cost element	Commentary
1. R&D costs of designing equipment to utilise alternative refrigerants.	R&D costs for using hydrocarbons, CO ₂ and NH ₃ have already been incurred by some manufacturers of commercial equipment.
2. Costs for certification of new product in some markets.	Products using alternatives are already in the marketplace. Certification may be required in some instances.
3. Difference in the cost of equipment using fluorinated gases and equipment using alternatives.	Evidence has been cited that systems using alternatives are cost-competitive, which matches their emergence in the market in recent years.
4. Variation in the costs of alternative refrigerants.	
5. Variation in running costs.	
6. In the event of increased energy losses through the use of technologies that are less energy efficient, additional costs of	For cost-competitive alternatives there is no evidence of a loss in efficiency.

Cost element	Commentary
abatement for greenhouse gas emissions elsewhere in the economy to ensure that climate goals and targets are met.	
7. Potential for PFAS-dependent operations to cease leading to reduced market share and possible closure of businesses.	For fluorinated gas manufacturers impacts will be dependent in part on the way that maintenance of existing equipment is handled in the restriction (see text below table). Equipment manufacturers that have not investigated alternatives could face problems if a restriction were rapidly introduced.

Larger systems need regular maintenance to ensure that they are running efficiently and that any leaks are detected early. In the event that a restriction prevented maintenance activities such as topping up equipment where leaks had occurred, equipment would become redundant and require replacement. This would generate significant costs to operators, depending on the anticipated remaining lifespan of equipment, given that drop-in alternatives that are not PFAS are unavailable. There may also be issues relating to the availability of engineers to replace units, given the number of installations involved and the fact that there is a major roll-out of heat pumps for domestic and other markets at the present time. Premature retirement of equipment would also incur environmental costs, for example through generation of waste.

Industrial refrigeration

There are many applications of refrigeration in the industrial sector, for example:

1. Electricity production
2. Oil and gas industries
3. Chemicals and petrochemical industry
4. Pharmaceutical industry
5. Food and drink industry (accounting for about 75% of the sector)

There is not a clear boundary between industrial and (particularly) commercial applications: ice rinks, food storage and electronics cooling are examples that could fit into other sectors. Hence, a restriction on use of fluorinated gases in 'industrial refrigeration' could vary in scope from country to country according to local interpretation of the term. Refrigerant charges range from a few kg to 80 t and charges over 100 kg are said to be typical (Schwarz et al., 2011). Data included in the exposure assessment (see Exposure Assessment Module) show little change in demand for fluorinated gases for industrial refrigeration in the last decade. However, some respondents to the CfE considered that the use of fluorinated gases is nearing phase-out in the industry sector, with usage representing less than 10% of the industrial refrigeration market and declining further.

The dominant refrigerant for the sector is ammonia, selected on the grounds of cost as well as performance, often used in cascade systems with CO₂. Indeed, there has been significant uptake of NH₃-based systems because they are cost-competitive with other options. Data on purchase, maintenance and electricity costs (Schwarz et al., 2011) demonstrate reasonably short pay back times compared to HFC use for examples of both small/medium (270 kW cooling) and large (5 MW cooling) systems in the region of 1 to 6 years. Higher capital costs

and some additional maintenance costs were offset by lower energy demand. A potential penetration rate in Europe of 95% was estimated (Schwarz et al., 2011). Concerns over the toxicity of ammonia are reduced for the industrial sector because the industrial setting provides a more controllable environment than commercial settings and because of the separation of systems from members of the public. Ammonia has been the most common option for industries transitioning from HCFCs and HFCs. Other natural refrigerants, CO₂, hydrocarbons, water and air also have a role in the industrial refrigeration market. The large charge sizes required in industrial settings are a barrier to the use of hydrocarbons on safety grounds (Schwarz et al., 2011).

Given the ready availability of alternatives for the industrial sector it may be considered that industrial refrigeration is an appropriate area for restriction. However, there may be applications where alternatives are not appropriate because of the location of the industry or specific operating conditions. This has previously been recognised by commentators on HFC controls (EIA, 2012). The following specific applications have been identified through the CfE and 2nd stakeholder consultation:

- Low temperature refrigeration below -50 °C,
- Laboratory test and measurement equipment
- Refrigerated centrifuges, where rotor crash failure would result in a hazard from both a high pressure system (CO₂) or flammable hydrocarbons

A number of constraints have been noted for such equipment, relating to precision control, the temperature ranges addressed and in the case of refrigerated centrifuges potential for rotor failure which could compromise high pressure CO₂ systems or lead to the release of a significant hydrocarbon charge. For these applications it does not appear that satisfactory alternatives are available on the market.

A maximum penetration rate for equipment not based on fluorinated gases of 95% by 2030 was provided by Schwarz et al. (2011), though a further update would be useful.

As was the case for commercial HVACR systems, there is a lack of options for retrofitting existing equipment using fluorinated gases to an alternative refrigerant (UNEP, 2019a). Performance can be improved by following proper maintenance regimes and ensuring that leaks are minimised. This is encouraged in part by the increasing prices of F-gas refrigerants stimulated by the phase down of HFCs under the F-gas regulation (EC, 2020a).

Electronics Cooling (e.g. at Data Centres)

Consideration here has been limited to the fluorinated gases used in the cooling systems. The use of PFAS as immersion fluids on the other side of the heat exchanger has not been considered though it is noted that there are a number of alternative immersion fluids available.

Data centres vary in size from small systems generating in the region of 10 kW of heat to systems generating many MW. Some are located in separate buildings whilst many are integrated with the office or other buildings that they serve. Cooling systems vary from basic ventilation and air conditioning for the smallest systems to industrial cooling for the largest.

The same issues on alternatives apply to the data centre market as others, relating to the flammability of hydrocarbon systems operating with anything but low charge sizes and the toxicity of ammonia. In both cases there are links to restrictive building codes that would limit application of these options. Overall, addressing concerns over safety seems to be the key for a complete move to alternative refrigerants.

On time scales, stakeholders commented that the existing stock would need to rely on HFOs and HFCs for the next 20 years at least. Accepting that existing alternatives are not compatible

with these systems, this time scale does not look unrealistic.

HVACR sector: Social impacts

Social impacts of the restriction can arise in several ways. Considering first, employment, the following could occur:

1. Increased employment through the development of innovative product lines
2. Reduced employment through loss of market share for EU companies
3. Downstream effects on society through changes in the quality of goods and the price for attaining an equivalent level of service

No evidence has been collected to indicate that these effects would be significant for most parts of the HVACR sector. Distributional impacts are a function of the time over which a restriction would be introduced. Companies currently focused on systems based on fluorinated gases would need to adapt to alternatives, whilst those that have already made the transition would benefit. A rapid transition could cause disruption to parts of the market whilst a slow transition would likely not. The number of organisations that would be affected at different parts of the value chain is indicated in Table E.89. The ubiquitous demands for heating and cooling mean that the number of organisations and facilities that could potentially be affected is very large. For some there could be a loss of business (e.g. manufacturers of fluorinated gases), for others there would be a need for retraining and retooling (e.g. installers and service agents). For some downstream users (e.g. many private households) there might be no direct impact. Key to the effects on these groups are the questions of when a restriction would be introduced and how it would be applied to existing facilities, in particular for how long they would be permitted to continue using fluorinated gases.

Table E.89. Value Chain for HVACR in the EU.

Refrigerant manufacturer, blender, importer	Fluorinated gas incumbents in Europe: 1 450
Equipment manufacturers	OEMs: >200 Major components: ~50 Minor components: hundreds
Installers of HVACR equipment	For buildings: >200 000 businesses Vehicle dealers and repairers: 336 720 ¹⁰³
Downstream operations and end-users	Shops with refrigeration, air conditioning: ~2.7 to 5.4 million ¹⁰⁴ Cold stores: >1 200 ¹⁰⁵ Food and drink companies: 286 000 (FoodDrinkEurope, 2019) Public facilities (governance, schools, hospitals, etc.): ~1 million Data centres: >2 000 Residential buildings: 215 million ¹⁰⁶ Number of motor vehicles: >280 million (ACEA, 2021)

HVACR sector: Summary

A detailed economic analysis of the HVACR sector is not possible. However, drawing on the information presented above, the following conclusions are reached (see Table E.90).

¹⁰³ <https://www.cecra.eu/>, date of access: 2023-01-13.

¹⁰⁴ <https://www.eurocommerce.eu/about-retail-wholesale/>, date of access: 2023-01-13.

¹⁰⁵ <https://ecsla.eu/>, date of access: 2023-01-13.

¹⁰⁶ https://ec.europa.eu/energy/eu-buildings-database_en, date of access: 2023-01-13.

Table E.90. Summary of economic effects on the use of fluorinated gases in new HVACR systems.

Area	New Products
Domestic refrigeration	Cost effective alternatives already widely used. No concerns on proportionality.
Domestic AC and heat pumps	Hydrocarbon based alternatives already on the market for smaller systems. Calls for relaxation of the limits on charge size. Specific situations may continue to be problematic, e.g. use in high rise buildings, where the risks of accidents may be considered to exceed the risks from exposure to fluorinated gases and their degradation products.
Domestic clothes dryers (tumble dryers)	Cost effective alternatives already widely used. No concerns on proportionality.
Commercial HVACR ¹	There is growing acceptance of the use of alternatives using particularly CO ₂ and hydrocarbons in the commercial sector. However, the sector is still dominated by using fluorinated gases, and the assumption that alternatives are ready to replace them is premature. Further research is being conducted in several areas.
Industrial heating and cooling ¹	Efficient systems based on ammonia have been in place for many years. Other alternatives to F-gases are also practicable for some industrial applications. 3 specific types of equipment where identification of alternatives is problematic were identified (low temperature refrigeration, laboratory test and measurement equipment and refrigerated centrifuges).
Electronics cooling	Large, isolated data centres may be able to use alternative refrigerants such as ammonia without problems. Very small systems may be cooled using basic ventilation or small-scale AC systems for which hydrocarbon charge size would not be problematic.

For existing systems, the rapid introduction of a restriction would be problematic because of the lack of drop-in alternatives, leading to significant economic impacts. The introduction of a restriction requiring large scale retrofitting of cooling systems or replacement of existing appliances seems infeasible. A further generic issue is the existence of building codes at local and national levels that may limit the type of alternatives that can be selected. Review of these codes would be useful to assess whether they reflect the current state of technology.

E.2.8.4.3. Foam blowing agents

Economic impacts to society of a restriction on the use of fluorinated gases as foam blowing agents arise in several possible ways:

1. R&D costs of developing new foam-blowing agents and of reformulation for different product lines
2. Costs for certification of new product in some markets
3. Costs of re-equipping manufacturing plant to allow the use of alternatives
4. Variation in the costs of input materials for new formulations
5. Variation in energy usage and associated costs linked to the use of different blowing agents in insulation
6. In the event of increased energy losses through the use of less efficient insulation additional costs of abatement for greenhouse gas emissions elsewhere in the economy to ensure that climate goals and targets are met

7. Costs to consumers from changes to insulation quality through increased heating bills
8. Costs to companies operating with the cold chain (food, liquids, pharmaceuticals, etc) from changes to cold storage during transport
9. Potential for PFAS-dependent operations to cease.

Hydrocarbons, particularly pentane, are favoured for a number of applications and are already widely used. The market share of hydrocarbons in the foam-blowing sector has increased from almost zero in 1990 to over 50% in the early 2000s and now to close to 60% (UNEP, 2015a). For XPS foams, one company stated that 75% of their XPS is CO₂ blown, the remainder is blown using an HFO. Switching to hydrocarbons has also occurred in the phenolic foam sector, where hydrocarbon blown foams are used in less demanding applications where there is scope for increased thicknesses of insulation to compensate for the reduced thermal performance and where fire performance is less critical.

Fluorinated gas blowing agents are more expensive than the alternatives. A cost differential of a factor 10 has been provided between for HFOs relative to CO₂ mixes. The cost of HFO in XPS can be as much as 55% of the total raw material cost, providing a strong rationale for switching to alternatives. The constraint is superior technical quality with respect to insulation, durability, transformation ability and non-flammability. The view of the industry stated several times in the CfE and 2nd stakeholder consultation is that continued use of fluorinated gases is limited to applications where they convey specific advantages that alternatives do not, for example with respect to non-flammability and their performance as an insulator. Indeed, there was some information provided in the CfE indicating that for the switch from HFC-134a there was an initial move to hydrocarbons on the grounds of price and GWP performance, but that the same customers were moving back to HFOs because of superior performance on insulation, by up to 20%, than either hydrocarbons or CO₂ (water) systems.

The price differential to hydrocarbons and CO₂ systems means that there has been a move from the use of F-gases in many parts of the foam market. Estimates were provided to indicate that around 10% of the thermal insulation market in Europe is served by PUR/PIR insulation products used primarily in buildings, construction and the cold chain, whilst a further 8-10% of the thermal insulation market in Europe is served by XPS insulation products, used primarily in construction sector and to a lesser degree, in the industrial sector (e.g. refrigerated transport, RV vans, etc). Key factors cited by stakeholders in the retention of market share for F-gases as blowing agents reflected the issues made above:

- For discontinuous board/block PU foam the use of pentane would not satisfy the demands of customers seeking better fire-rated products, and significant investment would have to be made to make those alternative production lines compliant with the safety regulations.
- For spray or dispensed foam, the alternative is to go to polyurethane open-cell products (with CO₂ or water blown system). This would not meet the needs of customers looking for better energy efficiency, insulating performance, strength, rigidity and water absorption resistance.
- There are also concerns over safety in the application of spray foams, particularly. Where foam is formed in-situ typically on building sites, the use of a flammable blowing agent is largely prohibited on safety grounds, recognising the potential exposure of fumes to naked flames and sparks. A further issue raised on this point is that the production of discontinuous board for cold room panels, refrigerated trucks, etc. is often carried out by SMEs for whom switching to pentane or other hydrocarbons is not possible, either because of a large required investment in explosion proof production lines or, more simply, because their operating permit does not allow the storage of highly flammable substances in quantity, providing a further regulatory barrier to the

adoption of alternatives.

- For continuous lamination of PU boards and panels as well as XPS foam boards the use of pentane and CO₂ would offer poorer insulation resulting in higher energy consumption, in particular, where space is constrained (e.g. building renovation projects). It also forces the use of thicker insulation (and higher use of raw materials) to compensate the extra insulation required.
- Furthermore, to use these alternatives, the design of systems in which PUR/PIR foam is integrated, from district heating pipes to water boilers, will have to be fully re-engineered (greater thickness of virtually all the alternative thermal insulation products, with higher density and poorer compressive strength). This will lead also to missed energy savings when thickness is a fixed parameter or when the alternative insulation product is burdensome to apply, with a likelihood of increased GHG emissions.

There was no evidence in either the CfE or 2nd stakeholder consultation that industry has taken steps to make a transition from HFOs for high specification applications, which should not be considered surprising given that the migration from HFCs to HFOs is ongoing and there is no regulatory pressure to go further, although there is pressure linked to the high price of HFOs. A major manufacturer cited a period of 7-10 years for developing future alternatives, similar to the time taken to develop HFOs. A number of steps would need to be taken:

- Chemical re-formulation of PU/PIR systems and XPS boards
- Development of production lines for manufacture of the new substance and adaptation of production lines for manufacture of foam products
- Re-testing and technical validation of the end-use application to meet its requirements
- Re-testing and obtaining approvals of European and national construction standards that they must comply with.

Other views on time frame indicated 15 years to identify an alternative to HFOs, 5 years to carry out all of the steps around reformulation once an alternative became available and 2 years to change moulds. Whilst these estimates can only be considered approximate, being based on a hypothetical substitution with as yet unidentified substances, they indicate that the process of making the transition to an alternative is not straightforward for the markets that would be affected.

Estimated costs of adaption to production lines based on responses to the CfE and 2nd stakeholder consultation provided estimates of €3 million (based on earlier costs of converting back to F-gases from having used hydrocarbons) to €100 million. It is not possible to extrapolate these figures to derive an overall total for the sector as there is no information of how representative they are of the wider market. However, it is clear that costs would be substantial for some producers.

Several regulatory barriers have been identified that could conflict with the introduction of a restriction:

- Permitting of the storage of flammable substances by SMEs
- Use of flammable substances on building sites
- Building codes that set standards for insulation quality and flammability
- International rules on the performance of insulated truck bodies
- Requirements for carbon emission controls under the EU Green Deal.

The issue of international rules on the performance of insulated truck bodies provides an interesting case where several regulatory factors come together. Vehicle size is, naturally, a function of the road network and other infrastructure. The maximum width of a truck body is

2600 mm. The internal width of a truck typically corresponds to the size of two pallets to be transported side by side. Pallet size is standardised (to facilitate trade), with the most common size being 1200 x 800 mm. The ATP agreement (agreement on the International Carriage of Perishable Foodstuffs and on the special equipment to be used for such carriage), drawn up by the Inland Transport Committee of the United Nations Economic Committee for Europe sets standards for insulation, requiring heavily insulated, mechanically refrigerated containers to have a K coefficient (for insulation) of $<0.4 \text{ W.m}^2/\text{°C}$. This certifies vehicles to refrigerate down to -20 °C (Refrigerated Vehicles Test Centre, 2020). The ATP agreement provides confidence through the cold chain that product leaving e.g. a storage facility or a food processing site will reach its destination in good condition. Insulation of the walls of these trucks has moved to the use of HFO blown XPS. The use of cheaper alternatives would require thicker insulation to meet the ATP standard, and this would affect the number of pallets that could be loaded. Companies could be affected in different ways: a reduction in the carrying capacity of vehicles would drive up transport costs, acceptance of lower insulation standards could reduce the shelf life of foods and other goods.

Given that foams are intended to be used for the lifetime of a product there are no problems associated with a restriction on those foams in respect of equipment that is already in use. This is not the case for the use of PFAS as refrigerants (as opposed to foam-blowing agents) for commercial refrigeration, where systems tend to be topped up periodically: in that case a restriction could lead to the premature retirement of existing equipment.

Most of the applications identified are for buildings, white goods (particularly refrigerators and freezers) and vehicles, though there are some exceptions such as use in shoes. Many of the foams have a closed structure that retains the blowing agent over the product lifetime. These characteristics may facilitate the collection of foams at end of life (10-20 years for vehicles, decades or centuries for building applications) for recycling. However, the low density and correspondingly high volume of the foams may be a deterrent to establishment of an efficient collection network for low value recycle.

The data collected from the literature and stakeholders does not permit a full economic analysis of the impacts of a restriction.

A negative impact arising from the restriction would be a reduction in the quality of insulation, in terms of both cell structure and the insulating quality of the gas trapped in closed-cell foams. This would lead either to an increase in greenhouse gas emissions or the use of thicker insulation. In some cases, the thicker insulation may be acceptable, though this will not always be the case. Given the life expectancy of foams used in construction and facilities such as district heating plant, there would be long-term consequences of a restriction for energy efficiency. Table E.91 demonstrates that cyclopentane has roughly a 25-30% higher thermal conductivity than alternative HFOs and HCFOs. Its global warming potential is higher than two of the F-gases shown in table below and lower than one of them.

Table E.91. Comparison of Insulation properties of HFO and HCFO foam-blowing agents with cyclopentane (EFCTC, 2020).

	HFO- 1336mzz(Z)	HFO- 1336mzz(E)	HCFO- 1233zd(E)	Cyclopentane
GWP	2	7	1	5
Thermal conductivity [mW/m.K]	10.7	11.5	10	13

The use and release of hydrocarbon blowing agents will increase atmospheric volatile organic compound levels, promoting the formation of ground level ozone that is linked to damage to crops, forest, materials and human health. The use of closed foams will limit these releases in the short to medium term through to the end of the service life of the foams.

Information on the thickness of alternatives required to match the insulating properties of F-gas blown-foam was provided by some stakeholders. Mineral wool and fibreglass need to be applied in layers approximately twice as thick as for F-gas foams. A better comparison on a like-for-like basis, however, is with cyclopentane where data in Table E.91 suggest that a thickness increase by about 25-30% would be needed to match insulation performance.

In addition to the effects described above, social impacts can arise in several ways:

1. Increased employment through the development of innovative product lines
2. Reduced employment through loss of market share for EU companies
3. Job losses through the closure of firms
4. Legacy burdens

Neither [1] or [2] seem likely to have a significant impact. Under the existing market there is a diversity of products, some F-gas based and others based on alternatives, depending on what the market will accept. It is unclear how a restriction would foster further product innovation. Information from the CfE indicated that there is limited import of foam-based products into the EU, making loss of market share unlikely for EU companies.

A restriction could have a significant effect [3] on SMEs that are less able to adopt alternatives, noting that they may not gain a permit for the handling of significant quantities of flammable hydrocarbons. They could move to the use of CO₂ based systems, though these have limited application given differences in the quality of foam. Market share would then move to companies that were able to use these substances. The magnitude of this effect cannot be estimated from the data collected.

Legacy burdens [4] arise through the use of materials that will need to be managed over long (inter-generational) periods. This applies particularly to construction materials where lifetimes are commonly in the order of decades. Low leakage rates from closed-cell foams mean that the blowing agents used will be present in significant quantity when they are no longer needed (either as a result of building renovation or demolition).

It has not been possible to provide a detailed economic assessment of the effects of a

restriction on the use of F-gases for foam-blowing. The following should be noted:

1. There has been a shift away from the use of F-gases since the 1980s in the PU, phenolic and XPS foam markets, with increased use of alternatives including particularly CO₂ based options and hydrocarbons.
2. There remains demand for the use of F-gases in areas where insulation quality, durability and fire protection are critical, and alternative blowing agents do not meet the performance required by downstream users and in some cases by regulation.
3. The higher price of F-gas blowing agents (as much as a factor 10, with blowing agents making up a significant part of the raw material cost of foams) provides a clear economic driver for the use of cheaper alternatives. This in itself provides some validation that the additional cost of using F-gases is outweighed by the value placed on their performance in specific applications.
4. The F-gases that are currently preferred for the remaining applications are increasingly HFOs, following the path laid down by the F-gas regulation. A restriction based on PFAS persistence should thus consider specifically the characteristics of HFOs, HCFOs and their degradation products relative to PFAS more generally as defined under the restriction.
5. One application where particular concerns have been noted concerns the use of spray foams on building sites (as distinct from the use of pre-formed boardstock). The use of hydrocarbons is considered to pose a significant fire hazard in this case. This is not to deny that there are other areas (e.g. truck insulation) where concerns have been raised.

There is no indication that alternatives that provide the same level of service as the F-gases relative to the key criteria discussed above are currently available. This means that the time taken to develop and market an alternative or alternatives that provide a similar level of service is highly uncertain, but it is clear that the necessary work would take several years to complete. The rapid introduction of a restriction would be problematic with respect to the time that businesses would need to adapt and the consequences for other regulation.

The specialist nature of some applications creates difficulty for the introduction of alternatives, recognising use in niche applications such as truck refrigeration systems, insulation of district heating pipes and insulation of cryogenic gas (LNG) where the use of hydrocarbon blowing agents would be unacceptable due to interference with leak detection devices.

E.2.8.4.4. Solvents

Given limited response to the CfE and 2nd stakeholder consultation and limited data on specific applications of F-gas based solvents elsewhere, it is not possible to provide a detailed economic analysis of the effects of a restriction on businesses involved in the production of F-gases, or solvents or solvent-based products based on them, or on the users of those products. The information gathered indicates that these solvents are used in niche applications where there are a number of constraints that make the identification of alternative solvents or approaches difficult, at best.

The applications that have been identified via the CfE and 2nd stakeholder consultation are:

- Industrial precision cleaning fluids
- Cleaning fluids for use in oxygen-enriched environments
- Solvent-based debinding systems in 3D printing for industrial and professional applications
- Smoothing agents for polymer 3D printing applications for industrial and professional applications.

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Impacts could arise in the following ways:

- Costs of developing new substances for the market
- R&D cost of reformulating products downstream of the bulk suppliers of F-gases
- Costs of changing production systems to factor in alternative cleaning methods.
- Costs of switching from F-gases to alternative solvents
- Loss of performance associated with switching to existing alternatives
- Increased costs of other regulation

These are discussed below:

Costs of developing new substances for the market

Industry estimates indicate that the past transitions to new molecules have cost individual companies developing new fluorocarbons in the region of USD 1 billion. An estimate has also been provided based on past experience that the development of new substances has taken in the order of 7 to 10 years. A number of activities need to be undertaken before such a substance could be placed on the market: Product development, product testing, production feasibility, building necessary production plant, certification and commercialisation. A complete switch from the use of fluorinated substances could take longer and be more expensive given that the expertise of those currently involved in the manufacture of the substances of concern here is strongly associated with fluorine-based compounds.

Discussion with stakeholders revealed no advanced plans for moving on to a next generation of substances. Theoretical possibilities for complying with a restriction and other legislation are:

- Development of a completely different chemistry that is not based on fluorine but provides similar technical properties regarding solvent strength, non-flammability, low toxicity etc., or
- Development of F-gases that provide similar performance to the current options but are not persistent in the environment and do not generate persistent breakdown products.

The costs and timescales for moving to either of these theoretical possibilities are unknown, but are clearly dependent on the time taken to identify suitable alternatives that are not yet on the market.

The estimate of USD 1 billion is understood to cover the costs of R&D. An additional cost has been given by the same respondent to say that the price of developing a new solvent and production facility would run to USD billions, though no further information was supplied to validate this figure. Whilst these costs are considerable, past experience with the F-gases suggests that they would be used across many product groups. Development costs could also be spread over the global market.

It may be expected that newly developed propellants meeting the necessary characteristics would be more expensive than the substances that they replace. However, it is not possible to estimate future prices of such alternatives with any confidence.

R&D cost of reformulating products downstream of the bulk suppliers of F-gases

One supplier estimated costs of reformulation in the order of €10 million to which should be added any cost-differential between existing chemicals and the alternatives. Another,

providing pharmaceutical packaging, indicated that transition would take at least 5 years if the alternative material already existed. Associated costs could range from a few €10 000s to several €100 000. Cost would rise further through the need for requalification of product and submission of evidence to other regulatory processes. It is to be anticipated that there would be significant variation across the solvents sector given the different constraints applying to different applications.

Costs of changing production systems to factor in alternative cleaning methods

The introduction of techniques such as plasma cleaning, use of ultrasound, use of supercritical fluids and use of no-clean fluxes would require purchase of new equipment.

Costs of switching from F-gases to alternative solvents

Available information from companies involved in the sector indicates that the F-gas solvents are a more expensive choice than others on the market. This indicates that the added service benefits of using the more expensive solvents are valued highly by customers.

The introduction of the quota system under the 2014 F-gas regulation introduced additional price pressures into the market. Between 2014 and the end of 2016 there was a modest increase in the price of some commonly used HFCs in the refrigeration market, but a very sharp increase through 2017 into 2018 of between a factor 6 and 13 (depending on substance) compared to prices at the end of 2014. Prices have declined since then, but by the end of 2019 were still between roughly 4 and 6 times more expensive than in 2014. The effect on lower GWP alternatives was much smaller, with some seeing prices fall after 2017, presumably in response to increased production as companies moved out of the market for the higher GWP substances that were targeted by the F-gas regulation (Kleinschmidt, 2020).

Loss of performance associated with switching to existing alternatives

This has effects at different parts of the value chain depending on application and the extent to which alternatives are able to substitute for the restricted substance. There are several possibilities:

- a. In the event that a satisfactory alternative is already available, providing exactly equivalent service compared to the substituted substance, end-users would not be affected. Producers of F-gas would be affected through lost sales, though these would be replaced by sales of other substances, either by the original supplier or a competitor.
- b. In the event that the alternative that is adopted is not as good as the currently used F-gases, impacts occur at several points in the value chain:
 - i. Producers of F-gases, who would lose sales, whilst producers of substitute products would benefit.
 - ii. Producers of existing options, who would lose business if they were unable to offer a substitute product. Impacts to these producers would be balanced to a greater or lesser degree by those gaining market share.
 - iii. Downstream users who would experience reduced quality of service from the product supplied. This may have several consequences, for example increased maintenance schedules for equipment, reduced equipment lifetime, an increase in interruptions to operations, or increased wastage of product.
- c. It is considered unlikely that a replacement for F-gases would provide superior service, partly because alternative solvents are often less expensive than the F-gas equivalent, and partly because of restrictions or the requirement for

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authorisation for other popular industrial solvents in recent years. In time, superior solvents may be developed, but they do not appear to be available at the present time.

It has not been possible here to place a value on the difference in performance, as this will vary extensively from user to user.

Increased costs of other regulation

One respondent noted that most users of trans-1,2 dichloroethylene, nPB and F-gases affected through the F-gas regulation intended to switch to PFAS-based solvents. A restriction that shut off this possibility would mean that the cost estimates used in previous impact assessments could be unreliable.

Potential for PFAS-dependent operations to cease

Several respondents to the consultation reported that they would not be able to continue operations in the markets for which they currently provide aerosols if a full restriction on the use of F-gases as propellants was introduced. For some, it was reported that this was likely to lead to company closure.

Effects through the value chain are summarised in Table E.92. No attempt has been made to provide an overall cost as insufficient data are available, including on the size of the F-gas solvent sector. The areas likely to be most negatively affected by a restriction would be specialist niche markets where current expertise is focused on continued use of F-gases and alternatives have not yet been identified. Table E.92 lists a number of potential positive impacts. Whilst these cannot currently be ruled out, at the present time they are considerably more speculative than the negative impacts. Few alternatives have been identified that could fit into this category: the most likely options appear to be supercritical fluids, ultrasonics and plasma cleaning for the precision cleaning market (NASA, 2016), though they do not cover all current uses relevant here and have not been subject to detailed assessment for current applications.

Table E.92. Potential Effects Through the Value Chain.

	Potential negative impacts	Potential positive impacts
Current producers, formulators and distributors of solvents based on F-gases	Abandonment of the F-gas solvent marketplace for some producers R&D for development of new substances (potentially shared across a range of applications) Development of new production lines (potentially shared across a range of applications) Closure for companies that are highly dependent on the use of F-gases	Increased market opportunity for producers of alternative solvents
Producers of products based on carrier solvents (lubricants, etc.)	Reformulation costs Recertification costs Closure for companies that are highly dependent on the use of F-gases	Increased market opportunity for producers of alternative cleaning systems and lubricants
Product manufacturers: • Electronics production • Electronics maintenance • Aerospace • Automotive • Pharmaceutical • Etc	Price increases in solvents and associated products Costs of changes in production systems to facilitate new approaches for precision and other cleaning (e.g. use of ultrasound, plasma cleaning) Recertification costs Increased costs of compliance with other regulations relative to estimates made in prior impact assessments	Possible development of alternatives through research that are: • Cheaper • Technically superior
End users: • Electronics production • Electronics maintenance • Aerospace • Automotive • Pharmaceutical • Etc	Price increases passed on through the value chain Increased maintenance requirements Increased product wastage Increased downtime of electronic equipment either through component failure or increased time taken for cleaning operations	Use of alternatives through research that are: • Cheaper • Technically superior leading to provision of improved service, lower wastage, etc.

Social impacts could arise in several ways:

1. Increased employment through the development of innovative product lines
2. Reduced employment through loss of market share for EU companies, including in the event of business closure
3. Downstream effects on society through changes in the quality of goods and the price

for attaining an equivalent level of service

Quantification of any of these effects at the present time would be speculative, given the lack of specific information on the availability of alternatives for niche applications, and, for example, the extent that they would affect existing participants in the market and new suppliers. However, it is noted that some respondents to the consultations carried out for this assessment are highly dependent on the use of F-gases, and have built their businesses around them. If these businesses are unable to adapt to the new restriction there is a significant risk that they may close leading to loss of employment in the manufacturing sector.

Whilst it has not been possible to quantify economic effects, the following observations can be made with confidence:

1. Affected sectors in addition to chemicals include aeronautics, automotive and electronics.
2. Alternatives have been identified for some cleaning applications, though it is not clear how widely these alternatives may be used across the range of current applications of fluorinated solvents. Existing applications of fluorinated gases are typically in niches where solvents are required to meet very specific characteristics, limiting potential to identify alternatives.
3. Alternatives have not been identified for carrier solvents in particular. Options are limited by the specific requirements for solvents and increasing regulation on alternatives such as nPB and trichloroethylene.
4. A restriction that affected all solvent uses would be problematic to the wider industries that are dependent on them if brought in over a short time period. Development of a new class of solvents would likely take many years, at least a decade, to move from the identification and testing of options through to manufacture and certification.

E.2.8.4.5. Propellants

Industry estimates indicate that the costs of bringing new product to market for past transitions to new molecules have cost individual companies developing new fluorocarbons in the region of USD 1 billion. The relevance of this cost estimate is questionable given that future transitions in response to a restriction on PFAS would almost certainly not lead to adoption of other fluorinated gases. More relevant is the estimate provided based on past experience that the development of new substances has taken in the order of 7 to 10 years. A number of activities need to be undertaken before such a substance could be placed on the market: Product development, product testing, production feasibility, building necessary production plant, certification and commercialisation. Development costs could be spread over the global market.

It may be expected that newly developed propellants meeting the necessary characteristics would be more expensive than the substances that they replace. However, it is not possible to estimate future prices of such alternatives with any confidence.

Downstream costs of re-equipping manufacturing plant to allow the use of alternatives also need to be considered. Alternatives with similar properties to the existing propellants (low toxicity, non-flammability, boiling points close to ambient temperatures, etc.) may take the form of drop-in alternatives where little or no modification to existing processes is needed. In the event that some manufacturers moved from non-flammable to flammable propellants (e.g. butane and propane) there could be added cost at manufacturing and storage facilities, to the extent that these had previously not handled flammable substances. However, any such costs would be offset by the cheaper price of the alternative propellant. The development of production lines for manufacture of BOV systems will require further investment. However, such systems are already present on the market, so much of the necessary development work has been carried out.

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Finally, there is potential for PFAS-dependent operations to cease. Several respondents to the consultation reported that they would not be able to continue operations in the markets for which they currently provide aerosols if a full restriction on the use of fluorinated gases as propellants was introduced. For some, it was reported that this was likely to lead to company closure.

Social impacts can arise in several ways:

- Increased employment through the development of innovative product lines
- Reduced employment through loss of market share for EU companies
- Downstream effects on society through changes in the quality of goods and the price for attaining an equivalent level of service

A restriction targeting products where alternatives are already widely used would seem likely to have very little impact: affected companies would most likely switch to the same propellants being used by others.

A restriction against use of all fluorinated gas propellants would have some significant effects. The largest potential for impacts appears to be in niche industries, for example supplying air dusting equipment, or propellant/solvents for applying specific finishes, lubricants, etc. in industrial settings. A small number of companies responding to the CfE reported that they would be vulnerable to restriction on fluorinated gases in their sector given the extent to which they have specialised their product lines. With this in mind, particular consideration should be given to propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required.

Changes in the quality of goods are possible in some areas under a restriction on all uses. Inferior cleaning of electronic equipment may lead to increased failure rates during manufacture or reduced service lifetimes. Inability to use some lubricants could also reduce service lifetimes of products or lead to a requirement for more frequent maintenance, for example in the automotive sector.

Effects of a restriction are traced through the value chain in Table E.93.

Table E.93. Value chain for fluorinated aerosol propellants.

Fluorinated gas producers: Small number of chemical companies	Impact likely to be small given that use of fluorinated gases for propellants is now not widespread, hence production volumes would be little affected. Stimulus to research alternatives that provide the same service as fluorinated gases but are not persistent.
Aerosol companies: 350 SMEs and multinationals in Europe (excluding manufacturers of medical and veterinary aerosols)	Small number still using fluorinated gases. Some of these could be seriously impacted by a restriction as their product portfolios are heavily based around use of fluorinated gases.
Downstream business users: Aerospace, automotive and electronic sectors	Reduced reliability of some equipment. More rapid deterioration of goods leading to reduced reliability of products (e.g. lubricants in the auto and aerospace industries).
Customers for downstream products: Business and general public	Reduced reliability of some equipment. More rapid deterioration of goods leading to more frequent maintenance, replacement or inferior service.

E.2.8.4.6. Cover gases

Table E.94 provides an overview of the value chain for the magnesium casting sector with respect to suppliers of cover gases and downstream uses of cast magnesium products. A relatively limited number of companies are involved in the production and distribution of HFC-134a. Foundry products can be used across a range of sectors, including some of the most economically important European manufacturing sectors.

Table E.94. Value Chain for Cover Gases Used for Magnesium Casting.

Stage ¹	NOVEC™ 612	HFC-134a	SO ₂
Production and distribution of cover gas	1 manufacturer has registered this substance under REACH in the ≥1 000 t range.	29 legal entities have registered this substance under REACH in the ≥10 000 to <100 000 t/y range. Amount used as cover gas not known.	Widely available
Foundries			
Die casting (EU)		~ 23 companies	~ 30 companies
Sand casting (EU)		~ 0 companies ²	~ 0 companies ²
Value of production			
Foundry customers			
Automobile assembly and engine production plants (EU)		~200	
Motorcycle companies (EU) ³		>10	
Major aerospace companies (EU)		>17	
Others		Unknown, but large number of companies	

Table notes: 1) Different stages do not always involve different companies: a producer of cover gas may also be a distributor, and a foundry may be located inside an automotive or aerospace factory. 2) It is understood that SF₆ is the dominant cover gas for sand casting. 3) The figure given for motorcycle companies reflects those based in Europe and excludes non-European companies such as Yamaha, Kawasaki and Harley Davidson. Many European motorcycle companies, such as Ducati and Moto Guzzi, are small in global terms, but leaders in the performance machine field and may thus use lightweight components such as those made from magnesium.

Information on the costs of cover gas systems for use in magnesium smelting is provided in the 2005 BREF (BAT – Best Available Techniques REference note) from the European IPPC Bureau (EC, 2005). As noted above, the purpose of the cover gas is to control oxidation of the surface of the magnesium. At the time that the BREF was written, three options were available to industry:

- Sulphur hexafluoride, SF₆ at a typical concentration of 0.3% in air or nitrogen
- Sulphur dioxide, SO₂ at a typical concentration of 1-2% in air or nitrogen
- Per- and polyfluoroalkyl substances (PFAS) such as HFC-134a and perfluoroketone (C₃F₇C(O)C₂F₅) which had been developed and successfully tested but not deployed in industry at the time the BREF was released.

The BREF provides data on the annual costs of gas and the cost of cover gas systems, using

SO₂ or SF₆, both for specific plant. To assess the costs of switching from HFC-134a to SO₂ calculations have been rerun as follows (the BREF compares costs for SO₂ and SF₆ rather than SO₂ and HFC-134a, so the calculations presented there need some adaptation):

- It is assumed that HFC-134a can be used as a drop-in substitute for SF₆ without significant adjustment.
- It is assumed that the mass dosage of HFC-134a is 30% greater than for SF₆ (3M, 2011) based on differences in starting concentration.
- It is assumed that the original cost data are from 2000 (no date is specified by (EC, 2005)).
- Current (19th November 2020) prices for SO₂ and HFC-134a, ex. VAT, are taken from the BOC Ltd website, based on use of 65 kg cylinders.
- Equipment costs are adjusted from 2000 to 2020 using a GDP deflator of 38%.

Results are presented in the following tables (Table E.95 and Table E.96).

Table E.95. Cost Comparison for Consumption of SO₂ and HFC-134a Used as Cover Gas. Source: (EC, 2005).

	Units	HFC-134a	SO ₂
Concentration of gas	%	0.4	0.7
Price ²	€/kg	28.95	7.45
Inverted density (at 0 °C and 1 atmosphere)	L/kg	153	350
Yearly consumption of gas	kg/y	441	259
Cost/year	EUR	12 758	1 930

Table notes:

1. Data are for 3 die-casting machines run for 300 d/y, 24 h/d with a flowrate to each machine of 10 L/min.
2. Costs for HFC-134a and SO₂ are based on current prices (see text). Significant volatility is noted in the costs of HFC-134a that is linked to the phase down under the F-gas regulation (Kleinschmidt et al., 2020).

Table E.96. Operational and Cost Data for Use of Cover Gases for a New Die-casting Plant of 1000 t/y Mg output. Source: (EC, 2005).

General Casting Data		
Net weight of the Mg parts	1 000 t/y	
Surface of the Mg baths	6 m ²	
Gas (carrier+cover gas)/m ² of surface	300 L/h, constant	
Extra dosage while charging	25%	
Gas Data	HFC-134a	SO ₂
Carrier gas	nitrogen	nitrogen

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Cover gas concentration in carrier gas	0.2% volume	1.5% volume
Cover gas dosage per hour	61.0 g	154.2 g
Cover gas dosage per year	668 kg	1 688 kg
Cover gas/t Mg output	0.66 kg/t	1.69 kg/t
Cost Data	HFC-134a	SO₂
1 kg cover gas	€28.95	€ 7.45
1 m ³ carrier gas (nitrogen)	€0.28	€0.28
Investment cost of new gas equipment	€32 424	€97 273
Discount rate per year	10%	10%
Depreciation period (years)	10 years	10 years
Annualised investment cost of equipment	€5 276	€15 830
Operating cost of cover gas	€19 339 ²	€12 575
Annual running cost (without nitrogen)	€24 615	€28 405
Additional total cost of using SO ₂		€3 791
Reduction cost/kg HFC-134a consumed		€5.68
Emission factor for HFC-134a per unit of HFC-134a consumption		Illustrative 10% to 90% ¹
Substitution cost/kg HFC-134a emitted		€6.3 - 57 ¹

Table notes:

1. No data have been identified to quantify the degradation of HFC-134a in use as the MgF₂ layer is formed. An illustrative range of 10-90% is applied, although for SF₆ many experts consider the level of degradation to be negligible (Schwarz, 2005). The purpose of adopting this range is to test whether uncertainty regarding degradation rate could affect the conclusion of the proportionality assessment (see text).
2. Costs for HFC-134a and SO₂ are based on current prices (see text). Significant volatility is noted in the costs of HFC-134a that is linked to the phase down under the F-gas regulation (Kleinschmidt et al., 2020).

Table E.95 indicates a significant saving in the costs of cover gas from switching to SO₂, reduced by over 80% for the case considered. Table E.96 shows a much smaller reduction in the costs of the cover gas and an overall increase in the cost when additional investment in machinery required for handling SO₂ is accounted for. The additional cost for using SO₂ according to calculations in Table E.96 equates to €5.68/kg HFC-134a consumed. Conversion of this figure to an estimate of cost per unit HFC-134a emitted is problematic given a lack of emission factors equating use to emission. There is a lack of such information even for SF₆,

which has been studied in more detail. Different views have been reported, that SF₆ undergoes minimal conversion (and hence use and emissions are broadly equivalent), whilst some have argued that there is extensive degradation (UBA, 2005). It seems reasonable to assume that levels of degradation for SF₆ and HFC-134a are broadly equivalent, given that they are applied in similar quantities. An illustrative range is given at the foot of Table E.96, assuming a very high level of degradation (emission = 10% of use) or a low level of degradation (emission = 90% of use). Neither figure should be regarded as a robust indication of the emission factor, but the broad range is useful for the purpose of testing whether conclusions reached on the proportionality of a restriction are sensitive to this assumption. Noting that one respondent to the consultation considered PFAS to be 'inert', the most robust estimate of the substitution cost seems most likely to be the lower end of the estimates made, between €6.3 and 57/kg HFC-134a.

Costs of switching for die-casters have been estimated at between 0% and 0.5% of the turnover from magnesium casting parts (Schwarz and Gschrey, 2009).

Given the low costs of switching as a fraction of turnover, it is anticipated that the costs to consumers will be insignificant.

No social impacts have been identified. It is unlikely that the introduction of a restriction would significantly affect operations in the sector, given the availability of alternatives that are well tested and already widely used. The low impact on turnover makes it unlikely that there would be job losses arising from a switch to SO₂ (Schwarz and Gschrey, 2009). There is also considered to be no potential for an increase in employment, given that additional investments are slight.

No wider economic impacts have been identified. It is unlikely that the introduction of a restriction would significantly affect competition in the sector, given the availability of alternatives that are well tested and already widely used.

The adoption of SO₂ as a cover gas should be easily implementable for magnesium recycling and die-casting activities. Costs seem low as a fraction of turnover, and conversion of plants, where it is needed, should not take long.

E.2.8.4.7. Fire suppressants

There has been a significant switch from the use of fluorinated gases to alternatives in the fire suppressant market, driven by price (UNEP, 2018c). One stakeholder estimated that F-gases comprised 5-10% by volume of all fire-fighting products including foams, though a higher percentage of revenues given the higher cost of the substances relative to other options. Residual use of F-gases occurs where it is concluded that alternatives are either less efficient or would cause damage to the staff, facilities, installations and goods that they are supposed to protect. This includes risks of asphyxiation from exposure to CO₂ and damage to electronics, paper goods and artworks from the use of water or salt solutions. Examples where efficiency is key include the use of fire suppressants in aviation and in military applications, where the size and weight of equipment is a major factor in determining applicability of options.

In the event that existing options are not suitable, new substances would need to be developed. With respect to time scale, one industry stakeholder reported that it would take a minimum of 4-7 years to transition to new molecule once it was identified, a position supported by the Halons Technical Options Committee under the Montreal Protocol (UNEP, 2018c). The bigger challenge concerns identifying substitute molecules in the first place (noting that it is unlikely that a single substance would be able to meet the requirements of all applications), that meet the requirements of a possible PFAS restriction while delivering

the performance and safety the market expects for HFC and HFO products. On this basis the time needed to transition to a new substance where the available alternatives are considered not appropriate could be well in excess of 10 years.

Once a molecular target is identified, there is significant R&D required to complete the process and product development R&D in order to produce a business case worthy of investment with manageable risks. The process development involves scouting possible synthetic routes, piloting reaction steps and developing thermodynamic and kinetic models. Product development requires property measurements, modelling and customer sampling to determine if the development product has the expected value proposition with the customer. Once these activities have been carried out and customers have validated demand for the product, an investment decision can be made by manufacturers. A commercial scale plant can often take 2 years or more from authorisation to start-up. In parallel, any new molecule would need to complete a full battery of toxicity and safety testing to support a global registration effort. It is reported that it is not uncommon for the global registration process including testing to take 3-4 years.

One stakeholder reported that the total R&D investment can exceed USD50 million to bring the molecule from concept to commercial scale. Follow up application development and product extensions, the total R&D investment can exceed USD250 million.

Capital investment is directly related to capacity. A stakeholder that provided information to this project has previously acknowledged its recent investment in HFO-1234yf capacity exceeded USD300 million. However, for fire suppressants for which market size is limited, costs could be significantly lower.

One manufacturer has reported that it would withdraw from the market in the event that current substances were restricted: the low volume of sales would not justify product development expenses.

Data was also provided by industry stakeholders for the fixed costs associated with plant operation and manufacturing technical support, ranging from USD10-100 million annually depending on the complexity and capacity of the operation. However, it is assumed here that these costs are similar to those currently incurred, so would not be an additional cost to the industry.

Wider economic impacts would be linked to differences in the efficacy of alternatives in comparison to the F-gases that they displace. Assuming that alternatives are less effective to a degree that is critical for some applications, there would be increased fire damage leading to, for example:

- Increased downtime at data centres with knock-on impacts through a business
- Possible loss of data (though the risk of this should be minimised through effective backup systems)
- Loss of cultural heritage through damage to museums and associated warehouses
- Increased risks for military personnel and equipment through using less efficient fire suppressants

These costs are not quantified here, but have potential to be substantial.

E.2.8.4.8. Other

Preservation of cultural paper-based materials

The preservation systems use fluorofluids to stop acid corrosion of paper-based cultural heritage materials. Alternatives have not been identified for preservation of cultural paper-based materials that provide specific optical, physical, mechanical, and cultural objectives

that are defined by customers. In the absence of even potential alternatives the following costs would arise from a restriction applied on a short time scale, recognising that new approaches would need extensive testing before reaching the market:

- Loss of business for the preservation companies, with potential for some social impacts via job losses
- Loss of opportunity to treat cultural paper-based materials in the EU (assuming that there are not other companies carrying out this work with alternatives), leading to the work potentially being undertaken outside of the EU.
- Possible damage to cultural materials if treatment is unavailable, which could generate significant consumer surplus losses.

Insulating gases

It is understood that the substitution of both SF₆ and fluorinated gases as insulating gas in electrical equipment is ongoing, using dry air (mix of nitrogen and oxygen) and vacuum. Switching is currently possible up to 145 kV and further work is being undertaken to deal with higher voltage switchgear. Information provided in the 2nd stakeholder consultation suggests that by 2026 high-voltage electricity products up to 420 kV may start to be replaced with non-PFAS alternatives. However, it is expected that time beyond 2026 will be needed before a full transition to clean air technology for high voltage applications is carried out. It is, however, unclear, whether this work covers the whole of the EU or only one or some countries.

The major cost impacts of a restriction would likely arise from socio-economic costs due to delayed power grid expansions, inadequate electricity transmission and increased risk of outages.

E.2.8.5. Summary of cost and benefit assessment

The preceding text demonstrates that there is widespread use of fluorinated gases. The following tables summarises the outcomes of qualitative assessment of costs and benefits for the fluorinated gas use drawing on information submitted to the CfE, 2nd stakeholder consultation and the literature. Further information can be found in the accompanying text following each table. Reference throughout this section to possible 5- and 12-year derogations is additional to the general transition period of 18 months. Uses considered in the tables below are as follows:

- Refrigeration (Table E.97)
- Air conditioning and heat pumps (Table E.98)
- Maintenance of HVACR equipment and national/local limitations on use of natural refrigerants (Table E.99)
- Foam blowing agents (Table E.100)
- Solvents (Table E.101)
- Propellants (Table E.102)
- Magnesium casting (Table E.103)
- Fire suppressants (Table E.104)
- Preservation of cultural paper-based materials (Table E.105)
- Insulating gas in electrical equipment (Table E.106)

Table E.97, Table E.98 and Table E.99 and the accompanying text summarise the outcomes of the assessment of costs and benefits for refrigeration, air conditioning and heat pumps, maintenance of existing equipment and response to local regulations on permissible refrigerants (e.g. bans on flammable refrigerants in high rise buildings). Discussion of the quality of evidence for all three tables is provided below Table E.99.

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Table E.97. Refrigeration - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban - 18 month transition period	Not applicable	Domestic refrigeration: Technically and economically feasible alternatives exist for all types of domestic refrigeration. [sufficiently strong evidence] Commercial and industrial refrigeration: There is growing acceptance of the use of natural refrigerants in the commercial and industrial markets across the range of environmental conditions experienced in Europe. [sufficiently strong evidence] Specialist applications: Three specialist applications have been identified where alternatives are not currently available. Refrigerants in low temperature refrigeration below -50 °C Refrigerants in laboratory test and measurement equipment Refrigerants in refrigerated centrifuges used for example in medical laboratories where natural refrigerants pose hazards due to flammability or the use of high pressures as rotor failure, which is understood to not be uncommon, could	It is estimated that RO1 would reduce emissions across all uses of fluorinated gases by 95% compared to the baseline.	Domestic refrigeration: No cost impacts given that equipment using fluorinated gases is no longer placed on the market given the price and performance of alternatives. [sufficiently strong evidence] Commercial and industrial refrigeration: There is growing acceptance of alternatives, indicating that they are cost-competitive with fluorinated gas systems. Negative cost impacts under RO1 are likely to focus on manufacturers that are slow to transition to the use of alternative refrigerants with significant loss of producer surplus and risk of business closure. [sufficiently strong evidence] Specialist applications: The lack of availability of alternatives would be problematic for both producers and consumers. RO1 would cause loss of producer surplus from the likely withdrawal of some product lines with some risk of business closure and loss of consumer surplus through the lack of availability of alternatives that are either safe to use or provide the necessary level of performance. [sufficiently strong evidence] With respect to the maintenance of existing equipment there are problems given a lack of drop-in alternatives. There are a limited number of trained and certified personnel for commercial and	Commercial and industrial refrigeration units will need maintenance over their service life. This issue is addressed in Table E.99. In some locations the use of certain refrigerants may be banned through concern over (for example) flammability. This issue is also addressed in Table E.99.

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		compromise the refrigerant system. [sufficiently strong evidence] Overall it is considered that there is high substitution potential at EiF for domestic, commercial and industrial refrigeration [sufficiently strong evidence] Low substitution potential at EiF for the three specialist applications identified [sufficiently strong evidence]		industrial refrigeration equipment for maintaining existing systems, including maintenance of equipment where leaks have occurred. Application of RO1 leading to an inability for maintenance of systems would generate significant added costs and associated environmental impacts through the early retirement of existing equipment. [sufficiently strong evidence]	
Ban with use-specific derogations: (i) Refrigerants in low temperature refrigeration below -50°C (ii) Refrigerants in laboratory test and measurement equipment (iii) Refrigerants in refrigerated centrifuges	5 years	Based on stakeholder feedback, there is some potential though not certainty for alternatives to be feasible for low temperature refrigeration below -50 °C in large capacities following a 5 year derogation on top of the 18 month transition period [sufficiently strong evidence base]. The situation for refrigerants in laboratory test and measurement equipment and in refrigerated centrifuges is more uncertain given that no potential alternatives are identified as of now and it is unlikely that they become available in the near future [sufficiently strong evidence base].	For (i): A 5-year derogation of all fluorinated gases use for industrial refrigeration causes additional emissions of 111 705 t. No evidence is available about the precise amount of additional fluorinated gases emissions from this specific derogation. However, emissions can be expected to be small compared to a derogation of fluorinated gases use for industrial refrigeration (about 10% as a worst case estimate). Compared to a maximum additional emission scenario (i.e. a derogation of all fluorinated gases use) additional emissions from the proposed derogation account of <1%.	For low temperature refrigeration below -50 °C, a 5 year derogation would permit a longer period for R&D and would reduce costs for producers whilst maintaining production rates and quality. This would also limit potential impacts on consumers and the risk of job losses. For laboratory test and measurement equipment and refrigerated centrifuges the lack of potential alternatives at the present time indicates a likelihood that alternatives would not be on the market even after a 5 year derogation, leading to producer and consumer surplus losses. Some job losses would also seem likely as some products would no longer be produced. Information on the ability of the companies supplying this market to continue in business if this equipment could not be marketed has not been identified. [sufficiently strong evidence]	
	12 years	The probability of alternatives reaching the	For (ii) : A 12-year derogation of all fluorinated gases use for industrial	A 12 year derogation would permit more opportunity to research and	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		market across the range of specialised uses naturally increases with further time allowed for the necessary R&D. [sufficiently strong evidence]	refrigeration causes additional emissions of 136 680 t. There is no evidence available about the precise amount of additional fluorinated gases emissions from this specific derogation. However, additional fluorinated gases emissions from this derogation can be expected to be very small (<10% compared to a derogation of all fluorinated gases use for industrial refrigeration). Compared to a maximum additional emission scenario (i.e. a derogation of all fluorinated gases use) additional emissions from the proposed derogation would account of <1%. For (iii): A derogation of all fluorinated gases use for industrial refrigeration causes additional emissions of 136 680 t. No evidence is available about the precise amount of additional fluorinated gases emissions from this specific derogation. However, emissions can be expected to be small (about 1% as a worst case estimate) Compared to a maximum additional emission scenario (i.e. a derogation of all fluorinated gases use) additional emissions from the proposed derogation are considered to be marginal (< 0.01%).	introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses, particularly in relation to laboratory test and measurement equipment and refrigerated centrifuges. [sufficiently strong evidence]	
Conclusion	For many applications it is apparent that there are already viable alternatives on the market and hence that transition to alternatives is feasible on a limited time base. Difficulties have been identified for some specialist applications regarding low temperatures and laboratory equipment and for these a derogation appears necessary if producer and consumer surplus losses are to be limited. It is not possible to forecast with certainty how much time would be needed for substitution in these areas. However, challenges appear greater for laboratory equipment, for example given the potential for failure of rotors in refrigerated centrifuges.				

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Table E.98. Air conditioning and heat pumps - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban – 18-month transition period	Not applicable	Domestic air conditioning: Technically and economically feasible alternatives exist for smaller (single-household) facilities, via use of hydrocarbons. Safety concerns have limited the application of hydrocarbons as an option in some domestic settings, for example shared residential space where refrigerant charge sizes may be large and high-rise buildings where there is heightened concern over fire risks linked to the flammability of natural refrigerants. In both cases local or national building codes may limit the use of hydrocarbon refrigerants. Commercial air conditioning: There is growing acceptance of the use of alternatives in this sector, particularly CO₂ and hydrocarbons, or CO₂ in cascade systems with other gases such as ammonia. Industrial air conditioning: Efficient systems based on ammonia have been in place for many years in industrial refrigeration and air conditioning. This is one possible solution for large data centres, though others exist. Small systems could be cooled using natural refrigerants or small air conditioning systems where refrigerant charge size is not problematic. Domestic tumble driers: Heat pumps using hydrocarbons for heat transfer have already gained a significant market share in the tumble drier market. Overall, there is high substitution potential at EiF for most stationary applications [sufficiently strong evidence]. However, there is low substitution potential at EiF for uses where (particularly fire) regulations	It is estimated that RO1 would reduce emissions across all uses of fluorinated gases by 95% compared to baseline.	Domestic, industrial and commercial air conditioning and heat pumps: It is noted from consultation that some manufacturers have expressed concern over safety issues related to the use of alternative refrigerants, whilst some others consider that alternative systems can operate safely. Risks to producer surplus and of business closure under RO1 for the domestic, industrial and commercial markets would be present for manufacturers that are slow to transition to the use of alternative refrigerants. However, business that are able to respond rapidly to a restriction or are already supplying products that would be compliant with it would be likely to gain additional business. It is not possible to estimate the extent to which these two effects would counteract one another. The same applies to the potential for job losses through the closure of businesses or business units: losses in one geographic area may be balanced by gains in another. [sufficiently strong evidence] Domestic tumble driers: Cost impacts linked to the domestic tumble drier market are likely negligible given widespread use of alternatives to fluorinated gases already, combined with the experience of the same companies in the domestic refrigeration market. [sufficiently strong evidence]	Commercial and industrial refrigeration units will need maintenance over their service life. This issue is addressed in Table E.99. In some locations the use of certain refrigerants may be banned through conven over (for example) flammability. This issue is also addressed in Table E.99.

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		prohibit use of hydrocarbons [sufficiently strong evidence] .			
Ban with use-specific derogations	5 years	n/a		n/a	
	12 years	n/a		n/a	
Conclusion	Air conditioning systems and heat pumps are available on the market already for a wide range of applications, leading to the conclusion that they are both technically and economically feasible. On this basis there appears no need for a derogation for new goods. Maintenance of existing equipment, and cases where national or local regulations limit the choice of refrigerant are considered in Table E.99.				

Table E.99. Maintenance of HVACR equipment and national/local limitations on use of natural refrigerants - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban - 18 month transition period	Not applicable	Maintenance of existing equipment leading to the need to top up or refill HVACR equipment would require use of refrigerants with similar properties to those used originally. Non-PFAS alternatives would not provide drop-in replacements as they would be incompatible with the equipment already in place, for example with respect to operating pressures. In some cases there are local or national regulations or building codes in force that limit the use of some materials, such as flammable refrigerants where charge sizes are greater than those used, for example, in domestic refrigerators. In both cases potential alternatives are considered technically not feasible. [sufficiently strong evidence]	It is estimated that RO1 would reduce emissions across all uses of fluorinated gases by 95% compared to baseline.	An inability to maintain existing equipment would lead to premature redundancy of equipment with associated environmental burdens and significant added costs to consumers. Given limited resource in terms of engineers and a lack of drop-in alternatives, a restriction with no or a short derogation would lead to losses to both business using refrigeration equipment and their customers. It may also interfere with the roll out of heat pumps as a climate mitigation measure by diverting available engineers from the installation of new heat pumps to other systems. A restriction that affected uses subject to local restrictions would impact the businesses that provide refrigeration equipment, businesses using refrigeration and their customers. [sufficiently strong evidence]	
Ban with use-specific	5 years	Under the restriction, the number of HVACR installations using fluorinated		Costs to businesses and consumers would be lower than under a full ban, but given (e.g.) the expected	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
derogations: (iv) Maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternatives exist		gases will decline over time as they are replaced by new equipment. Building codes may also be changed through recognition of safe operation by alternatives. However, a 5-year derogation seems insufficient for these changes to occur to a significant extent. [sufficiently strong evidence]		lifespan of equipment, these costs are expected to remain high. [sufficiently strong evidence]	
	12 years	The trends identified under a 5 year derogation would strengthen under a 12 year derogation, with fewer existing HVACR installations using fluorinated gases and wider acceptance of the safety of alternatives. [sufficiently strong evidence]	For (iv): No evidence is available about the precise amount of additional fluorinated gases emissions from this specific derogation. A 12-year derogation of all fluorinated gases use in commercial and industrial refrigeration, mobile and stationary air conditioning will lead to additional emissions of 349 889 t , which is more than 3 times higher than emissions under a ban of fluorinated gases (RO1) and would be about 50% of a maximum additional emission scenario (i.e. a derogation of all fluorinated gases use).	Under a 12 year derogation there would be a further decline in costs to businesses and consumers as older equipment reaches the end of its service life and as building codes and other regulations adapt to new technologies.	
Conclusion	Issues concerning maintenance and building codes/regulations are relevant to a restriction on the use of fluorinated gases. The high cost and environmental impact of premature retirement of HVACR equipment need to be recognised. Whilst a 5 year derogation seems too little time for				

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
	sufficiently significant change in either the stock of HVACR equipment or building codes, it is possible, though not certain that this may change within 12 years.				

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The Dossier Submitters consider based on evidence/knowledge from the literature, CfE and 2nd stakeholder consultation that the evidence is:

- Sufficiently strong that technically and economically feasible alternatives are available in the quantities required for use in domestic, commercial and industrial refrigeration and air conditioning and heat pumps and that the substitution potential is high under RO1.
- Sufficiently strong that that technically and economically feasible alternatives are not available in the quantities required for use as refrigerants in low temperature refrigeration below -50 °C, laboratory test and measurement equipment and refrigerated centrifuges, and hence substitution potential is low under RO1. Evidence is considered strong that alternatives will become available with a 5 year derogation for low temperature refrigeration, though a longer period, 12 years, is considered more reasonable for laboratory test and measurement equipment and refrigerated centrifuges.
- Sufficiently strong that technically and economically feasible alternatives are not available in the quantities required for use for maintenance and refilling of HVACR equipment or for use in locations where the use of flammable or toxic refrigerants is banned under local or national regulations or building codes under RO1. Evidence is strong that the stock of equipment dependent on fluorinated gases will remain in service for many years in the absence of regulation to force its shut down. Evidence is also strong that national regulations and building codes designed to reduce the risk of fire or release of toxic substances will take many years to change. This suggests in both cases a lengthy derogation could be appropriate.

RO1 would naturally provide the greatest benefit in the form of reduced emissions. There is strong evidence supporting the quantification of emissions given submissions made under the F-gas regulation and the UNFCCC (UN Framework Convention on Climate Change). Evidence on the savings made under 5- and 12-year derogations is weaker given uncertainty on the precise time-schedule for the introduction of alternative systems, and the precise scope of derogations, but they would naturally lead to increased emissions.

Given the availability on the market of alternatives for domestic, commercial and industrial refrigeration, evidence is sufficiently strong that cost-effective alternatives are available. Impacts on companies operating in the sector will, however, be variable, depending on the speed with which they can transition to alternatives if they are not already working with them. There may be some possibility of closure of businesses or business units, and associated loss of jobs. Loss of consumer surplus is not expected to be large.

The situation is different for the specialist applications (refrigerated centrifuges, etc.) where alternatives are not already on the market. For these applications there is sufficiently strong evidence of significant loss of both producer and consumer surplus under RO1. This is reduced under RO2 as the probability of development of equipment that is not dependent on fluorinated gases increases.

There is sufficiently strong evidence that costs would be high under RO1 if it were applied to the maintenance of existing HVACR equipment. The lack of drop-in alternatives means that equipment that would currently need servicing including some top up of refrigerant levels could not be repaired. Added costs would arise from the premature retirement of existing equipment, the early purchase of replacement equipment and added environmental burdens from disposal of equipment. To further complicate matters it is also likely that there would be insufficient engineers available to do the work. There is also sufficiently strong evidence of high costs in cases where national or local regulations and building codes limit the use of alternatives, where businesses manufacturing or using HVACR equipment and their customers would all be impacted. Table E.100 and the accompanying text summarise the outcomes of the assessment of costs and benefits for foam blowing agents.

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Table E.100. Foam blowing agents - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban - 18 month transition period	Not applicable	The major use that has commonly used fluorinated gases as blowing agents relates to foams used for insulation in buildings and vehicles. There has been some shift away from the use of fluorinated gases in some parts of the market. Alternatives are available but have performance constraints linked to fire performance, energy efficiency and durability. Hydrofluoroolefins (HFOs) provide the best level of insulation (the gases contained within the foam themselves providing an effective barrier to heat transfer). To provide a similar level of insulation alternatives would need to be applied in a thicker layer, which may or may not be feasible, depending on location. In some applications (e.g. spraying on-site) the use of hydrocarbons would not be permitted given the risk of flammability. Some stakeholders indicate that low-pressure spray polyurethane foams in self-contained cylinders is a niche reliant on fluorinated gases as blowing agents. Overall it is concluded that there is high substitution potential at EiF for most applications [sufficiently strong evidence] but low substitution potential at EiF for foam blowing agents in PU spray foam [weak evidence].	It is estimated that RO1 would reduce emissions across all uses of fluorinated gases by 95% compared to baseline.	Loss of producer surplus through loss of market for high value fluorinated gases that are significantly more expensive than alternatives (by as much as a factor of ten). However, there is also a likelihood of some loss of consumer surplus through lower performance of alternatives in some insulation applications. This may lead to increased heat loss (conflicting with climate mitigation actions) or the need for thicker insulation which may be problematic where space is limited or valued (e.g. cargo space in vehicles) There could also be welfare losses linked to increased risks of flammability in some applications, notably on-site spraying. [sufficiently strong evidence].	
Ban with use-specific derogations: (vi) [Foam	5 years	A 5 year derogation would provide opportunity to develop alternatives where current options are not considered viable. This is considered	For (vi): A 5-year derogation of all fluorinated gases use in closed cell	Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
blowing agents in expanded foam sprayed on site for building insulation]		here to apply particularly to foams sprayed on site for building insulation, where other activities on site lead to a significant risk of fire. [weak evidence]	foam blowing will lead to additional emissions of 108 047 t , which is slightly higher than emissions under a ban of fluorinated gases (RO1). Though evidence on the precise amount of emissions resulting from this use-specific derogation is lacking , it is expected that additional emissions of the derogation correspond to approximately 10% compared to the maximum additional emission scenario scenario (i.e. a full derogation of fluorinated gases use).	and welfare losses from use of less effective or more hazardous foam blowing agents. [weak evidence]	
	12 years	The likelihood of identifying more efficient alternatives will increase over time. [weak evidence]		Further time would permit more gradual adaptation in the market to possible alternatives, reducing cost impacts to both producers and consumers. [weak evidence]	
Conclusion	It is noted that there has already been a shift away from the use of fluorinated gases for foam blowing, linked in part to an increase in price as new gases have been introduced to the market to meet the requirements of the F gas regulation. The view from the industry is that the more expensive gases are only used where alternatives do not provide a sufficient level of performance or pose additional risks such as flammability. Whilst alternatives are available, they do not have the same insulating properties as fluorinated gases and hence would either provide a lower level of insulation or need to be applied in a thicker layer to match performance. The most likely area where a derogation could be justified is concluded to be use for foams blown on site for building insulation, where there may be a significant risk of fire linked to the use of hydrocarbon blowing agents. However, in light of uncertainty regarding the precise circumstances under which alternatives would be unavailable, such a derogation is not proposed at this point but marked for reconsideration. A derogation might be proposed at a later stage if additional information on alternatives becomes available.				

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The Dossier Submitters consider based on information from the literature, the CfE and the 2nd stakeholder consultation that there is sufficiently strong evidence that technically and economically feasible alternatives are available in the quantities required for use as foam blowing agents for a range of applications where fluorinated gases may currently be used. An exception concerns foam blowing agents in PU spray foam, where fire hazards linked to use of hydrocarbons may be a significant concern, and substitution potential is considered low. A precise date by which alternatives may become available for this use is not known, though the probability of identifying and commercialising an alternative will increase over time.

RO1 would provide the greatest benefit in the form of reduced emissions. 5- and 12-year derogations under RO2 would naturally lead to increased emissions.

There is sufficiently strong evidence that the use of alternatives would lead to some level of compromise in performance. The fluorinated gases provide a higher contribution to the insulation properties of foam than alternatives such as hydrocarbons. This means either that the foam will be less insulating when alternatives are used leading to higher energy costs and greater carbon emissions, or that it will need to be applied more thickly to achieve the same performance. In some cases it will not be problematic to apply a thicker layer of foam, whereas in others it will be. For some installations thicker foams will lead to reduced storage capacity, adding a further burden. Whilst derogations will lead to higher emissions, they may also permit identification of further alternatives to those considered here that are able to address some of these compromises. Table E.101 and the accompanying text summarise the outcomes of the assessment of costs and benefits for solvents.

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Table E.101. Solvents - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban - 18 month transition period	Not applicable	This is a very diverse sector with solvents used for a wide variety of applications. In many cases, there are alternatives. However, in addition to the literature search, stakeholders have reported that there are no alternatives to fluorinated gases for: Industrial precision cleaning fluids Cleaning fluids for use in oxygen-enriched environments For 3D printing, limited information has been submitted by industry to indicate alternatives do not exist for some specific applications: Solvent-based debinding systems in 3D printing for industrial and professional applications Smoothing agents for polymer 3D printing applications for industrial and professional applications. A case has been made for 3D printing of metals and medical devices though not for other parts of the 3D printing market. Comparative evidence of the performance of alternatives is lacking. It is concluded that there is high substitution potential at EiF across a diverse range of applications [sufficiently strong evidence] and low substitution potential at EiF for specialist cleaning fluid applications [sufficiently strong evidence] and for 3D printing [weak evidence].	It is estimated that RO1 would reduce emissions across all uses of fluorinated gases by 95% compared to baseline.	Use of fluorinated gases as solvents is limited to niche parts of the solvents market, typically where cheaper alternatives have yet to be identified. With this in mind, it is likely that there would be consumer surplus losses for European manufacturers of products currently using fluorinated gas solvents. For precision cleaning uses linked to production of goods this could place EU producers at a disadvantage internationally as the restriction would not apply to goods brought into the EU that had been manufactured using PFAS but did not themselves contain PFAS. For industrial precision cleaning fluids there are further potential impacts on consumers through flammability of alternatives, increased drying times, inability of solvent to penetrate confined spaces leading to reduced performance, incompatibility with electronic systems, etc. These may feed through to impacts on the durability of systems. [Sufficiently strong evidence] It is not clear how broadly the 3D printing sector would be affected by a restriction – whether difficulties are restricted to a few producers of 3D printed metals and medical devices, or all, or whether they affect other products as well. This clearly affects the scale of producer and consumer surplus losses linked to a restriction. With 3D printing finding new markets it is possible that a restriction could have a significant impact on innovation in EU manufacturing. [Weak evidence]	
Ban with use-specific derogations:	5 years	Applications identified here where substitution appears most difficult concern: Industrial precision cleaning fluids		Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses from use of less effective solvents.	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
(vii) Industrial precision cleaning fluids (viii) Cleaning fluids for use in oxygen-enriched environments (ix) [Industrial and professional use of solvent-based debinding systems in 3D printing] (x) [Industrial and professional use of smoothing agents for polymer 3D printing applications]		Cleaning fluids for use in oxygen-enriched environments Industrial and professional use of solvent-based debinding systems in 3D printing Additional time is considered necessary for development of alternatives for these applications. It is considered doubtful that a 5 year derogation on top of the 18 month transition period would be sufficient for the applications listed here.		It has not been possible to quantify these economic effects given uncertainty in the time required to develop alternatives that are able to adequately replicate the functions of fluorinated gases.	
	12 years	There is weak evidence that alternatives will not be available in the short-medium term for: Industrial precision cleaning fluids Cleaning fluids for use in oxygen-enriched environments Industrial and professional use of solvent-based debinding systems in 3D printing On this basis, a 12 year derogation may be appropriate for these applications.	For ((vii), (viii), (ix) en (x): A 12-year derogation of all fluorinated gases use in solvents will lead to additional emissions of 92 730 t , which is slightly higher than emissions under a ban of fluorinated gases (RO1). Evidence for a qualitative evaluation of expected additional fluorinated gases emissions in this application is lacking , but they are expected to be small compared to the maximum additional emission scenario scenario.		
Conclusion	The use of fluorinated gases in the solvents market addresses a number of niche applications. For some of these, notably industrial precision cleaning fluids, cleaning fluids for use in oxygen rich environments and some profession and industrial 3D printing applications, information has been identified to				

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
					indicate that alternatives are not likely to be available on the short to medium term. An inability to use these solvents could have a significant impact on innovative industries within the EU, leading to significant loss of both producer and consumer surplus, though quantification of impacts is not possible. A derogation for these applications may therefore be considered appropriate. Improved characterisation of applications that could benefit from a derogation would be beneficial. However, in light of uncertainty regarding the necessary scope for a derogation for industrial precision cleaning fluids, cleaning fluids for use in oxygen-enriched environments and 3D printing, such a derogation is not proposed at this point but marked for reconsideration. A derogation might be proposed at a later stage if additional information to clarify the scope becomes available.

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The Dossier Submitters consider based on information from the literature, the CfE and the 2nd stakeholder consultation that there is sufficiently strong evidence that technically and economically feasible alternatives are available in the quantities required for use as solvents for a range of applications where fluorinated gases may currently be used. However, there is also evidence of applications where alternatives are not considered feasible at the present time:

- Industrial precision cleaning fluids
- Cleaning fluids for use in oxygen-enriched environments
- Industrial and professional use of solvent-based debinding systems in 3D printing

It is concluded that there is sufficiently strong evidence that alternatives are unlikely to become available by the time that RO1 would be effective for this set of applications. No evidence has been identified to suggest that other applications would be in a similar position.

There is no information available suggesting a specific time by which alternatives could become available, though there is weak evidence that it would take longer than a 5 year derogation on top of the 18 month transition time.

RO1 would provide the greatest benefit in the form of reduced emissions. 5- and 12-year derogations under RO2 would naturally lead to increased emissions.

It is difficult to draw conclusions on the potential economic impacts of a restriction applying at different times in the future. There is potential for significant producer and consumer surplus losses if the introduction of alternatives compromised manufacturing processes for technical products to any significant degree. The view of the industry is that the high price of fluorinated gases means that they are only used where there is a sound economic case for their use, which itself indicates potential for socio-economic costs at some level. A restriction could also generate scope for advantage for competitors outside of the EU, given that they would remain free to use fluorinated gas propellants in the production of goods destined for the EU as the propellants would not remain on those goods after production. Table E.102 and the accompanying text summarise the outcomes of the assessment of costs and benefits for propellants.

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Table E.102. Propellants - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban - 18 month transition period	Not applicable	There has been a substantial level of switching away from fluorinated gases to alternatives in the propellants market in recent decades. A variety of options are available on the market in the form of alternative propellants and delivery systems (e.g. bag-on-valve) though in some applications toxicity and flammability of alternatives are a concern. Limitations apply, for example, where the propellant is the payload (air dusters) or the propellant is a solvent for the payload (cans that need to be shaken before use). A small number of companies in niche industries (e.g. supplying air dusting equipment, or propellant/solvents for applying specific finishes, lubricants, etc. in industrial settings), indicated that they would not be able to continue operations in the markets for which they currently provide aerosols given the extent to which they have specialised their product lines. It is concluded that there may still be high substitution potential at EiF across a diverse range of applications [sufficiently strong evidence] but low substitution potential at EiF in niche industries [weak evidence] .	It is estimated that RO1 would reduce emissions across all uses of fluorinated gases by 95% compared to baseline.	The increasing price of fluorinated gas propellants via the move from HFCs to HFOs already provides encouragement to switch to alternatives. Acceptance of this added cost has been cited by several in industry as strongly indicative of the added value of using fluorinated gases, though there appears to remain some use in personal and household care products where any added benefit cannot be significant. However, safety and performance constraints for some technical aerosols should be recognised as these could lead to significant consumer surplus losses [sufficiently strong evidence for some applications].	
Ban with use-specific derogations: (xi) [Propellants for technical	5 years	A derogation may be particularly useful for propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required. Better characterisation of such applications would be beneficial		Whilst additional time would assist in the development of alternatives, a 5 year derogation does not appear sufficient on current evidence to both identify alternatives and bring them to market. This would lead to producer losses for propellant manufacturers and their customers. A restriction could put EU manufacturing at a disadvantage given that	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
aerosols for applications where non-flammability and high technical performance of spray quality are required]	12 years	to focus a derogation appropriately [weak evidence]. Given the lack of potential alternatives at the present time for the market for technical aerosols for applications where non-flammability and high technical performance of spray quality are required, a longer derogation may be required to identify suitable alternatives and bring them to market [weak evidence]	For (xi): A 12-year derogation of all fluorinated gases use in propellants will lead to additional emissions of 102 142 t, which is slightly higher than emissions under a ban of fluorinated gases (RO1). Evidence for a precise evaluation of expected additional fluorinated gases emissions in this application is lacking, but they are expected to be small.	competitors would still be able to use fluorinated gases in the production of goods intended for the EU. Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses from use of less effective or more hazardous propellants.	
Conclusion	Whilst alternatives to fluorinated gases have made major inroads to the market in recent decades there remain some niches where fluorinated gases remain as the leading option as propellants, in particular for technical aerosols for applications where non-flammability and high technical performance of spray quality are required. Improved characterisation of the specific applications where fluorinated gases confer significant advantage would be useful if a derogation is to be developed for them. The introduction of a restriction with no derogation beyond the 18 month transition time would affect manufacturers of the propellants and aerosols, and could place parts of EU manufacturing at a disadvantage to international competitors who would remain free to use them in the manufacture of goods destined for the EU market. A precise time frame for development of alternatives is not possible, but the lack of potential alternatives at the present time indicates that a longer derogation may be appropriate.				

The Dossier Submitters consider based on information from the literature, the CfE and the 2nd stakeholder consultation that there is sufficiently strong evidence that technically and economically feasible alternatives are available in the quantities required for use as propellant gases for a range of applications. However, the extent of substitution may be limited given the extent to which the aerosol industry has switched away from the use of fluorinated gases in recent decades. Potential for alternatives is considered low for some niche applications such as supplying air dusting equipment, or propellant/solvents for applying specific finishes, lubricants, etc. in industrial settings. Fluorinated gases have a number of properties that favour their use in such applications, including low conductivity, good and consistent spray quality and non-flammability. Evidence regarding the time at which alternatives providing adequate performance will be available on the market was lacking.

RO1 would provide the greatest benefit in the form of reduced emissions. 5- and 12-year derogations under RO2 would naturally lead to increased emissions.

Without a clearer understanding of the scale of usage of fluorinated gas propellants it is difficult to draw conclusions on the potential economic impacts of a restriction applying at different times in the future. There is potential for significant producer and consumer surplus losses if the introduction of alternatives compromised manufacturing processes for technical products to any significant degree. The view of the industry is that the high price of fluorinated gases means that they are only used where there is a sound economic case for their use, which itself indicates potential for socio-economic costs at some level. A restriction could also generate scope for advantage for competitors outside of the EU, given that they would remain free to use fluorinated gas propellants in the production of goods destined for the EU as the propellants would not remain on those goods after production.

Table E.103 and the accompanying text summarise the outcomes of the assessment of costs and benefits for the use of fluorinated gases in magnesium casting.

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Table E.103. Magnesium casting - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban – 18-month transition period	Not applicable	It is known that alternatives are already widely used already to act as cover gases in magnesium diecasting to prevent oxidation at the metal/air interface, and it is concluded that there is high substitution potential at EiT [sufficiently strong evidence] In contrast, no information specific to sand casting has been identified. However, no respondents to the CfeE or 2 nd stakeholder consultation raised concerns over this activity and hence it is concluded that alternatives are also available for that part of the sector.	It is estimated that RO1 would reduce emissions across <u>all uses of fluorinated gases</u> by 95%.	SO ₂ has been identified as a cost-effective alternative to HFC134a for die casting operations, with a substitution cost in the order of €6 to €60/kg of HFC134a emitted. Very limited data has been identified for sand casting operations, but there is no indication that a restriction without derogation would not be proportionate [sufficiently strong evidence] .	
Ban with use-specific derogations	5 years	n/a	n/a	n/a	n/a
	12 years	n/a	n/a	n/a	n/a
Conclusion	Alternatives are already available and widely used in the sector. Substitution costs are estimated in the range of €6 to 60/kg of PFAS emitted. It is concluded that a full ban following an 18 month transition period is appropriate.				

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The Dossier Submitters consider based on evidence/knowledge from the literature that the evidence is sufficiently strong that technically and economically feasible alternatives are available in the quantities required for use in magnesium casting and that the substitution potential is high under RO1. No evidence has been submitted or identified to indicate that a derogation would be necessary or beneficial.

Table E.104 summarises the outcomes of the assessment of costs and benefits for fire suppressants. More detailed information can be found in the accompanying text following the table.

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Table E.104. Fire suppressants - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban - 18-month transition period	Not applicable	Alternatives are available and already used in many fire suppressant applications. However, for some applications these alternatives have a range of drawbacks, for example risk of asphyxiation (e.g. CO ₂), potential to damage protected assets (e.g. water), slower speed of action than fluorinated gases. Examples of applications where these characteristics are important include aviation, military vehicles some data centres and historical archives and museums. High substitution potential at EiF for some uses [sufficiently strong evidence] and low substitution potential at EiF for other applications [sufficiently strong evidence] .	It is estimated that RO1 in <u>all fluorinated gas applications</u> would reduce emissions of fluorinated gases by 95% compared to the baseline.	Price already provides a mechanism favouring alternatives to fluorinated gases and has led to a significant shift in the market where they are not considered necessary. Remaining uses which include safety critical applications and protection of cultural assets, consider the benefits of fluorinated gases sufficient to accept higher prices indicating potential for significant consumer surplus losses, including through potential for loss of life and cultural and other assets, in the event that a full ban is adopted. [sufficiently strong evidence]	
Ban with use-specific derogations: (xii) Clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health	5 years	Alternatives are yet to be identified for critical applications, making it unlikely that they would be available for adoption on a timescale of 5 years. [sufficiently strong evidence]		As RO1	
	12 years	A 12 year derogation may provide sufficient time for the development of alternatives that can provide the necessary level of protection in the critical applications identified. However, the current lack of alternatives, long-term experiences in seeking alternatives (driven by the Montreal Protocol and F-gas regulation indicate that there is no certainty that alternatives will become available on this timescale. Current research on alternatives seems to focus on alternative fluorinated gases	A 12-year derogation of all fluorinated gases use in fire suppressants will lead to additional emissions of 102 183 t , which is slightly higher than emissions under a ban of fluorinated gases (RO1). Given this evidence additional emissions	In the event that alternatives are identified that sufficiently replicate the performance of fluorinated gases, cost impacts of the restriction with a 12 year derogation could be small. However, as noted elsewhere, the development of alternatives even on the 12 year time scale cannot be guaranteed. In this case there would be potential for significant consumer surplus losses, including through potential for loss of life and cultural and other assets after the derogation had expired.	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		rather than non-PFAS groups [weak evidence]	of the proposed derogation will account of about 14% of emissions under the maximum additional emission scenario (i.e. a derogation of all fluorinated gases).		
Conclusion	A derogation is necessary given the lack of alternatives to avoid significant risk to human life and cultural and other assets. Given the failure of past research into alternatives it is likely that a 5 year derogation would be insufficient and a longer derogation would be needed. [sufficiently strong evidence]				

The Dossier Submitters consider based on evidence/knowledge from the literature, CfE and 2nd Stakeholder consultation that the evidence is sufficiently strong that technically and economically feasible alternatives are available in the quantities required for use for some applications of fire suppressants. However, these applications may constitute only a small part of the current market for fluorinated gases in the sector. These are most likely to be used in applications subject to constraints regarding the toxicity of fire suppressants, their speed of action and the need for 'clean action' whereby the fire suppression agent does not damage the assets to be protected (e.g. data centres or cultural artefacts that would be damaged by the use of water). For applications in aviation, museums, the military and some data centres, there is sufficiently strong evidence that the substitution potential is low under RO1. It is noted that this is an area that has been investigated for many years under the Montreal Protocol and F-gas regulation, without acceptable fire suppression agents that are not fluorinated gases being identified.

RO1 would naturally provide the greatest benefit in the form of reduced emissions. There is strong evidence supporting the quantification of emissions given submissions made under the F-gas regulation and the UNFCCC (UN Framework Convention on Climate Change). Evidence on the savings made under 5- and 12-year derogations is weaker given uncertainty on the precise time-schedule for the introduction of alternatives, but they would naturally lead to increased emissions.

Given the lack of alternatives for fire suppression in sensitive situations such as those identified above, evidence is sufficiently strong that cost-effective alternatives are not available at the present time. As a result, there is sufficiently strong evidence of significant loss of both producer and consumer surplus under RO1. This is reduced under RO2 as the probability of development of systems that are not dependent on fluorinated gases increases, though the historically slow rate of development of alternatives in this field indicates that producer and consumer loss could still be significant under RO2. Indeed, no evidence was identified to indicate that a 5 year derogation would be much more beneficial than RO1.

Table E.105 summarises the outcomes of the assessment of costs and benefits for preservation of paper-based cultural materials. Further information can be found in the accompanying text following the table.

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Table E.105. Preservation of cultural paper-based materials - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban – 18-month transition period	Not applicable	This process involves suspending magnesium oxide (MgO) in a fluorinated gas solvent for treatment of paper materials to stop acid corrosion hence preserving artefacts. Fluorinated gas solvents have the ability to deliver the alkaline buffer without degrading ink, binding materials, glue or discolour the paper. Alternative approaches have not been described. New approaches would need extensive testing to ensure that they are safe to use on irreplaceable materials. From the information that is available it is concluded that there is low substitution potential at Eif, but this is based on feedback from a small number of stakeholders [weak evidence] .	It is estimated that RO1 in <u>all fluorinated gas applications</u> would reduce emissions of fluorinated gases by 95% compared to the baseline.	There would be some loss of producer surplus through the loss of market opportunity, though associated use volumes may be small. It is not clear to what extent businesses have specialised in this activity: those that have specialised specifically in preservation of paper materials could be significantly affected leading to some job losses. Consumer surplus losses are likely more important, with potential long-term consequences for the preservation of cultural materials if inappropriate alternatives are adopted [sufficiently strong evidence] .	
Ban with use-specific derogations: (xiii) [Preservation of cultural paper-based materials]	5 years	Accepting that alternatives are not available and given the research that is needed to establish safe alternatives, a 5 year derogation would likely be insufficient [weak evidence] .	Evidence for a qualitative evaluation of expected additional emissions is lacking . Still, considering the marginal use of PFAS in this application, additional emissions are likely very small to marginal.	Same as under RO1	
	12 years	Information obtained here suggests that new approaches would need extensive R&D and testing, which may be feasible under a 12 year derogation. However, only limited responses were received relative to this activity. [weak evidence] .		Additional time would permit more opportunity to research and introduce cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses from an increased risk of damage to cultural assets.	
Conclusion	A derogation appears necessary to bring alternatives to the market. However, the evidence informing this position is only weak , reflecting limited feedback from stakeholders to the CfE and 2 nd stakeholder consultation and limited information identified in the literature. A derogation is therefore not proposed at this time, with more information being required from the consultation process.				

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The Dossier Submitters consider based on evidence from the 2nd Stakeholder consultation that there is weak evidence that technically and economically feasible alternatives are not available in the quantities required for preservation of cultural paper-based materials and that substitution potential under RO1 is low. The 'weak' rating arises because the evidence is from a small number of stakeholders, and it is not known how representative they are of the overall market for preservation of cultural paper-based materials.

RO1 would provide the greatest benefit in the form of reduced emissions. 5- and 12-year derogations under RO2 would naturally lead to increased emissions.

Accounting for the current lack of alternatives for at least some companies working in the field, evidence is sufficiently strong that there would be some loss of producer and consumer surplus under RO1. Consumer surplus losses may be more significant given the nature of the goods being preserved and potential for long term damage to them. No evidence was identified to indicate that a 5 year derogation would be much more beneficial than RO1, given the current lack of candidates for alternatives.

Table E.106 summarises the outcomes of the assessment of costs and benefits for the use of insulating gas in electrical equipment. Further information can be found in the accompanying text following the table.

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Table E.106. Insulating gas in electrical equipment - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban – 18-month transition period	Not applicable	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. However, for high-voltage switchgear the technology is still in development. A full fluorinated-gas-free portfolio up to 145 kV is already available and in operation. For high-voltage switchgear >145 kV, alternatives are not yet on the market. [sufficiently strong evidence] .	It is estimated that RO1 would reduce emissions across <u>all uses of fluorinated gases</u> by 95% over the period 2025 to 2055 compared to the baseline.	The major cost impacts are likely to arise from socio-economic costs due to delayed power grid expansions, inadequate electricity transmission and increased risk of outages.	
Ban with use-specific derogations: (xiv) Insulating gases in high-voltage switchgear (above 145 kV)	5 years	Information provided in the 2 nd stakeholder consultation suggests that by 2026 high-voltage electricity products up to 420 kV may start to be replaced with non-PFAS alternatives. However, it is expected that time beyond 2026 will be needed before a full transition to clean air technology for high voltage applications is applicable [sufficiently strong evidence] .	Evidence for a qualitative evaluation of additional emissions is, however, not available . It can be expected that a derogation will cause limited emissions due to low leakage rates.	Additional time provides manufactures and downstream users the opportunity to substitute instead of ceasing operation thereby limiting producer surplus losses, employment impacts and impacts on customers. Given the direction of travel away from PFAS in the industry it is expected that costs would be negligible if sufficient time is given for the transition, and that a 5 year derogation would be sufficient for this.	
	12 years	n/a	n/a	n/a	
Conclusion	It is concluded that there is a high substitution potential at EiF for most uses but low substitution potential at EiF for high-voltage switchgear (above 145 kV) [sufficiently strong evidence] . A 5 year derogation seems sufficient for the transition for high-voltage switchgear, and associated costs are considered likely to be negligible. Without a derogation, however, there are risks of disruption for electricity transmission that would have potentially significant economic consequences to society.				

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The Dossier Submitters consider based on evidence from the literature and the 2nd Stakeholder consultation that there is sufficiently strong evidence that technically and economically feasible alternatives are available in the quantities required for use as insulating gases in electrical equipment up to 145 kV. However, evidence is also sufficiently strong that alternatives are not currently available for high voltage equipment (>145 kV). Stakeholder information indicates that alternatives are gradually being introduced to higher voltages, but that a full transition will not be achieved until some time after 2026. This provides a sufficiently strong basis for concluding that a 5-year derogation on top of the 18 month transition period would be sufficient.

RO1 would provide the greatest benefit in the form of reduced emissions. 5- and 12-year derogations under RO2 would naturally lead to increased emissions.

There is sufficiently strong evidence that RO1 could lead to significant socio-economic costs due to delayed power grid expansions, inadequate electricity transmission and increased risk of outages. Given that the power sector in many European countries is currently undergoing significant development to expand use of renewable technologies, RO1 may also delay some important climate mitigation actions. The information presented on alternatives indicates that a 5 year derogation on top of the 18 month transition period would be sufficient time to permit alternatives to be developed to the point where they are able to fully substitute out the existing use of fluorinated gases.

E.2.9. Medical devices

E.2.9.1. Baseline

The market for PFAS applications in the medical sector is assumed to grow considerably in the short- and medium term. For instance, the use of prescribed PFAS-pharmaceuticals in the EU in 2019 is estimated to increase with 3.4%/y by the Dossier Submitters. For European anesthesia drugs a growth of 5.5% is expected between 2020 and 2025¹⁰⁷. 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. As a conservative approach a yearly real growth rate of 5% was assumed at sector level for assessing emissions under the baseline, and under the different restriction options.

The start year of the assessment is 2020. Baseline tonnage and emission estimates are projected for a time path of 30 and 45 years (2025-2070) as presented in Table E.107.

Table E.107. Projected yearly PFAS use and emissions in the medical devices sector of the EEA in tonnes (mean values based on market data).

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	43 899	56 027	71 507	91 263	116 477	148 658	189 729	309 048	503 407
PFAS emissions	5 674	7 242	9 242	11 796	15 055	19 214	24 523	39 945	65 066

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage).

Emission estimates were derived from use/tonnage estimates. In case of polymeric PFAS it was assumed that 1% of PFAS use is emitted. For fluorinated gases release fractions between 10% (gases used in industrial processes related to medical applications) and 100% (e.g. propellants, anaesthetics, contrast media) were applied. Figure E.14 shows expected low and high PFAS emissions between 2020 and 2070 in tonnes.

¹⁰⁷ <https://www.mordorintelligence.com/industry-reports/europe-anesthesia-drugs-market>, date of access: 2023-01-12.

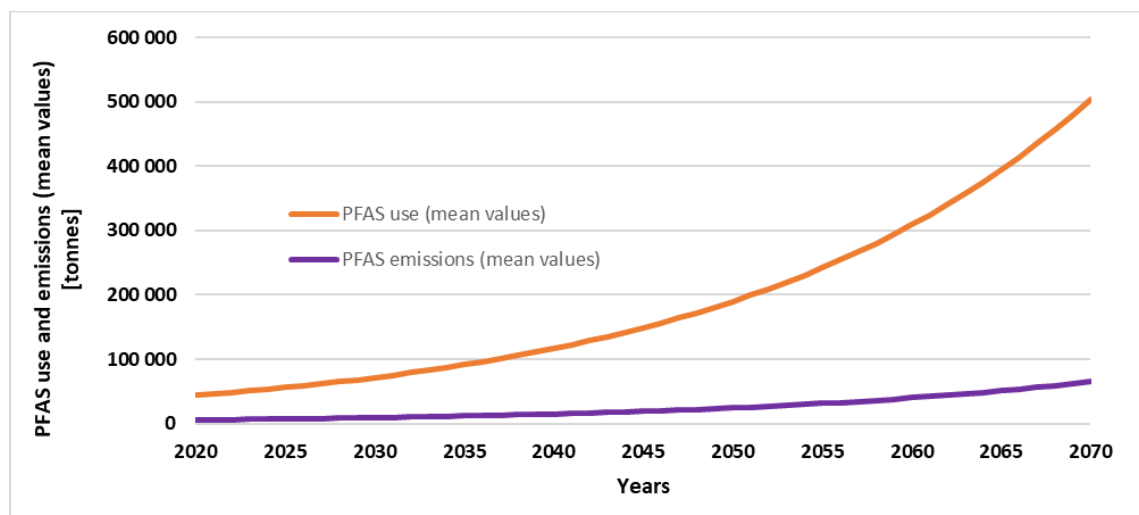


Figure E.14. Expected PFAS use and emissions in the EEA under the baseline for the medical devices sector (mean values) [tonnes].

Based on the assumptions made about market trends for PFAS use in medical applications, emissions can be expected to increase over time. Specifically, between 2025 and 2055 an increase by 400% can be expected. The largest fraction of PFAS emissions are fluorinated gases, followed by fluoropolymers, and non-polymeric PFAS (including PFAA precursors).

E.2.9.2. Alternatives

E.2.9.2.1. Availability, technical feasibility and economic feasibility

Implantable medical devices

Fluoropolymers are used in a broad range of implantable medical devices (see Appendix A.3.10. of Annex A). Applications where PFASs are used include for example sutures, stents and pacemakers.

Meshes, wound treatment products (bandages, surgical tapes, surgical staples), tubes and catheters are covered in separate sections below.

As indicated in Appendix A.3.10. of Annex A, various other polymers are used in some of the implants where fluoropolymers are commonly used, but the Dossier Submitters do not have information on the technical and economic feasibility of these alternatives.

The general feedback from the second stakeholder consultation on alternatives is that:

- Material properties like biocompatibility, heat resistance, low friction, chemical inertness of fluoropolymers like PTFE, PFA, FEP and PVDF are unique. Alternative materials available for this type of applications do not cover the whole range of properties.
- Fluoropolymers are generally relatively costly compared to alternatives. For applications where alternatives are technically feasible, substitution of fluoropolymers is already ongoing or finished.
- The properties of fluoropolymers provide increased lifetime of implants reducing risk of failure and risk of replacement.

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- If any alternatives are identified, the lead time for substitution is likely to be several years to assess suitability and to go through the relevant approval processes.

The Dossier Submitters conclude that the evidence is [sufficiently strong] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [implantable medical devices] and that the substitution potential is [low].

Hernia meshes

Typically, meshes are made of the basic materials polypropylene (PP), polyester, polyvinylidene fluoride, or PTFE. The use of pure PP meshes and polyester meshes are not recommended for laparoscopic intraperitoneal onlay mesh, where the mesh is placed over the abdominal wall defect and secured from inside the peritoneal cavity. It is accepted that PP and polyester meshes are coated either with a protective membrane or a protective film (absorbable or nonabsorbable) or with a titanium layer to protect the viscera. These composite meshes and ePTFE meshes are generally recommended for intraperitoneal use. It is assumed that the use of these meshes reduced adhesion formation and hence lowered the risk of intestinal damage and fistula formation (Bittner et al., 2014).

No information on alternatives has been received during the CfE or the second stakeholder consultation.

The available information indicates that alternatives to PFAS-based hernia meshes are widely available, but that their functionality is lower and lead to increased risk of adverse health impacts (intestinal damage and fistula formation) in patients. Therefore, the alternatives are assessed to not be technically feasible. The Dossier Submitters note that this information is based on a publication from 2014 and that no information has been obtained or received on the eventual development of alternatives in the period after that. Therefore, the Dossier Submitters see a need for further justification for (or against) the assessment (that technically and economically feasible alternatives are not available) in the Annex XV report consultation.

The Dossier Submitters conclude that the evidence is [weak] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [hernia meshes] and that the substitution potential is [uncertain].

Wound treatment products

Regarding wound treatment products (bandages, surgical tapes, surgical staples), submissions from two stakeholders indicate that technically feasible alternatives are not widely available.

The Dossier Submitters conclude that the evidence is [weak] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [wound treatment products] and that the substitution potential is [low].

Tubes and catheters

Tubes and catheters made of fluoropolymers (primarily ePTFE, but FEP, PFA and PVDF were also mentioned in the second stakeholder consultation) are important in minimally invasive procedures. The use of catheters is a cost-effective technique compared to more invasive procedures. Especially the lubricity (smoothness) of the catheters is desired in medical applications (Bates and Campbell, 2015). The insertion of tiny, flexible and very smooth tubes enable small pathways and precision manoeuvring at the treated tissue and accelerate patients recovery.

Some of the main properties of ePTFE tubes are listed in Table E.108, along with the equivalent properties of some of the available alternatives. The example resins shown are all materials that have medical grades available (Teng, 2012). The lubricity (smoothness) is so

critical to the guiding catheters function that alternatives are insufficient as a catheter liner in many types of procedures (Wagner et al., 2020). Even the chemically most closely related alternative show a significant change in crucial properties. The replacement of only one C-F bond by a C-H bonds leads to a material that is less smooth (as indicated by the coefficient of friction) and stiffer (as indicated by the flex modulus). This could lead to more damage and complications during operations. For instance, catheters that are stiffer are pushed into non-target tissue or through the vessel walls more easily, leading to internal trauma and tissue irritation.

Table E.108. Overview of properties of ePTFE tubing compared to alternative materials.

Material	Test method	Property being measured	ePTFE	Poly-ethylene (UHMWPE)	Polyether-ether-ketone (PEEK)	Pebax 7233 (Polyether block amide)
Coefficient of Friction	ASTM D1894	Lubricity (lower = more slippery)	0.05-0.1	0.12-0.2	0.35-0.5	0.36
Flex Modulus (MPa)	ASTM D790	Flexibility/Stiffness (higher = stiffer)	496	606	4065-4275	518
Tensile strength (MPa) at break	ASTM D638	Brittle/Ductile (higher = more brittle)	10-50	40	98-100	56
Elongation at break	ASTM D638	How far it can stretch before breaking (higher = further)	200-600%	300%	50%	>300%

It should be emphasized that there are limitations of PTFE that include low tensile strength, wear resistance, creep resistance and radiation resistance. Therefore, FEP is sometimes used since FEP has better impact strength and wear resistance, yet slightly higher frictional properties and lower resistance to thermal stress cracking than PTFE (Teng, 2012).

The feedback in the second stakeholder consultation generally supports the assessment above. One respondent note that alternatives are feasible in some procedures, but it will be more painful for the patient, due to the higher friction coefficient.

The Dossier Submitters conclude that the evidence is [sufficiently strong] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [tubes and catheters] and that the substitution potential is [low].

Coatings

Regarding coating of metered dose inhalers, several stakeholders in the second stakeholder consultation indicate that alternatives to fluoropolymers are either non-compatible with the medicine, do not resist the corrosive environment or do not have the required non-stick properties that facilitates accurate dosage of the active pharmaceutical ingredients.

One respondent in the second stakeholder consultation noted that the bio-inertness of fluoropolymers can be matched by other substances, such as precious metals (e.g. gold, platinum). The Dossier Submitters have not been able to assess whether precious metals are technically feasible alternatives for the relevant coating applications. Regarding economic

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feasibility, the respondent also noted that the price for precious metals is >1 000 times higher than that for fluoropolymers.

The Dossier Submitters conclude that the evidence is [sufficiently strong] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [coatings of Metered Dose Inhalers] and that the substitution potential is [low].

The Dossier Submitters conclude that the evidence is [weak] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [other uses of coatings of medical devices] and that the substitution potential is [uncertain].

Cleaning and heat transfer: engineered fluids

Two potential alternatives to perfluorinated engineered fluids are n-propyl bromide (nPB or 1-bromopropane) and trichloroethylene (TCE). These two substances are on Annex XIV of REACH and requires authorisation to be used. ECHA initiated calls for evidence investigating whether to initiate a restriction under REACH Article 69(2) in 2021. In both cases ECHAs conclusion after the calls for evidence was that the information on the use and presence of the substances in articles was minimal and that before any further action on the substances it will monitor the presence of the substance in articles via SCIP (Substances of Concern In articles as such or in complex objects) and Substances in Articles notifications.

The Dossier Submitters note that transition towards the two alternatives mentioned above can be considered regrettable substitution. No other information on alternatives to perfluorinated engineered fluids have been obtained or found by the Dossier Submitters.

The Dossier Submitters conclude that the evidence is [weak] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [engineered fluids] and that the substitution potential is [uncertain].

Sterilization gases

Mixtures of ethylene oxide and HFCs are available for use in hospital sterilizers (A. 3.10.).

The Medical and Chemicals Technical Options Committee (MCTOC) of the Montreal Protocol reviewed alternatives to HCFCs in sterilization applications and noted that there is a wide range of technical and chemical alternatives available (UNEP, 2018b). The alternatives are categorised in four main groups: heat, radiation, alkylating agents, and oxidising agents. MCTOC concluded that many of these alternative technologies provided significant advances, such as better safety profiles, turn-around times, and reduced cost per cycle, and that the complete phase-out of HCFCs in sterilization uses to meet the Montreal Protocol schedule was readily achievable.

The Dossier Submitters note the wide range of alternatives available. The Dossier Submitters assume that some of the alternatives listed in MCTOC report are technically and economically feasible in the relevant applications. No information that contradicts this conclusion was received in the calls for evidence. This conclusion is an issue for clarification in the Annex XV report consultation.

The Dossier Submitters conclude that the evidence is [weak] that technically and economically feasible alternatives are [generally available] for the quantities required for use in [sterilization gases] and that the substitution potential is [high].

Diagnostic laboratory testing

The sector organisation Spectaris has provided input regarding these applications during the 2nd stakeholder consultation process. The stakeholder claims that PFAS are used in these applications because of their chemically/biologically stable, unreactive, nature and their

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hydrophobic and oleophobic properties. It is an important feature of PFAS that they do not degrade or decay in the presence of chemical or biological agents; if they did, they would not be fit for purpose. In most cases there are no currently identified alternatives with appropriate properties to test and there is a concern that the potential alternatives would also be persistent in the environment due to their necessary characteristics.

Input from another stakeholder in the second stakeholder consultation supports this assessment and claims that in the case of laboratory equipment, alternative polymeric materials have been assessed, but they are poorly biocompatible and can lead to the absorption of foreign substances, such as fibrinogen, immunoglobulin G, insulin, histone, and carbonic anhydrase.

The Dossier Submitters conclude that the evidence is [sufficiently strong] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [diagnostic laboratory testing] and that the substitution potential is [low].

Vision applications – rigid gas permeable contact lenses and ophthalmic lenses

The following information has been obtained during the second stakeholder consultation and through a report submitted by the sector organisation Spectaris (RINA, 2021). For ophthalmic lenses, alternative coatings are available, but they are associated with lower quality (hydrophobicity and anti-fouling/anti-fingerprint properties) and shorter durability. Alternative coatings with similar properties are not reported as having been identified to date. For rigid gas permeable (RGP) contact lenses, both technical and chemical alternatives exist. Technical alternatives include glasses and soft hydrogel contact lenses. In most cases these alternatives are more comfortable, softer or cheaper but have not been a useful solution for the user, implying that RGP contact lenses have superior characteristics.

Fluorinated methacrylate monomers have been introduced into the polymer matrix as a complement to the predominantly silicone methacrylate structure of the 1st generation gas permeable products. The silicone/fluorine part of the polymer gives the product its high oxygen transmissibility, while the methacrylate enhances optical quality and stability. Higher amounts of silicone tend to have detrimental effects on lens performance, including poor surface wettability, greater protein deposition, increased flexure and instability, and decreased lens durability. The incorporation of fluorine monomers helps to overcome many of these shortcomings, thus significantly improving the overall performance of the RGP products. In short, the 1st generation is an available alternative, but it has lower technical functionality in some respects.

The Dossier Submitters note that alternatives are widely available for both applications, but that stakeholder input indicates that these alternatives lead to articles with lower functionality for (some of) the users. The importance of these differences in functionality needs further justification for a derogation to be considered.

The Dossier Submitters conclude that the evidence is [weak] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [vision applications] and that the substitution potential is [uncertain].

Propellants in Metered Dose Inhalers (MDIs)

According to the consultancy report, MDIs currently use HFC-134a or HFC-227ea as propellants. These substances are within the scope of this restriction proposal.

There are mainly two types of alternatives: technical alternatives and non-PFAS propellants.

Technical alternatives include alternative ways of administering the active pharmaceutical ingredient in the human body, such as dry powder inhalers (DPIs) or by pill, liquid or intravenous solution. Each administration method has its own benefits and drawbacks, and in

some countries, DPIs are more popular than MDIs. These technical alternatives are not suitable for all types of patients. MDIs are particularly beneficial to patients with little breathing power or who lack the coordination to handle a DPI, for instance young children, frail elderly or severely weakened or panicking persons. The Medical and Chemicals Technical Options Committee (MCTOC) of the Montreal Protocol notes the exact proportion of these groups depends on the definition of satisfactory use (UNEP, 2018b). It is probably less than 20 percent, although there is no real-world data.

HFC 152a is a non-PFAS propellant for MDIs with a substantially lower global warming potential (GWP) than HFC-134a and HFC-227ea. HFC-152a would not require any change of usage by the patients that are used to the current HFC MDI inhalers, which implies that HFC-152a can be considered as a “drop-in” alternative. According to the Commissions impact assessment (EC, 2022) for the ongoing review of the F-gas regulation and input in the 2nd stakeholder consultation, HFC-152a will be available on the market starting in 2025 after an extensive period of testing, homologation and necessary approval by the European Medicines Agency that is currently ongoing. A production facility for the substance was opened in 2022¹⁰⁸.

The Commission also notes that research is also currently conducted on the safety of HFC-1234ze for use in MDIs. HFC-1234ze has an even lower GWP¹⁰⁹ than HFC-152a and is expected to be a favoured alternative for the implementation of the F-gas regulation objectives in the long term (post-2030). But since HFC-1234ze falls within the substance scope of this restriction proposal it is not considered as a viable alternative here. It is, however, important to note that in the absence of a regulation of PFAS-propellants in MDIs, HFC-1234ze is expected to be a long-term substitute for both the currently used propellants (HFC-134a and HFC-227ea) and the non-PFAS alternative HFC-152a. This introduces a trade-off between the objectives of the F-gas regulation and the objectives of this proposal for restriction of PFAS.

The Dossier Submitters conclude that the evidence is [sufficiently strong] that technically and economically feasible alternatives are [generally available] for the quantities required for use in [propellants in Metered Dose Inhalers] and that the substitution potential is [high].

Membranes used for venting of medical devices

Hydrophobic/oleophobic membranes based on PTFE and PET with fluorinated C6 based side chain coatings are used for (sterile) venting of several medical devices, for example cell culture devices, analytical devices, blood tube systems for dialyzer systems, tube systems for eye surgery (second stakeholder consultation). One stakeholder claims that technically feasible alternatives are not available. The Dossier Submitters have no other information. More information is needed for a derogation to be considered.

The Dossier Submitters conclude that the evidence is [weak] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [membranes used for venting of medical devices] and that the substitution potential is [uncertain].

Packaging of medical devices

The Dossier Submitters note the following information received during the CfE and the second stakeholder consultation:

- **Flash-spun non-woven packaging material for medical devices.** One stakeholder claimed that it is not possible to find non-fluorinated alternatives. The

¹⁰⁸ <https://www.kouraglobal.com/5899/>, date of access: 2023-01-11.

¹⁰⁹ The GWP of HFC-1234ze is 7, while HFC-152a has a GWP of 124. The currently used HFC-134a and HFC-227ea have GWPs of 1430 and 3220, respectively.

Dossier Submitters note that the use of PFAS as processing aids in thermoplastic packaging is covered in Annex E.2.3. No further assessment of this use in this section.

- **PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics.** One stakeholder claims that several non-fluorinated alternatives have been tested in the past, in both medical and general packaging applications, without success. Suitable alternatives in terms of performance have not yet been identified. This claim is supported by a submission from another stakeholder.
- **PTFE in ophthalmic solutions packaging.** One stakeholder claims that PTFE acts as hydrophobic membrane in certain ophthalmic solutions' packaging, allowing the venting of air, while retaining fluid within the container, preventing leakage. The critical characteristics of PTFE mentioned are chemical inertness and hydrophobicity. The stakeholder has no knowledge of technically feasible alternatives for this use.
- **Packaging of terminally sterilised medical devices.** One stakeholder claims that materials based on C6 telomer chemistry provide a permeable bacterium barrier (to meet the requirements of ISO 11607-1/2) and that this function requires dirt, oil, grease and water repellence properties, which cannot be reached by existing non-fluorinated alternatives.
- One stakeholder noted that the **bio-inertness of fluoropolymers in packaging of pharmaceuticals and medical devices can be matched by other substances, such as precious metals** (e.g. gold, platinum). The price for precious metals is >1000 times higher than for fluoropolymers.

The information indicates that technically and economically feasible are not available for all uses of packaging of medical devices. The Dossier Submitters note that derogations for some uses in this area could be considered, but also that more information is required before a broad derogation covering packaging of medical devices in general could be considered.

The Dossier Submitters conclude that the evidence is [weak] that technically and economically feasible alternatives are [not generally available] for the quantities required for use in [packaging of medical devices] and that the substitution potential is [uncertain].

Concluding remarks on the availability, technical feasibility and economic feasibility of alternatives

The Dossier Submitters conclude based on information from the CfE and the second stakeholder consultation, that:

1. the evidence is [sufficiently strong] that technically and economically feasible alternatives are [not generally available] and that the substitution potential is [low] for the following medical device applications:
 - a. implantable medical devices (not including meshes and wound treatment products),
 - b. tubes and catheters,
 - c. coatings of Metered Dose Inhalers, and
 - d. diagnostic laboratory testing.
2. the evidence is [weak] that technically and economically feasible alternatives are [not generally available] and that the substitution potential is [uncertain] for the following medical device applications:
 - a. hernia meshes,
 - b. wound treatment products,
 - c. coatings (other than MDIs),
 - d. engineered fluids,
 - e. membranes used for venting of medical devices, and
 - f. rigid gas permeable contact lenses and ophthalmic lenses.
3. the evidence is [sufficiently strong] that technically and economically feasible alternatives are [generally available] and that the substitution potential is [high] for propellants in metered dose inhalers (MDIs).

4. the evidence is [weak] that technically and economically feasible alternatives are [generally available] and that the substitution potential is [high] for sterilization gases.

Regarding packaging of medical devices, the Dossier Submitters conclude that there is [weak] evidence that technically and economically feasible alternatives are [not generally available] for the following uses:

- PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics,
- PTFE in ophthalmic solutions packaging, and
- Packaging of terminally sterilised medical devices.

For any other potential uses of PFAS in the packaging of medical devices, no information on alternatives have been provided. The Dossier Submitters note that derogations for some uses in this area could be considered, but also that more information is required before a broad derogation covering packaging of medical devices in general could be considered.

E.2.9.2.2. Stakeholder input on timeframe for substitution and transition periods

A visualisation of the process of finding a technically suitable alternative – provided by a sector organisation – is the so-called “substitution hopper” illustrated in Figure E.15. This sets out the steps required starting from the identification of potential alternatives to the selection of materials/substances through to the final substitution in production (assuming success). Each step is essential and takes time. Should an alternative have sufficient of the desired properties to warrant testing, there is no guarantee that it can make it through the testing and approval loops necessary for the product to reach market. After an alternative is identified, the certification process applicable according to the products use (e.g. the approval process under the Medical Devices Regulation), also needs to be undertaken and can take a considerable amount of additional time, especially for medical and in-vitro medical devices. For a substitution to be successful, it must pass through all the stages successfully. As time goes on, more alternatives are ‘filtered out’ as they do not meet the requirements of each step in the process.

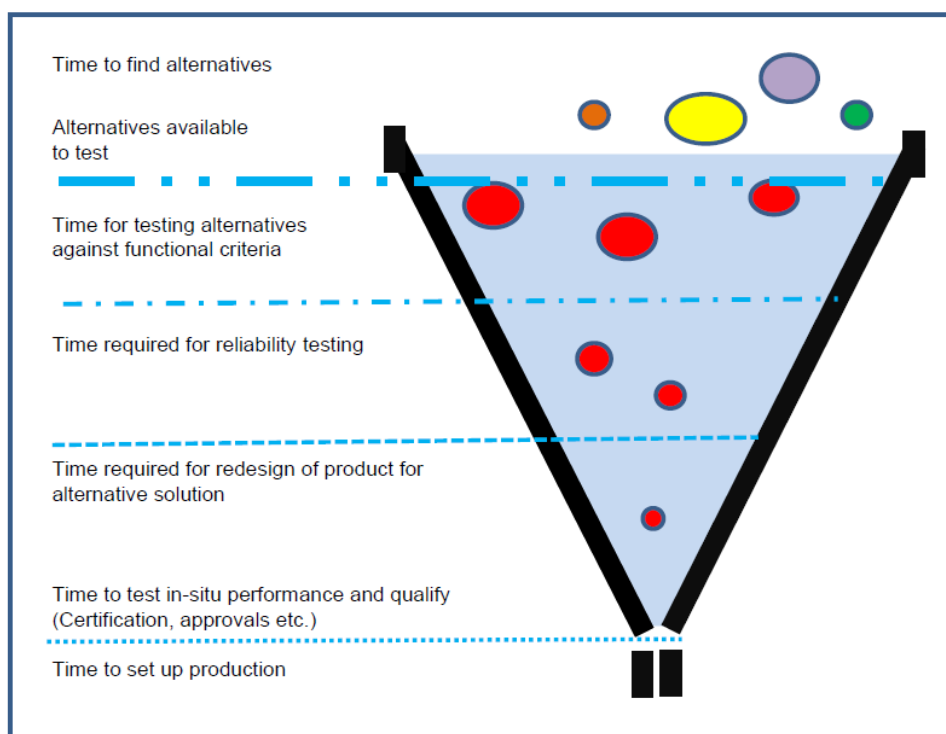


Figure E.15. Illustration of the “Substitution Hopper” (RINA, 2021).

The timeframes for substitution are highly dependent on the type of article in question, as well as the end use of the article. In general, the more stringent the technical requirements applicable to the application concerned and the greater the degree of regulation, the longer the expected implementation timeframe will be.

The majority of respondents to the second stakeholder consultation indicated that regulatory approval under the Medical Devices Regulation is expected to take up to 2 years. Some stakeholders noted that the approval time is dependent on the capacity of the regulatory authorities and that a restriction of PFAS could lead to a substantial number of applications for the authorities to process, thus extending the timeline of the approval process. It is also possible that the initial submissions may not be approved by regulatory authorities and in these cases approval times are extended. This approval process would follow a rigorous development process for an additional 2-5 years.

Stakeholders indicate that the process prior to approval can also be expected to take several years. Most respondents indicate that the complete process from identification of alternative to approved product takes at least 5-10 years, if alternatives are identified at all.

The Dossier Submitters conclude that in cases where technically and economically feasible alternatives have not already been identified, there is sufficiently strong evidence that identification, development and certification of alternatives would take more than five years to complete.

E.2.9.2.3. Human health and environmental hazards

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log K_{ow}) and bioconcentration factor (BCF) was assessed. Additionally, it was assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHA's dissemination site.

In relation to medical devices, the list of alternatives contained 13 unique CAS numbers. Two of these substances were classified according to CLP (self-classification). One substance (Parylene C) was, according to the registration dossier, a PBT substance. None of the remaining substances were known to fulfil the PBT or vPvB criteria, since they either did, according to their registration dossier, not fulfil the PBT or vPvB criteria or no data was found. For one substance with CAS number (PDMS), it was indicated that it may contain residues of D4, D5 and D6, cyclic siloxanes. D4, D5 and D6, and cyclic siloxanes are PBT/vPvB substances and D4 is an endocrine disruptor.

The list contained an additional 8 substances for which no CAS numbers were available. For these substances, no information on classification or PBT and vPvB assessments were available. For one substance group (silicones), it was indicated that it may contain residues of D4, D5 and D6, cyclic siloxanes. For one substance group (polyamides), it was indicated that it may contain residues of primary aromatic amines (PAA). Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.9.3. Environmental impacts

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.9.1, assuming business-as-usual and, consequently, on-going PFAS use and emissions. The analysis of environmental impacts focuses on two restriction options:

- **RO1**, adopting a ban of all PFAS used in medical applications after an 18-month transition period;
- **RO2**, adopting a ban on PFAS in combination with use-specific derogations. Regarding the duration of the derogations two variants are distinguished, i.e. a 5-year derogation and a 12-year derogation.

Environmental impacts of RO1 are analysed quantitatively. In contrast, for the use-specific derogations emission data were largely lacking. There is information available about the PFAS group which will be affected by a derogation. Therefore, environmental impacts of RO2 are evaluated qualitatively in relation to worst-case (maximum) additional environmental emission scenarios, i.e. a full derogation of each of the relevant PFAS groups (polymeric PFAS, fluorinated gases, PFAAs in precursors, or a combination of these). Note that these maximum additional emission worst-case scenarios do not represent restriction options. Table E.109 below summarizes the characteristics of the restriction options, and the maximum additional emission scenarios.

Table E.109. Characteristics of restriction options and maximum additional emission benchmark scenarios.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---
RO2	Ban with use-specific derogations	(i) Proposed derogation: Implantable medical devices (not including meshes, wound treatment products, and tubes and catheters) (ii) Potential derogation marked for reconsideration: Hernia meshes (iii) Potential derogation marked for reconsideration: Wound treatment products (iv) Proposed derogation: Tubes and catheters (v) Proposed derogation: Coatings of Metered Dose Inhalers (MDIs) (vi) Potential derogation marked for reconsideration: Coating applications for medical devices other than Metered Dose Inhalers (MDIs) (vii) Potential derogation marked for reconsideration: Cleaning and heat transfer: engineered fluids for medical devices (viii) Proposed derogation: Diagnostic laboratory testing (ix) Potential derogation marked for reconsideration: Rigid gas permeable (RGP) contact lenses and ophthalmic lenses (x) Potential derogation marked for reconsideration: Membranes used for venting of medical devices (xi) Potential derogation marked for reconsideration: PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics (xii) Potential derogation marked for reconsideration: PTFE in ophthalmic solutions packaging (xiii) Potential derogation marked for reconsideration: Packaging of terminally sterilised medical devices	18 months	12 years
Maximum additional emission scenario	Ban with full derogation of entire PFAS groups	Polymeric PFAS; polymeric PFAS + PFAAs (incl. precursors); fluorinated gases; polymeric PFAS + fluorinated gases + PFAAs (incl. precursors)	18 months	12 years

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, restriction options are expected to be implemented in 2027. All emission estimates represent mean values. Table E.110 shows mean emissions and the expected mean emission reduction for

time paths of 30 and 45 years (starting in 2025).

Table E.110. Total mean emissions and emission reduction of RO1 (medical devices sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	512 432	---	---
RO1	14 845	497 578	97
Maximum additional emission scenario '12-year derogation of polymeric PFAS ^{r*}	16 116	496 397	97
Maximum additional emission scenario '12-year derogation of fluorinated gases ^{r*}	39 915	472 508	92
Maximum additional emission scenario '12-year derogation of polymeric PFAS and PFAAs (incl. precursors) ^{r*}	27 647	484 775	95
Maximum additional emission scenario '12-year derogation of PFAAs and precursors, polymeric PFAS and fluorinated gases ^{r*}	50 023	462 400	90
2025-2070			
Baseline	1 221 554	---	---
RO1	14 845	1 206 709	99
Maximum additional emission scenario '12-year derogation of polymeric PFAS ^{r*}	16 116	1 205 429	99
Maximum additional emission scenario '12-year derogation of fluorinated gases ^{r*}	39 915	1 181 639	97
Maximum additional emission scenario '12-year derogation of polymeric PFAS and PFAAs (incl. precursors) ^{r*}	27 647	1 193 907	98
Maximum additional emission scenario '12-year derogation of PFAAs and precursors, polymeric PFAS and fluorinated gases ^{r*}	50 023	1 171 531	96

* Maximum additional emission scenarios denote worst-case emission scenarios (assuming a full derogation of a particular PFAS group) against which emissions of proposed use-specific derogations are evaluated qualitatively. They do not represent restriction options.

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage). The expected emission reduction is highest under RO1 (full ban of all PFASs after the 18 months transition period). RO1 achieves a total PFAS emission reduction of about 96% of baseline emissions. Environmental impacts of RO2 are discussed qualitatively below for each of the proposed derogations.

(i) Proposed derogation: Implantable medical devices (not including meshes, wound treatment products, and 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. Compared to a ban (RO1), a derogation will cause additional **polymeric PFAS** emissions. There is **no evidence available** about the precise amount of additional emissions from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric PFAS in this sector, maximum additional emissions would be 16 116 t (30-year period), which is slightly higher than emissions under RO1. However, it can be expected that additional emissions arising from the proposed derogation will be lower than the (worst-case) reference scenario.

(ii) *Potential derogation marked for reconsideration: Hernia meshes*

The derogation is marked for consideration for a duration 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. There is **no evidence available** about the precise amount of additional emissions that are to be expected from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric PFAS use in this sector, maximum additional emissions would be 16 116 t (30-year period), which is slightly higher than emissions under RO1. However, considering available information about tonnage levels for medical plastics it can be assumed that additional emissions will be a small fraction of emissions under the reference scenario (=full derogation of polymeric PFAS).

(iii) *Potential derogation marked for reconsideration: Wound treatment products*

The derogation is marked for consideration for a duration 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, and emissions of **PFAAs** and their precursors. There is **no evidence available** about the precise amount of additional emissions from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric and PFAA PFAS use in this sector, maximum additional emissions would be 27 647 t (30-year period), which is considerably higher than emissions under RO1.

(iv) *Proposed derogation: 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. Compared to a ban (RO1), a derogation will cause additional **polymeric PFAS** emissions. There is **no evidence available** about the precise amount of additional emissions to be expected from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric PFAS use in this sector, maximum additional emissions would be 16 116 t (30-year period), which is slightly higher than emissions under RO1.

(v) *Proposed derogation: Coatings of Metered Dose Inhalers (MDIs)*

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, and emissions of **PFAAs** and their precursors. There is **no evidence available** about the precise amount of additional emissions from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric and PFAA PFAS use in this sector, maximum additional emissions would be 27 647 t (30-year period), which is considerably higher than emissions under RO1. According to the data available to the Dossier Submitter, the amounts of PFAS use in this application can be considered to be very low (<100 kg), and emissions arising from this derogation are expected to be far below the (worst-case) reference scenario (i.e. a full derogation of polymeric and PFAA PFAS use in this sector).

(vi) Potential derogation marked for reconsideration: Coating applications for medical devices other than Metered Dose Inhalers (MDIs)

The derogation is marked for consideration for a duration 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, and emissions of **PFAAs** and their precursors. There is **no evidence available** about the precise amount of additional emissions from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric and PFAA PFAS use in this sector, maximum additional emissions would be 27 647 t (30-year period), which is considerably higher than emissions under RO1.

(vii) Potential derogation marked for reconsideration: Cleaning and heat transfer: engineered fluids for medical devices

The derogation is marked for consideration for a duration of 12 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. There is **no evidence available** about the precise amount of additional emissions from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all fluorinated gases' use in this sector, maximum additional emissions would be 39 915 t (30-year period), which is substantially higher than emissions under RO1. This would reduce the overall effectiveness of the restriction in this sector from 97% to about 80%.

(viii) Proposed derogation: Diagnostic laboratory testing

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 emissions of **PFAAs and PFAA precursors, fluorinated gases, and polymeric PFAS**. There is **no evidence available** about the precise amount of additional emissions from the derogation in this sector. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric PFAS, fluorinated gases and PFAA PFAS in this sector, maximum additional emissions would be 50 032 t (30-year period), which is substantially higher than emissions under RO1. However, considering available information about a use quantity of < 5 t per year, it is assumed that additional emissions arising from a derogation of this application will be a small fraction of emissions under the reference scenario (=full derogation of PFAAs and PFAA precursors, fluorinated gases, polymeric PFAS, see also Spectaris submission; <https://webgate.ec.europa.eu/s-circabc/ui/group/881f9fd7-9e57-4de5-ab12-35ce08dbf09b/library/ab4adafa-a315-428c-af1d-ff9bf547b6b8/details>).

(ix) Potential derogation marked for reconsideration: Rigid gas permeable (RGP) contact lenses and ophthalmic lenses

The derogation is marked for consideration for a duration 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. There is **no evidence available** about the precise amount of additional emissions from this derogation. However, considering available information about the use quantity of about 1 t/y, it is assumed that additional emissions will be of a small fraction compared to emissions under the reference scenario of 16 116 t (=full derogation of Polymeric PFAS, see also Spectaris submission; <https://webgate.ec.europa.eu/s-circabc/ui/group/881f9fd7-9e57-4de5-ab12-35ce08dbf09b/library/ab4adafa-a315-428c-af1d-ff9bf547b6b8/details>).

(x) Potential derogation marked for reconsideration: Membranes used for venting of medical devices

The derogation is marked for consideration for a duration of 12 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause **polymeric PFAS** emissions, and emissions from **PFAAs**. There is **no evidence available** about the precise amount of additional emissions from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric and PFAA PFAS use in this sector, maximum additional emissions would be 27 647 t (30-year period), which is considerably higher than emissions under RO1. Based on examples mentioned in the second consultation (culture devices, analytical devices, blood tube systems for dialyzer systems, tube systems for eye surgery) it is assumed that additional emissions will be a small fraction of emissions compared to the reference scenario (=full derogation of polymeric PFAS and PFAAs).

(xi) Potential derogation marked for reconsideration: PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics

The derogation is marked for consideration for a duration 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. There is **no evidence available** about the precise amount of additional emissions to be expected from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric PFAS use in this sector, maximum additional emissions would be 16 116 t (30-year period), which is slightly higher than emissions under RO1. Considering available information about tonnage levels for medical plastics, however, it is assumed that additional emissions will be a small fraction of emissions under the reference scenario (=full derogation of polymeric PFAS).

(xii) Potential derogation marked for reconsideration: PTFE in ophthalmic solutions packaging

The derogation is marked for consideration for a duration 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. There is **no evidence available** about the precise amount of additional emissions to be expected from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric PFAS use in this sector, maximum additional emissions would be 16 116 t (30-year period), which is slightly higher than emissions under RO1. Considering available information about tonnage levels for medical plastics it is assumed that additional emissions will be a small fraction of emissions under the reference scenario (=full derogation of polymeric PFAS).

(xiii) Potential derogation marked for reconsideration: Packaging of terminally sterilised medical devices

The derogation is marked for consideration for a duration of 12 years after EiF of the restriction and the 18 months transition period. Compared to a ban (RO1), a derogation will cause additional emissions from **polymeric PFAS** emissions, and emissions from **PFAAs**. There is **no evidence available** about the precise amount of additional emissions from this derogation. Under the (worst-case) reference scenario, assuming a full derogation of all polymeric and PFAA PFAS use in this sector, maximum additional emissions would be 27 647 t (30-year period), which is substantially higher than emissions under RO1. Considering available information about tonnage levels for medical plastics it is assumed that additional emissions will be a small fraction of emissions under the reference scenario (=full derogation of polymeric PFAS and PFAAs).

Figure E.16 below shows the time paths of mean emissions for the baseline scenario, RO1 and maximum additional emission scenarios for PFAS groups covered by the proposed derogations.

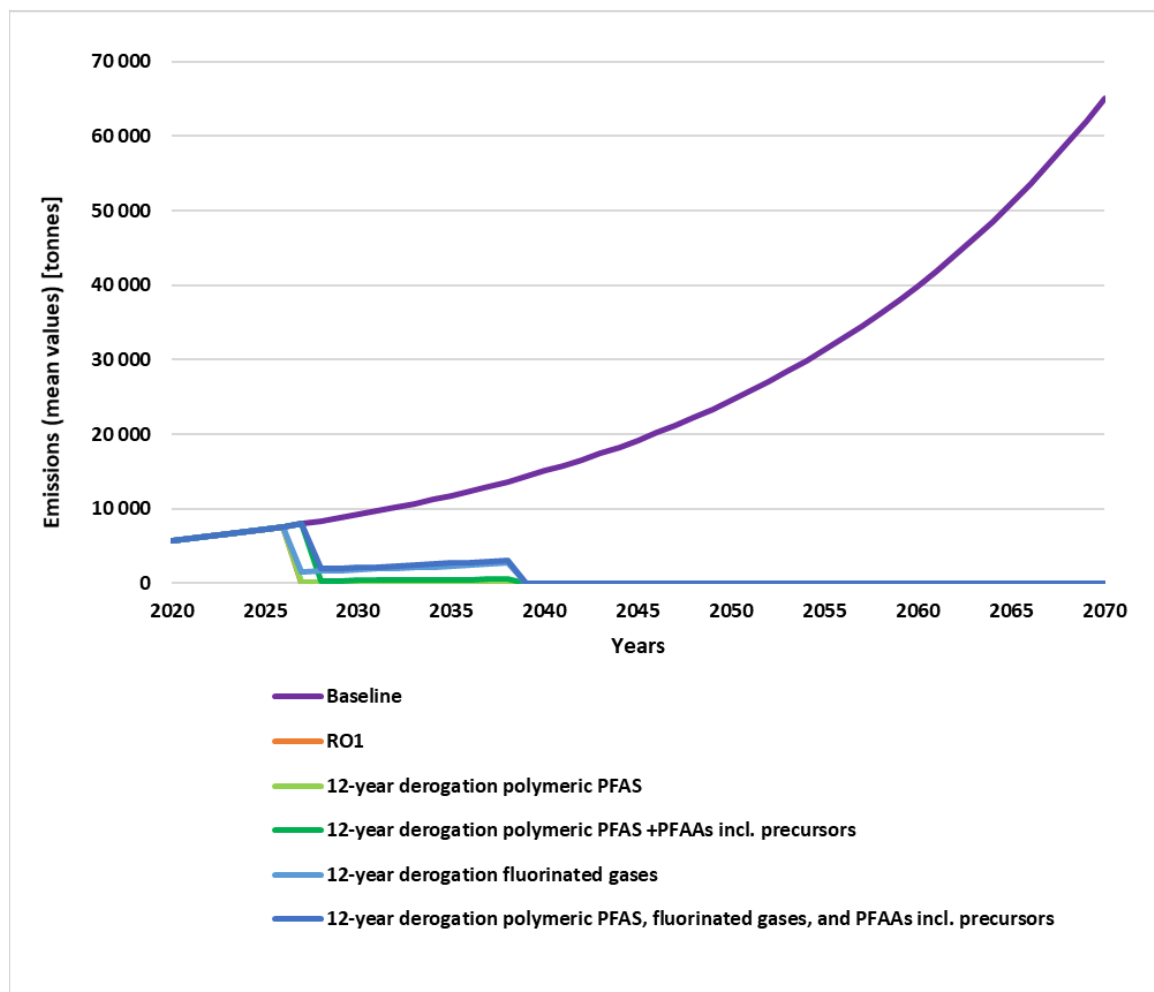


Figure E.16. Time path of mean emissions in the medical devices sector under the baseline, RO1 and maximum additional emission scenarios [tonnes] *

* The time path for a full ban (RO1) is very close to the time path of a 12-year derogation of polymeric PFAS. The orange line therefore overlaps with the light green line. Source: Own calculations based on data compiled by the Dossier Submitters.

E.2.9.4. Economic and other impacts

E.2.9.4.1. Implantable medical devices

Tubes and catheters, meshes and wound treatment products are covered in separate sections below. The conclusion from the assessment of alternatives is that there is sufficiently strong evidence that technically and economically feasible alternatives are not available.

The general feedback from the second stakeholder consultation on the impacts of a transition to alternatives is that:

- Fluoropolymers are generally relatively costly compared to alternatives. For applications where alternatives are technically feasible, substitution of fluoropolymers is already ongoing or finished.
- The properties of fluoropolymers provide increased lifetime of implants reducing risk of failure and risk of replacement.

Based on this input from stakeholders, the Dossier Submitters conclude that there is [sufficiently strong evidence] that a ban of the use of PFAS in implantable medical devices is

[likely] to have considerable impacts on the use of implantable medical devices and, consequently, on public health and that it would lead to [high socioeconomic costs].

Furthermore, the Dossier Submitters note that the second stakeholder consultation indicated that the complete process from identification of alternative to approved product takes at least 5-10 years in this sector. This indicates that a relatively long derogation period is required to avoid these costs.

E.2.9.4.2. Hernia meshes

The available information indicates that available alternatives are widely available, but that their functionality is lower. In the assessment of alternatives, the Dossier Submitters concluded that further justification for (or against) this assessment is needed in the Annex XV report consultation.

The Dossier Submitters note that, if technically feasible alternatives indeed are not available, a ban on PFAS would lead to increased risk of adverse health impacts (intestinal damage and fistula formation) in patients. These impacts are likely to be associated with high socioeconomic costs.

The Dossier Submitters conclude that there is [weak evidence] that a restriction of the use of PFAS in hernia meshes is [likely] to have [high socioeconomic costs]. This conclusion is an issue for clarification in the Annex XV report consultation.

E.2.9.4.3. Wound treatment products

Submissions from two stakeholders in the second stakeholder consultation indicate that technically feasible alternatives are not widely available. No further information on the impacts of a potential restriction was provided.

The Dossier Submitters conclude that the socio-economic costs of a ban on PFAS in wound treatment products is [uncertain].

E.2.9.4.4. Tubes and catheters

The assessment of alternatives above indicated that technically and economically feasible alternatives are not generally available. One respondent in the second stakeholder consultation noted that alternatives are feasible in some procedures, but it will be more painful for the patient, due to the higher friction coefficient. The use of catheters is a cost-effective technique compared to more invasive procedures. Especially the lubricity (smoothness) of the catheters is desired in medical applications (Bates and Campbell, 2015). The insertion of tiny, flexible and very smooth tubes enables small pathways and precision manoeuvring at the treated tissue and accelerate patients' recovery.

The Dossier Submitters note that the information obtained indicates that a ban on PFAS in these applications would lead to more procedures that are more invasive and/or more painful for the patient. The socio-economic costs related to these implications can be expected to be substantial.

The Dossier Submitters conclude that there is [sufficiently strong evidence] that a ban of the use of PFAS in tubes and catheters is [likely] to have considerable impacts on public health and that it would lead to [high socioeconomic costs].

Furthermore, the Dossier Submitters note that the second stakeholder consultation indicated that the complete process from identification of alternative to approved product takes at least 5-10 years in this sector. This indicates that a relatively long derogation period is required to avoid these costs.

E.2.9.4.5. Coatings

Regarding **coating of metered dose inhalers**, several stakeholders in the second stakeholder consultation indicate that alternatives to fluoropolymers are either non-compatible with the medicine, do not resist the corrosive environment or do not have the required non-stick properties that facilitates accurate dosage of the active pharmaceutical ingredients. The lack of technically feasible alternatives and the high societal value of the medicinal product indicates that this RO would be associated with substantial socio-economic costs. The Dossier Submitters conclude that there is [sufficiently strong evidence] that a ban of the use of PFAS in coatings of MDIs is [likely] to have considerable impacts on public health and that it would lead to [high socioeconomic costs]. Furthermore, the Dossier Submitters note that the second stakeholder consultation indicated that the complete process from identification of alternative to approved product takes at least 5-10 years in this sector. This indicates that a relatively long derogation period is required to avoid these costs for coatings of MDIs.

For **other coating applications**, no information on the impacts of a proposed restriction was provided and the Dossier Submitters conclude that the socio-economic costs of a ban on PFAS in these applications is [uncertain].

E.2.9.4.6. Cleaning and heat transfer: engineering fluids

The Dossier Submitters have no information on feasible alternatives. No information provided on the cost impacts of a ban.

The Dossier Submitters conclude that the socio-economic costs of a ban on PFAS in these applications is [uncertain].

E.2.9.4.7. Sterilization gases

The Dossier Submitters note the wide range of alternatives available and assumes that some of the alternatives listed in the assessment report from The Medical and Chemicals Technical Options Committee (MCTOC) of the Montreal Protocol are technically and economically feasible in the relevant applications. No information that contradicts this conclusion was received in the CfE or in the second stakeholder consultation.

The Dossier Submitters conclude that there is [weak evidence] that a restriction of the use of PFAS as sterilization gases is [likely] to have [low socioeconomic costs]. This conclusion is an issue for clarification in the Annex XV report consultation.

E.2.9.4.8. Diagnostic laboratory testing

In the assessment of alternatives above we concluded that there is sufficiently strong evidence that alternatives to PFAS are not generally available in this field of applications.

The Dossier Submitters note that a ban on PFAS could have substantial impacts on the feasibility of diagnostic laboratory testing, which in turn would have severe implications on public health.

The Dossier Submitters conclude that there is [sufficiently strong evidence] that a ban of the use of PFAS in diagnostic laboratory equipment is [likely] to have considerable impacts on public health and that it would lead to [high socioeconomic costs].

Furthermore, the Dossier Submitters note that the second stakeholder consultation indicated that the complete process from identification of alternative to approved product takes at least 5-10 years in this sector. This indicates that a relatively long derogation period is required to avoid these costs.

E.2.9.4.9. Vision applications – rigid gas permeable contact lenses and ophthalmic lenses

PFPE-coatings of ophthalmic lenses are applied make them easy to clean, hydrophobic, oleophobic and scratch resistant. The assessment of alternatives indicates that (unspecified) alternatives have lower quality and shorter durability. One stakeholder claims that this could imply lower quality of life for eyeglass users as well as increasing costs due to higher replacement frequency of eyeglasses. The Dossier Submitters note that these types of socio-economic impacts are not unlikely but does not have information to conclude on the magnitude of the impacts.

For rigid gas permeable (RGP) contact lenses, the assessment of alternatives indicates that both technical and chemical alternatives are widely available. According to information provided by the sector organisation Spectaris the technical alternatives (including eyeglasses and soft hydrogel contact lenses) are generally more comfortable or cheaper, but users still prefer RGP contact lenses, which indicates that RGP contact lenses have other superior characteristics (RINA, 2021). Spectaris also claims that the chemical alternative has lower technical functionality in some respects. The Dossier Submitters note that a ban on PFAS could have negative impacts on the quality of life for users of RGP contact lenses, but the severity of these impacts is unclear.

According to the sector organisation EUROMCONTACT, a ban on PFAS in RGP contact lenses soft contact lenses and ophthalmic solutions packaging would result in job losses in a range of 1 800 to 2 000 across production, packaging and distribution operations for the affected products sold within the EU, assuming that no alternatives are available (second stakeholder consultation).

The Dossier Submitters note that alternatives are available, but that a transition away from PFAS could lead to some negative socio-economic impacts. The information provided does not allow for quantification of these impacts. Further justification on the severity of the quality-of-life reductions and the increased costs due to more frequent replacements of eyeglasses is required to conclude on the magnitude of the socio-economic impacts of a ban on PFAS in these applications.

The Dossier Submitters conclude that the socio-economic costs of a ban on PFAS in these applications is [uncertain].

E.2.9.4.10. Propellants in Metered Dose Inhalers (MDIs)

Phasing out the use of PFAS propellants in MDIs can be partly met by increased use of technical alternatives, primarily dry powder inhalers (DPIs). As noted in the assessment of alternatives, the technical alternatives are not suitable for all types of patients. So, part of the phasing out of PFAS propellants – in case of a restriction – will need to be met by increased use of the non-PFAS propellant HFC-152a. In the absence of a policy driver, the market uptake of HFC-152a is expected to be rather slow. In the baseline scenario of the Commissions impact assessment for the review of the F-gas regulation, it is assumed that HFC-152a will be used in 1 % of the new MDIs in 2026, increasing to 50% in 2050 (EC, 2022). If the F-gas Regulation is revised in line with the proposal from the Commission (April 2022) the transition to HFC-152a is expected to happen more quickly. In the “proportionate action scenario” of an external preparatory study for the Commissions impact assessment, the penetration rate of HFC-152a increases sooner than in the baseline scenario and is estimated to reach an average of 47% over the period 2024-2036 (Öko-Institut et al., 2022).

One stakeholder in the 2nd stakeholder consultation claims that ongoing trials indicate that most (by volume), if not all, MDI treatments can be reformulated and approved to use HFC 152a, but the time needed for a complete transition away from the current propellants is unclear.

The expected year of the adoption of this restriction proposal is 2025. This will be followed by a transition period. The default transition period in this proposal is 18 months. Whether this period will be enough to facilitate a complete transition away from the currently used propellants is unclear. It is also unclear to what extent a transition that is faster than expected in the baseline scenario will lead to additional one-off capital costs or other transitional costs. These issues will need to be clarified in the Annex XV report consultation.

Apart from potential transitional costs, the costs of substituting to HFC-152a are likely to be very small. The price of HFC-152a is equivalent with the price of the currently used propellants in MDIs and the price of the gas is only a very small part of the price of the overall MDI product (less than 1%) which is mostly determined by the medicinal agent (Öko-Institut et al., 2022).

The pharmaceutical sector is a high margin industry. This implies that potential costs of substitution are likely to be internalized by the producers (in the form of lower profit margins) rather than passed on to consumers.

Since the approval process of HFC-152a in MDI applications is already ongoing, the Dossier Submitters assume that a ban on PFAS in these applications will not lead to any additional administrative costs for industry or authorities.

A long-term (post 2030) impact of a ban on PFAS-propellants in MDIs is that the low-GWP propellant HFC-1234ze is not a viable alternative. Unless alternative non-PFAS propellants with similar, or lower, GWP properties (or alternative technologies) are developed, a ban on PFAS propellants will make it more challenging (and probably more costly) to fulfil the objectives of the F-gas regulation. This implies that there is a trade-off between the objectives of the F-gas regulation and the objectives of this proposal for restriction of PFAS.

The Dossier Submitters conclude that the evidence is [sufficiently strong] that a restriction on PFAS as propellants in MDIs is [likely] to have [low socioeconomic costs]. The main uncertainty that needs to be clarified in the Annex XV report consultation is whether the 18-month transition period will be enough to facilitate a complete transition away from the currently used propellants and to what extent the transition will lead to additional one-off capital costs or other transitional costs.

E.2.9.4.11. Membranes used for venting of medical devices

The assessment of alternatives above concluded that there is weak evidence that technically feasible alternatives are not generally available. The Dossier Submitters have no information on the socio-economic implications of a ban on PFAS in these applications, if feasible alternatives indeed are not available. The Dossier Submitters conclude that the socio-economic costs of a ban on PFAS in these applications is [uncertain].

E.2.9.4.12. Packaging of medical devices

The assessment of alternatives above concluded that there is weak evidence that feasible alternatives are not generally available for the following packaging applications:

- PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics.
- PTFE in ophthalmic solutions packaging.
- Packaging of terminally sterilised medical devices.

For other packaging of medical devices there was no evidence on the availability or feasibility of alternatives.

The Dossier Submitters note that packaging in some instances is of high importance for the functionality and safety of medical devices and that changes in packaging require renewed

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quality assessments and regulatory authorisations.

The Dossier Submitters conclude that in applications where packaging is of high importance for functionality and safety, and where there are no available alternatives that meets the technical requirements, there is [sufficiently strong] evidence that a ban on PFAS is [likely] to have [high socioeconomic costs]. The Dossier Submitters do not have the information available to identify these applications. Further information is requested in the Annex XV report consultation.

In applications where packaging is not of high importance 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 on PFAS would have [low socioeconomic costs].

E.2.9.5. Summary of cost and benefit assessment

Table E.111 summarises the outcomes of the assessment of costs and benefits for medical devices. For further information on cost impacts, see section E.2.9.4.

Table E.111. Medical devices - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Medical devices					
Full ban	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives are generally available, and that the substitution potential is high for propellants in metered dose inhalers (MDIs). Weak evidence that technically and economically feasible alternatives are generally available, and that the substitution potential is high for sterilization gases. Sufficiently strong evidence that technically and economically feasible alternatives are not generally available, and that the substitution potential is low for implantable medical devices (not including meshes and wound treatment products), tubes and catheters, coatings of MDIs, and diagnostic laboratory testing equipment.	According to available evidence, which is considered sufficiently strong, the expected emission reduction from the restriction is 497 578 t for a 30-year period (2025-2055), and 1 206 709 t for a 45-year period (2025-2070). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as	Sufficiently strong evidence that a ban in propellants in MDIs is likely to have low socioeconomic costs. Weak evidence that a ban in sterilization gases is likely to have low socioeconomic costs. Sufficiently strong evidence that a ban in implantable medical devices (not including hernia meshes and wound treatment products), tubes and catheters, coatings of MDIs, and diagnostic laboratory testing equipment is likely to have considerable impacts on public health and would consequently lead to high socioeconomic costs. Weak evidence that a ban in hernia meshes would have high socio-economic costs. The cost impacts of a ban on wound treatment products, coatings (other than coating of MDIs), engineered fluids, rigid gas permeable contact lenses and ophthalmic lenses and membranes used for venting of medical devices are unknown. Packaging. In applications where packaging is of high importance for the functionality and safety of	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		Weak evidence that technically and economically feasible alternatives are not generally available, and that the substitution potential is uncertain for wound treatment products, coatings (other than coating of MDIs), engineered fluids, rigid gas permeable contact lenses and ophthalmic lenses, hernia meshes, membranes used for venting of medical devices and the following packaging of medical of devices: PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics, PTFE in ophthalmic solutions packaging, and packaging of terminally sterilised medical devices. For other packaging of medical devices, there is no evidence on alternatives available.	well as emissions avoided as a result of the restriction are likely underestimated.	the medical devices, and where there are no available alternatives that meets the technical requirements, there is sufficiently strong evidence that a ban would have high socioeconomic costs. The Dossier Submitters do not have the information available to identify these applications. In applications where packaging is of now or low importance 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 would have low socioeconomic costs.	
Ban with use-specific derogations: Derogation for (i) implantable	5 years	Sufficiently strong evidence that the substitution potential is low for implantable medical devices (not including meshes and wound treatment products), tubes and catheters, coatings of MDIs, and diagnostic laboratory testing	Compared to a 12-year derogation, expected additional emissions will be lower, but the same	Same or similar as under a full ban.	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
medical devices, (ii) hernia meshes, (iii) wound treatment products (iv) tubes and catheters, , (v)coatings of MDIs,, (vi) coating applications for		equipment. Sufficiently strong evidence that technically and economically feasible alternatives are not generally available for these uses and sufficiently strong evidence that identification, development and certification of alternatives would take more than five years to complete. Weak evidence that technically and economically feasible alternatives are not generally available for the other use-specific derogations.	conclusions can be drawn in relation to a full ban (RO1).		
medical devices, (vii) cleaning and heat transfer (viii) diagnostic laboratory testing equipment , and (ix) rigid gas permeable contact lenses and ophthalmic lenses (x) membranes	12 years	Unknown, depending on R&D progress, but continued R&D increases the chance that alternatives for the relevant applications will be identified.	No evidence available about the precise amount of additional emissions from this derogation. For (i), (ii), (iv), (ix), (xi), (xii): Under the (worst-case) reference scenario, assuming a full derogation of all polymeric PFAS in this sector, maximum additional	If feasible alternatives are identified, developed and approved, the public health concerns (and their related socio-economic costs) due to reduced functionality of the medical devices where derogations are considered would be avoided. The process of identifying and developing alternatives will be associated with considerable costs. If feasible alternatives are not identified (or not approved) then the socio-economic costs after the end of the derogation period would be equivalent with the costs outlined in the full ban scenario above.	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
for venting of medical devices (xi) PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics , (xii) PTFE in ophthalmic solutions packaging, (xiii) packaging of terminally sterilised medical devices.			emissions would be 16 116 t (30-year period), which is slightly higher than emissions under RO1. Additional emissions arising from the proposed derogation are expected to be lower than the (worst-case) reference scenario. For (iii), (v), (vi), (x), (xiii): Under the (worst-case) reference scenario, assuming a full derogation of all polymeric and PFAA PFAS use in this sector, maximum additional emissions would be 27 647 t (30-year period), which is considerably		

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
			higher than emissions under RO1. Additional emissions from these derogations can be expected to be a small fraction of emissions compared to the reference scenario. For (vii): Under the (worst-case) reference scenario (= full derogation of all fluorinated gases' use in this sector) maximum additional emissions would be 39 915 t (30-year period), which is substantially higher than emissions under RO1. This would reduce the overall effectiveness of		

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
			the restriction in this sector from 97% to about 92%. For (viii): Under the (worst-case) reference scenario, assuming a full derogation of all polymeric PFAS, fluorinated gases and PFAA PFAS in this sector, maximum additional emissions would be 50 023 t (30-year period), which is substantially higher than emissions under RO1. Factual emissions from this derogations are assumed to be a small fraction of emissions under the reference scenario.		
Conclusion	A full ban of PFAS with a <u>transition period of 18 months is proposed for:</u>				

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		• propellants in Metered Dose Inhalers, • sterilization gases, and • packaging of medical devices, excluding: ○ PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics, ○ PTFE in ophthalmic solutions packaging, and ○ packaging of terminally sterilised medical devices. A full ban of PFAS with a time-limited <u>derogation period of 12 years (after the 18 months transition period) is proposed</u> for: • implantable medical devices (not including meshes and wound treatment products), • tubes and catheters, • coatings of Metered Dose Inhalers, and • diagnostic laboratory equipment. A full ban of PFAS with a time-limited <u>derogation period of 12 years (after the 18 month transition period) is under consideration</u>, but further justification is needed, for: • hernia meshes, • wound treatment products, • coatings applications for medical devices (other than coating of Metered Dose Inhalers), • engineered fluids for medical devices, • membranes used for venting of medical devices, • rigid gas permeable contact lenses and ophthalmic lenses, and • the following packaging of medical of devices: ○ PCTFE-based packaging for medicinal preparations, medical devices and molecular diagnostics, ○ PTFE in ophthalmic solutions packaging, and ○ packaging of terminally sterilised medical devices. In light of the weak evidence that technically and economically feasible alternatives are not available for these applications is not proposed at this point but marked for reconsideration. A derogation might be proposed at a later stage if additional information on the (lack of) availability of feasible alternatives is provided.			

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A full ban with a transition period of 18 months is proposed for uses where the Dossier Submitters have identified that technically and economically feasible alternatives are available (propellants in MDIs and sterilization gases), or where there is no information explicitly indicating that technically and economically feasible alternatives are not available (packaging of medical devices, with some exceptions).

A 12-year derogation, after the 18 months transition period, is proposed for uses where there is a sufficiently strong evidence base showing that significant R&D efforts did not identify PFAS-free alternatives and it is likely that they will not become available in the near future and/or that there is sufficiently strong evidence provided that certification of PFAS-free alternatives cannot be achieved within a five-year derogation period. The Dossier Submitters note that the second stakeholder consultation indicated that the complete process from identification of alternative to approved product takes at least 5-10 years in this sector. All uses where the Dossier Submitters have assessed that the evidence is sufficiently strong that technically and economically feasible alternatives are not generally available, are proposed to get a 12-year derogation.

A 12-year derogation after the 18 months transition period is under consideration for uses where the justification of a derogation (i.e. non-availability of technically and economically feasible alternatives) is based on a weak evidence base.

E.2.10. Transport

The transportation sector covers all modes of transport, by road, rail, air and sea. PFAS are used in a wide range of functions in the transportation sector, listed in Annex A.3.11. This section concerns use of PFAS in:

1. Sealing applications, such as o-rings, seals in valves, gaskets, pistons, draft shafts to prevent loss of fluids and to protect components
2. Other uses in drive systems such as lines and hoses, use in gas turbine engines for improving efficiency and reducing emissions, lubrication free bearings
3. Other uses relevant to vehicle safety, such as in seat belt mechanisms and brake pads
4. Corrosion inhibitors in hydraulic fluids
5. Mobile air conditioning (MAC) systems
6. Refrigeration systems

Other uses with relevance to transport are covered elsewhere in the dossier, including:

- TULAC: Annex E.2.2
- Metal plating and manufacture of metal products: Annex E.2.4
- Electronics and semiconductors: Annex E.2.11
- Energy (Batteries and fuel cells): Annex E.2.12
- Lubricants: Annex E.2.14

Such uses are not discussed further in this section, but the conclusions reached in other sections apply equally to transport.

There are a wide range of functions and characteristics of PFAS in the transportation sector, including:

- Durability
- Flexibility
- Resistance to chemical attack
- Resistance to UV
- Electrical properties
- Heat transfer properties
- Performance over a range of operating conditions
- Low weight
- Low or non-flammability
- Non-stick properties

E.2.10.1. Baseline

For assessing the time path of PFAS use (tonnage) and emissions in the transportation sector a mean real growth rate of 1%/y was assumed¹¹⁰. 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. The start year of the assessment is 2020. Baseline tonnage and emission estimates are projected for a time path of 30 and 45 years (2025-2070) as presented in Table E.112.

¹¹⁰ <https://www.acea.auto/figure/vehicle-sales-mirror-economic-growth-2006-2019-trend/>, date of access: 2023-01-11.

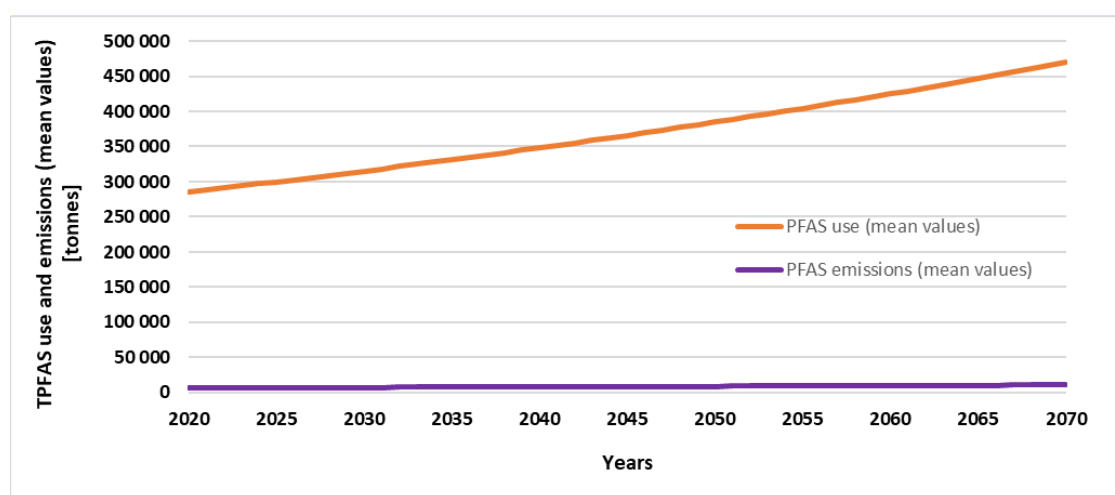
Table E.112. Projected yearly PFAS use and emissions in the transportation sector of the EEA in tonnes (mean values based on available market data).

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	285 391	299 949	315 249	331 330	348 231	365 994	348 664	424 908	469 363
PFAS emissions	6 723	7 066	7 426	7 805	8 203	8 622	9 062	10 010	11 057

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage).

Based on the assumptions discussed above, PFAS use and emissions in the transportation sector are expected to grow considerably under the baseline scenario. Since the assumed market growth rate is uncertain, especially in the long run (beyond 2050), PFAS use, and emission estimates have to be treated with care. Still, considering the continued expansion of E- documented in Annex, it is likely that PFAS use (and, in turn, emissions) will continue to grow in the long term without a restriction. This growth is predominantly caused by continued demand for fluoropolymers used in sealing applications, and by the use of fluorinated gases for mobile refrigeration and air conditioning.

Figure E.17 shows expected PFAS use and emissions for the sector, based on available market data documented in Annex A, and assumptions on growth rates explained above. Emissions during the use phase occur from the use of PFASs used in HVACR-systems and fluoropolymers and are calculated from PFAS use estimates and relevant ERCs. Therefore, emission trends mirror the trends for PFAS use. Despite the large tonnage of PFAS used in the transportation sector, emissions account for less than 1% of PFAS use. This low fraction can be explained by the assumed very low emissions from fluoropolymer use. The start year of the projection of tonnage and emission estimates is 2020 as presented in Table E.112.

**Figure E.17. Expected PFAS use and emissions in EEA under the baseline in the transport sector (mean values) [tonnes]**

Source: Own calculations based on market data collated by the Dossier Submitters.

E.2.10.2. Alternatives

E.2.10.2.1. Technical feasibility

Information on alternatives is only available for a few applications. The applications where information on alternatives is provided are presented below. If provided, also information on legal approval schemes and possible timelines for transitions to alternatives are described for the different applications. Also, some general information on the availability of alternatives and legal approval schemes was provided by stakeholders during the CfE and 2nd stakeholder consultation. This will briefly be presented below. The information presented in the next chapters is summarized in Table E.113.

The manufacturers of transportation vehicles usually do not prescribe the use of individual substances to their suppliers but rather stipulate performance requirements that the individual parts have to meet. Performance requirements are laid down for example in industrial standards (e.g. DIN, EN, ISO), or individual company standards, but may also be dictated by legal frameworks (e.g. Regulation (EU) 2018/858 or 2013/168). In an economically driven and competitive sector, such as the manufacture of transportation vehicles, suppliers are incited to provide the most cost-effective solutions that still meet the performance requirements. Since the production of fluorine containing materials usually is more expensive compared to most other materials (e.g. PE $\approx$ 1€/kg and PTFE $\approx$ 12.75 €/kg, information received from stakeholder) it could be assumed that fluorinated materials are used only where performance requirements leave no other option. Yet, it should be carefully considered whether this holds true for all transportation applications. Performance or safety requirements are most likely not relevant for the application of PFAS in e.g. the coating of trim materials to achieve stain protection and give surfaces a valuable feel and look. Similarly, the treatment of textiles e.g. for seats, carpets, roof linings, to give the textiles water and dirt repellent properties. This indicates that PFAS are used if it is considered that there is a quality improvement that customers are willing to pay for.

One stakeholder provided information, that in automotive and aerospace applications silicones are usually banned due to the high risk of contamination, without specifying what kind of contamination this refers to, or legal texts or standards where this is fixed.

A different stakeholder presented information regarding transition times for road vehicles. It was stated that, if alternatives were available and suitable for the dedicated applications, a transition can be estimated to take 5 - 10 years taking into account the time for new material development, manufacturing process adaptations or set-up of new manufacturing technologies and alternative product designs. New vehicles whose development begins today would be on the market in 6 - 7 years (for trucks 10 - 12 years). For already developed vehicles, it was stated that a transitional period of 15 years is needed until the end of the production of these vehicles.

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Table E.113. Alternatives for PFAS substances used in transportation products and articles. Empty cells indicate that no information was received. The estimate of time needed for substitution is taken from estimates provided by stakeholders and accounts only for the time needed for substitution once an alternative has been identified.

Application	Non PFAS alternative	Substitution potential	Estimate of time needed for substitution
Body-, hull-, and fuselage construction	No information identified or submitted to the consultation process		2-3 years
Sealing applications	- Non-fluorinated polymers (e.g. NBR, ACM, CR), - mechanical seals made of ceramics	Suitable for some specific applications but overall disadvantages compared to fluorinated polymers (e.g. reduced lifetime, emissions, friction)	>5 years
Combustion engine system (lines and hoses)	- Nylon - All-metal fuel lines	- Nylon fails to fulfil the emission requirements - All-metal fuel lines do not meet crash test standards	
Hydraulic fluids	None available (for aviation sector)		>10 years
Coating and finishes	Hydrophobic coatings for windshields: - Varnishes (e.g. poly acrylates) - Silicon based materials - Polypropylated aromatics - Fatty alcohols - Fatty acids - Alkylsilanes - Nano-particles For sliding element applications - UHMW-PE PTFE coated tubes - PEX (irradiation crosslinked Polyethylene) Control cable liners - Non-PFAS based polymers Lubrication free bearings:	- scratch sensitive - sensitive to hydrolysis - no grafting function - weak adsorbance to glass - sensitive to hydrolysis - low resistance to UV-B - superhydrophobicity could not be observed in practice - only if no special requirements regarding service temperature or chemical resistance - only if no special requirements regarding service temperature or chemical resistance - must still contain some PTFE filler to meet the gliding properties alternatives are missing one or two of the key requirements: either low friction, low stiffness or high temperature resistance	>2 years >10 years >10 years

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Application	Non PFAS alternative	Substitution potential	Estimate of time needed for substitution
	- Polyamid (PA) - Polybutylene Terephthalate (PBT) - Polyetheretherketone (PEEK) - Polypropylene (PP) - Silicone pavement markings and reflective sheetings	none-available	3 months – 4 years (depending on the country)
HVACR-systems in transport vehicles	• Air • Water • Ethylene glycol • Mineral oils • Silicone oils • Alcohols • Natural gases: HC-600 (n-butane), R-717 (Ammonia), R-744 (CO₂) • R152a Alternatives are not drop-in replacements but require adaptation of equipment.	Disadvantages: a) Electrically conductive b) Create corrosion c) More energy necessary to reach low temperatures d) Flammable and/or explosive e) Higher levels of toxicity f) Higher global warming potential (GWP) levels g) Not thermally stable h) High working pressure i) Water reactive j) Require periodic replacement and need to be disposed of Advantages: (i) Air, water, CO₂ etc. are widely available, cheap, have non to low GWP and are easier to handle during service and end of life. (ii) Modern HVAC-solutions with natural alternatives may even be more energy efficient than the use of fluorinated gases.	5-11 years

Body-, hull and fuselage construction

No information on alternatives for this application was received during the CfE and 2nd stakeholder consultation.

Legal approval schemes and timelines for transition

Stakeholders mentioned two specific standards regarding the manufacture of parts for automotive vehicles: ASTM2000, ISO/TS16949. Additionally, there are individual manufacturers specifications. Transition times where alternatives are available, were predicted to be 2-3 years to run function tests and give sufficient time for approval.

Sealing applications

Currently, fluorinated polymers are used to produce various seals for transportation vehicles. They provide important functions such as protection from dust and aggressive chemicals (lubricants, fuels, diesel) to ensure functionality and reduce service intervals. Furthermore, they prevent leakage and are therefore important for emission reduction.

Alternatives to fluorinated polymers for sealing applications in transportation vehicles need to meet various requirements. They need to have a durability against lubricants, fuels, diesel, cooling agents and/or other fluids and have to provide good sealing properties over wide range of temperatures.

In the following Table E.114 potential alternatives and their suitability for different sealing applications (if specified) are summarized.

Table E.114. Alternatives for sealing applications.

Alternative	Application	Suitability
Non-fluorinated polymers (e.g. nitrile butadiene rubber (NBR or HNBR), acrylate rubber (ACM or AEM), silicone rubber, mechanical seals (ceramics)	General sealing applications	Provide good properties over a wide range of temperatures (ca. -30 - +150 °C) but significant disadvantages concerning overall performance and emissions Nitril rubber has approx. 10% of the lifetime of fluorocarbon and above 100 °C even lower
Tribo-modified Polyurethane	Sealing piston rings at high pressure	
NBR or neoprene rubber (CR)	water-lubricated bearings in stern tube seals for marine vessels	Generally suitable but are inferior in friction and wear characteristics compared to PTFE

Legal approval schemes and transition times

One stakeholder informed about specifications BS EN 14432 & BS EN 14433 for lined valves used in the transportation of dangerous goods suitable for liquid and gas. BS EN 14433 is currently under review by the technical committee which has to be performed not more than 5 years after publication. Thus, these approval schemes could be revised within a timeframe of 5 years. However, the simultaneous revision of many standards would take longer because of limited availability of qualified and experienced personnel, possibly a decade.

One stakeholder informed the consultation that stern tube sealing devices on marine vessels have to be approved by the Ship Classification Society. Accordingly, it is necessary to re-

acquire all ship class approvals when the seal is changed to a substitute material. The time required for a transition was estimated to be >5 years for R&D activities. Timelines for the approval of new materials for existing standards were not mentioned.

Combustion engine system

PFAS-containing materials are used in combustion engine systems because of their durability and resistance against heat, pressure and corrosive chemicals. Further, these materials are much lighter than e.g. metal-based materials. The main use of PFAS-containing materials in combustion engines is in sealing and coating applications (see respective sections in Annex A). Non-woven textiles are applied as cover in the engine bay area of many vehicles as acoustic insulation inside the vehicle engine compartment. They are treated with PFAS to achieve oil repellence and high temperature resistance i.e. to make them non-flammable.

Regarding alternative materials for lines and hoses one stakeholder commented that alternatives based on nylon fail to fulfil emission requirements, and all-metal fuel lines do not meet crash test standards, though further details were not provided. Other information on alternatives to the use of fluorinated polymers or non-woven textiles in combustion engine systems were not mentioned. There are alternatives available for the treatment of textiles (see Section E.2.2.2) but it remains unclear to the Dossier Submitters if those alternatives meet the requirements for the application in combustion engine systems.

Legal approval schemes and timelines for transition

Combustion engines need to comply with the current and future European CO₂ and other emission legislation. It is particularly notable that the Council and the European Parliament have reached a provisional political agreement on stricter CO₂ emission performance standards for new cars and vans for moving towards zero-emission mobility. Pending formal adoption, the following targets have been agreed:

- 55% CO₂ emission reduction target for new cars and 50% for new vans by 2030 compared to 2021 levels
- 100% CO₂ emission reduction target for both new cars and vans by 2035.

Hydraulic fluids

According to stakeholder information the anti-corrosion agent added to hydraulic fluids can contain several fluorinated cyclohexanes and trace amounts of unidentified residual fluorochemicals. These are considered to be a byproduct of the manufacturing process. The information provided only referred to hydraulic fluids in aircrafts but it might also be valid for other transportation vehicles.

So far, no acceptable non-PFAS alternatives have been approved for use in the aviation sector, according to stakeholder information. No information for other sectors of transportation was provided during the CfE.

One stakeholder provided a non-exhaustive sample list regarding approval schemes for military and industry specifications for hydraulic fluids:

- Boeing Material Specification (BMS)3-11: Hydraulic Fluid, Fire Resistant
- MIL-PRF-8328: Hydraulic Fluid, Fire Resistant, synthetic hydrocarbon base, metric, NATO code number H-537
- MIL-PRF-87257: Hydraulic Fluid, Fire Resistant, synthetic hydrocarbon base, low temperature, aircraft and missile
- SAEAS1241: Fire-Resistant Phosphate Ester Aviation Hydraulic Fluid

Transition times were estimated by the stakeholder to be at least ten years. Based upon

previous experience, this is the time needed to develop, qualify and certify alternatives.

Coating and finishes

Fluorinated polymers are used in coating applications in the transportation sector because of their good performance over a wide range of temperatures (anti crack resistance), abrasion resistance, fire resistance and resistance to aggressive chemicals. In some special coating applications fluorinated polymers are used due to their dielectric properties, low thermal conductivity, non-stick properties and UV-stability.

There are some fluorine free materials available which can be used to achieve a protective coating (e.g. for coated trim materials)

- Silicone based chemicals
- Sulfosuccinates
- Propylated aromatics
- Fatty alcohol polyglycol ether sulphates
- Alkyl acrylates
- Polyurethanes and -acrylics

According to one stakeholder, a disadvantage of these materials is their higher layer thickness and the likelihood of cracking under high temperatures.

Extensive information was provided by one stakeholder regarding alternatives for PFAS-based coatings on windshields. Varnishes, which may contain polyacrylics, alkyl acrylates or polyurethane are not suitable as they are too scratch sensitive. Silicone-based solutions have good hydrophobicity but low durability (sensitive to hydrolysis) as the grafting on glass is not dense. OH-terminated silicone has also been tested: although such substances are relatively UV stable they are very sensitive to hydrolysis. Polypropylated aromatics do not have a grafting function. Sulfosuccinates are more suitable for metals. Fatty alcohols are absorbed only by physisorption via their OH functions. Fatty acids may absorb slightly more strongly to glass but their hydrolytic resistance is low. Different alkylsilanes have been tested with different carbon chain length: long chain alkylsilanes have a very low resistance to UV-B compared to the current substance used. Short chain alkylsilanes have a too low hydrophobicity and intermediate sizes are neither stable nor significantly hydrophobic. Solutions based on nanoparticles and hydrophobic grafting (fluorinated in this case) have also been tested. These solutions promise superhydrophobicity but it was not observed in practice. Above all, there is no grafting on glass, so the stability to water (wet heat) is very low.

For sliding element applications made from PTFE (such as used in the sliding components of roofs of convertibles) ultra-high molecular weight polyethylene (UHMW-PE) can be used as a non-PFAS alternative as long as there are no special requirements regarding service temperature or chemical resistance (stakeholder information).

As a potential alternative for PTFE-tubing, PEX (irradiation crosslinked Polyethylene) was mentioned by one stakeholder. However, this is only applicable in cases where the temperature is low and chemical attacks do not occur.

Other polymers can be used for control cable liners, but according to stakeholder input, must still contain some PTFE filler to meet the gliding properties.

According to stakeholders, alternatives are not available for coatings for lubrication free bearings, failing on one or two of the key requirements: either low friction, low stiffness or high temperature resistance. More rigid materials (e.g. polyamid (PA), Polybutylene Terephthalate (PBT), or Polyetheretherketone (PEEK)) cannot be used as they are not flexible enough. Additionally, they cannot adjust to edge loading. Materials of lower thermal stability (e.g. PE, polypropylene (PP)) do not survive the temperatures which occur during the curing of the paint on the car body or in the exhaust gas stream. High temperature materials (PA,

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PEEK, Silicone) do have significantly higher friction (4 to 10 times) (stakeholder information)

One stakeholder provided information, that for PTFE waxes no drop-in replacements with equal performance are available.

Approval schemes and timelines for transition

Timelines for approval of new standards were estimated from 1 (automotive) to 7 (aerospace) years (stakeholder information).

Regarding the aerospace industry one stakeholder informed that it is regulated by the FIA and must conform to ISO AS9100 and follow the NADCAP system for product introduction

One stakeholder estimated transition times for non-critical applications in the automotive sector to be around 3 years whilst for the most demanding applications in aeronautics this could be much longer, citing global aero and auto norms (e.g. EN9100, or IATF16949).

According to the CS25 (aeronautic standard, by the EASA) aircraft must be equipped with technology allowing a clear portion of the windshield during rainy conditions. Modification of the certification of these aircraft types, which is a process that can take up to 2 years, to which is added the time needed for the actual modification of all aircraft in service.

Transition time to switch to non-PFAS alternatives for tube coatings or sliding element applications are estimated by one stakeholder to be at least 10 years.

For alternatives for PTFE waxes typical reformulation times can take up to 5-10 years (stakeholder information)

Regarding alternatives for interior coatings of public transportation vehicles to achieve fire resistance timelines were estimated to be at least 15 years by one stakeholder: 5 years for the actual paint development and 10 years for qualification and certification.

HVACR-systems: Overview

This section provides an overview of HVACR (Heating, Ventilation, Air Conditioning and Refrigeration) applications in the transportation sector. These cover a range of situations including cooling of passenger/operative cabins, regulation of battery temperature, refrigeration of goods in transit and refrigeration in the fishing industry. Further information on individual sectors within transportation is given below.

Refrigerant charges (PFAS or other heat transfer agents) across these uses range from a few hundred grams in light vehicles to several tonnes in factory ships.

PFAS are commonly used as heat-exchange media in HVACR-systems of transport vehicles due to their technical properties e.g. good thermal capacity, wide range of operating temperatures, low-/non-flammability, and non-corrosivity. Further information on alternatives to PFAS as heat transfer media is provided in section E.2.8.2.

A limited number of alternatives to the use of fluorinated gases has been identified for further consideration (Table E.115). Inclusion in the table does not indicate that options identified for the different sectors are alternatives that can be deployed now or in the future, but simply summarises what has been identified from consultation and literature review for further discussion below.

Table E.115. Summary of the identified alternatives to fluorinated gases in HVACR applications in transport.

	Transport refrigeration	Mobile air conditioning
CO ₂ refrigerant	✓	✓
NH ₃ refrigerant	✓	
CO ₂ , N ₂ as direct coolant	✓	
Propane	✓	✓
R152a		✓
Not in-kind refrigeration: Insulation	✓	

R152a is listed in Annex I of the F-gas Regulation (517/2014) and has a global warming potential of 124, though this is below the threshold GWP of 150 specified in the MAC Directive (2006/40/EC). Although an HFC, it has no F-saturated carbon atoms and hence does not meet the criteria for PFAS defined in this proposal.

Stakeholders raised a number of disadvantages for non-PFAS heat transfer agents (though not all are relevant in all cases):

- Lack of drop-in replacements, with alternatives needing systems engineered to cope with different operating conditions of the alternative heat transfer agents
- Electrically conductivity
- Reactiveness, with potential for degradation with the possibility of periodic replacement, potential for creating corrosion
- Energy efficiency especially for lower temperatures
- Added risk of flammability or toxicity
- Global warming potential (GWP)
- High working pressure due to a higher boiling point, leading to the need for more robust engineering.

However, there are also some advantages associated with the use of non-PFAS alternatives, especially regarding the use of “natural” alternatives i.e. air, water, CO₂ etc. They are widely available, cheap, have no or only a low GWP (R152a being a partial exception) and are easier to handle during service and end of life. Modern HVACR-solutions with natural alternatives may even be more energy efficient than the use of PFASs. An air-cycle system for a train HVACR-system was reported to render up to 28% of annual energy savings compared to R-134a systems (Aigner R., 2019). Another UBA report shows, that the use of R-744 (CO₂) instead of R134a can reduce the fuel consumption of a passenger car HVAC-system from 14-54%, depending on the ambient temperature (UBA, 2009). Stakeholder provided information, that the use of R-744 (CO₂) requires a higher working pressure of the HVAC-system and that it is challenging to contain the refrigerant in the flexible hoses needed to manage vibration during vehicle use (Papavasvva and Moomaw, 2014). This may lead to higher leakage rates compared to systems using R-1234yf.

Approval schemes and timelines for transitions

One stakeholder provided input regarding the transition to non-PFAS heat transfer agents for HVACR-systems for road vehicles. According to this information, obtaining legal approval for an alternative to e.g. R-134a and R-1234yf outside the F-gas regulation starts with registration with the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) and is followed by vehicle road-worthy and safety legal approval (type approval). For flammable refrigerants, compliance with ATEX requirements (regulation on protection from explosions) is mandatory. Certain regions or jurisdictions also require a risk assessment to be completed before installation. ASHRAE and ISO817 registration typically

take between 12-18 months. The vehicle type approval typically takes 24-48 months after ASHRAE registration. A suggestion for a timeframe for a complete transition could be taken from article 6 of Directive 2006/40/EC (mobile air conditioning systems (MAC) directive), where the provision allowed for an overall period of 11 years the retrofitting and refilling of vehicles.

Transport refrigeration systems by sector

Road Transport

Road vehicles vary from small vans to large articulated vehicles, with coolant charge varying from several hundred grams to 10 kg. Refrigeration units for vans (with direct drive from vehicle engine) cost about €3 000; for trucks (diesel engine) €10-20 000 and for trailers approximately €20 000 (Schwarz et al., 2011).

Much as in other sectors, the problem of flammability of hydrocarbons is a major concern for transport refrigeration. Trucks would need a significant charge size (1 kg and upwards) in equipment that has a higher risk of leakage than for example domestic refrigeration given operating environment subject to prolonged vibration and changing environmental conditions. There are further constraints regarding the use of CO₂ as an active refrigerant relating to the size of refrigeration units and the limited space available in current designs of truck. One option to accommodate CO₂ based systems would be to shorten the load space within the trailer unit. This has not been investigated by the industry as it would reduce carrying capacity of vehicles and there is currently no driver for such action given ability to comply with the F-gas regulation.

An alternative system is the use of liquefied gases, CO₂ or N₂. This solution is available on the market already¹¹¹, using CO₂ from industrial processes that would be emitted to air in any case. However, the widespread use of this system is dependent on the availability of an extended network for filling up the refrigerant tank that as yet does not exist at the European level though it is expanding and is extensive within some countries (Norway and the Netherlands). Application in warmer climates may be more challenging through the higher demand placed on refrigeration (and hence greater consumption of refrigerant). There may also be health concerns linked to potential gas leakage in confined spaces, such as tunnels or parking garages.

Reefer Containers

Reefers are refrigerated containers used for intermodal transport (sea, road, rail). The container industry generally has focused on a transition from high GWP gases to lower GWP fluorinated gases, particularly R-513A. However, as of 2018, 3 shipping lines had placed orders for containers refrigerated using CO₂¹¹². A barrier to introduction of CO₂ is its lower efficiency at medium to high temperatures, though it performs well at lower temperatures (UNEP, 2019a). Limitations on movement of containers as a consequence of the use of CO₂ as a refrigerant can clearly be problematic in an industry that moves goods globally, but less of a problem for goods where movement is more regionalised. There is also research on the use of flammable refrigerants (IIF-IIR, 2016) with safety issues prominent given potential for build-up of gases in enclosed spaces.

Fishing Industry

Fishing vessels vary from small trawlers to factory ships with fluorinated gas charge sizes

¹¹¹ <https://europe.thermoking.com/>, date of access: 2023-01-13.

¹¹² <https://www.carrier.com/container-refrigeration/en/worldwide/news/news-article/largest-ever-order-naturaline-goes-to-msc.html>, date of access: 2023-01-13.

ranging from <100 kg to more than 8 t. The costs of refrigeration units vary from €2 to €6 million for medium to large vessels (Schwarz et al., 2011). It is reported that ammonia has already a significant presence in the fishing industry, and that CO₂ is also being used both as cascade and in trans-critical systems regarded as a good choice for small refrigeration systems (UNEP, 2019a).

Other Transport Refrigeration

There have been some moves in the shipping industry towards adoption of ammonia and CO₂ for refrigerated cargo and for cruise ships (Schwarz et al., 2011). However, widespread adoption of ammonia or hydrocarbons seems unlikely at the present time as it would likely require radical redesign of equipment (UNEP, 2019a).

Not in-kind alternatives are available in the form of advanced cool boxes that maintain the temperature of goods through the cold chain from producers to end users for some applications including provision of medical supplies. Temperatures down to -65 °C can be maintained for several days using some of these boxes¹¹³. Whilst such systems might replace some use of fluorinated gases, they will only ever have a niche role, for example when carrying large loads that need to be distributed across a number of sites, leading to regular opening and closing of the refrigerated environment. The more extreme the chilling regime, the smaller the quantity of material that can be transported using such options.

Shipment of goods by air involve little use of refrigeration and so is not considered here. Cold chain options for air freight are mainly insulation based.

Summary for Transport Refrigeration

There is some transition in the transport refrigeration sector to non-fluorinated alternatives, including some use of CO₂ in trucking and reefer containers and of ammonia in the fishing industry. However, there are barriers to expansion of the use of alternatives across the sector relating to the range of temperatures that equipment is required to operate in, the size of refrigeration units, the safety of some options in a transport environment that can include restricted spaces (e.g. tunnels) etc. The expected lifespan of equipment (roughly 12 to 30 years across applications) makes retrofitting unattractive, particularly at the lower end. Longer lifespans of equipment raise the need for continued supply of spare parts and an appropriate refrigerant.

Mobile Air Conditioning and cooling

Consideration of alternatives identified two major barriers for the use of alternatives to fluorinated gases in the mobile air conditioning market:

- ▶ Safety concerns linked to the use of hydrocarbons or ammonia.
- ▶ Cost concerns relating to the use of CO₂ given the need for higher engineering standards to deal with the higher pressures used.

As a cooling agent, CO₂ is considerably cheaper than the fluorinated gases (Blumberg and Isenstadt, 2019). The higher cost of CO₂ systems arises through:

1. Changes in components to account for higher pressures
2. Differences in materials used to account for the different physical and chemical properties of the refrigerant gases
3. An inability with very low demand to account for economies of scale that would be expected if CO₂ systems were adopted more widely.

¹¹³ <https://pelibiothermal.com/>, date of access: 2023-01-13.

However, of the alternatives that are available, CO₂ is the leading contender as a replacement. Positive experience in the use of such a vehicle has been reported by UBA in Germany (UBA, 2009). CO₂ based systems are on the market from one OEM (original equipment manufacturer), but at additional cost (€300/vehicle) compared to the fluorinated gas option. This is understood to be for a petrol or diesel engine vehicle. The development work on CO₂ based systems may be useful for setting tighter leakage limits for systems based on fluorinated gases, noting the experience reported by UBA (UBA, 2009).

Retrofit of existing systems to permit use of alternatives is not feasible. These systems would therefore require availability of fluorinated gases for vehicle servicing if they are to continue operating. Cutting off supplies opens potential for illegal trade, which has been a problem in the historic control of fluorinated gases.

A constraint on the applicability of alternatives for the mobile air conditioning sector is the linkage between the AC system and cooling and heating of traction batteries (the batteries used in electric vehicles). These batteries need cooling and heating during operation, recharging and storage. It is possible that the systems so far researched and costed have been for AC serving the passenger cabin of vehicles only, rather than systems that serve also traction batteries. This issue highlights potential for increased demand for fluorinated gases as electric vehicles enter the market in larger numbers.

An estimate was made in a submission to the CfE of the need for a 15-year transition from the current R-1234yf based systems to CO₂ based systems. Given that one OEM offers this option already, and others have investigated it, this figure seems excessive. In the 2nd stakeholder consultation a major stakeholder for the automotive industry indicated that the transition from fluorinated gases was not a problem for electric and hybrid vehicles, but some additional time would be needed for combustion-engined vehicles with mechanical compressors.

Use of R152a has been investigated by industry (Hill, 2003). It has a higher GWP than R1234yf (124 vs <1, though substantially lower than R134a used previously with a GWP of 1300). It has an ASHRAE rating of A2, indicating low toxicity and low flammability. In contrast, hydrocarbon refrigerants such as propane have an ASHRAE rating of A3, indicating higher flammability, and R1234yf a rating of A2L, indicating that it is weakly flammable. The paper by Hill (2003) makes specific comparisons with R134a given that it was the market leader at the time. As a drop-in replacement for R134a without system optimisation, R152a showed improved cool-down performance. The system also required a 35% smaller refrigerant charge and was subject to lower leakage rates. The lower system charge meant that additional safety systems could be integrated with no penalty on the weight of vehicles. An alternative system designed to separate the low flammability coolant from the passenger cabin of vehicles involved a secondary loop system. The primary loop would cool using R152a, whilst a secondary loop would operate using a non-flammable coolant. Estimates of additional costs were modest and are discussed in more detail below. Hill's findings, though now dated, are supported by other more recent reports such as Andersen et al. (2017).

One industry stakeholder in the automotive sector commented that the use of alternatives for electric and hybrid vehicles was not problematic. However, further work would be needed to integrate alternatives with vehicles with combustion engines that used mechanical compressors in the MAC system.

A manufacturer of construction equipment raised additional concerns to the CfE in 2020 specific to that market, linked to energy consumption of alternative systems, potential conflict in the use of higher pressures with the Pressure Equipment Directive (EC, 2014) and the Machinery Directive (EC, 2006) and possible issues with visibility linked to an increase in the size of AC units. As construction equipment is a small niche area in the vehicles market, no independent view on these issues has been identified, but as in many other areas investigated for fluorinated gases, the potential for niche markets to have very specific concerns that may affect the practicability of a restriction should be noted.

Whilst retrofitting existing vehicles is not practicable, it has been noted that there is some sale of R-134a to the do-it-yourself market for topping up MAC units. Andersen et al. (2017) report analysis from the USA indicating that half of service refrigerant emissions occur from the 10% of vehicles that are serviced by the do-it-yourself market. Information on the size of the European do-it-yourself market has not been identified, though seems likely to be smaller than in the US given lower penetration of air conditioning in the vehicle fleet. However, prevention of sales to non-professionals would generate some possibly significant emission savings.

Timelines for transition

Hill (2003) reported that a reasonable transition period to convert vehicle MAC systems away from the prevalent PFAS-based option at the time (R134a in 2003) was 2 years to optimise systems and assure refrigerant manufacturing capacity and an additional 2 to 4 years for introduction to global vehicle production.

From comments received during the 2nd stakeholder consultation, a longer transition period seems necessary for military vehicles to permit further research on alternatives for use in extreme conditions. Refrigeration in military transport equipment (including ships and submarines) faces several barriers to substitution due to some strong operating and safety conditions: sizing, compactness (and impact on armament equipment), sea motions, shocks, vibrations, noise, closed compartments, pressure conditions and health related issues of natural fluids such as NH₃ and CO₂.

Military applications for MAC and refrigeration

Comments were provided to the 2nd stakeholder consultation from 3 national defence ministries. Specific activities of concern were the following uses of fluorinated gases:

- As refrigerants for the storage of sensitive material (e.g. ammunition, pharmaceuticals, fuels) within the required climate range.
- Cooling of sensitive military electronics
- Mobile air conditioning to provide military personnel with a comfortable environment in a stressed and sometimes dangerous situation.

A broad range of military equipment was identified covering land, air and sea, the latter including submarines as well as surface vessels.

Further uses identified by stakeholders included fire extinguishing systems, though these are addressed separately (see E.2.8).

Specific characteristics of PFAS cited by these stakeholders related to non-toxicity and non-flammability, both heightened by the risks of operating in a hostile military environment. The higher operating pressures of some alternatives (e.g. MACs running on CO₂) are also relevant.

Stakeholders commented that refrigeration in military transport equipment faces several barriers to substitution due to some strong operating and safety conditions: sizing, compactness, impact on armament equipment, sea motions, shocks, vibrations, noise, closed compartments, pressure conditions and health related issues of natural fluids such as NH₃ and CO₂. Whilst it is accepted that the military environment will include high risk conditions specific to the military, several of these factors apply outside of the military where alternatives are already being used. Also, many activities undertaken by military services (e.g. general procurement, housing staff and their families) do not involve working in hostile environments.

A further barrier identified by stakeholders concerned standards developed specifically for the military, though further details on how these standards affect the suitability of alternatives beyond the requirements for equipment not specifically designed for military use were not provided.

Several of the responses made to the consultation specific to military applications focused on problems linked to retrofitting existing equipment, noting that the life of these vehicles can extend as long as 30-50 years.

It is apparent that the adoption of alternatives in military applications is more complicated than for civilian applications given the need to meet added criteria, particularly the use of equipment in hostile environments.

Other uses related to transportation

According to stakeholder information, the listed non-PFAS alternatives for pavement marking tape and reflective sheeting: do not provide sufficient thermodynamic differentiation from the binder which connects the beads to the product to ensure reproducible embedment of the beads. If the beads are embedded too far, they are no longer optically active. If the beads are embedded too little (50% or less), then they will not be durably attached. If they are not durably attached, the pavement markings will then quickly lose optical activity.

Approval schemes

For pavement markings and reflective sheeting's approval times depend on the country: In Germany the typical approval time can be 3 months. In France, typical approval time will be 1-2 years, depending on the expected lifetime of the product. Other jurisdictions vary depending on local regulations. Most countries require road trials, which will tend to take up to 2 years before approval.

For AFT (used e.g. to fix wheel weights) no alternate chemistry has been identified that enables the performance needed in foam tape applications. Fluorosurfactants lower the surface tension to a value half of what is attainable by using hydrocarbon surfactants, and fluorosurfactants are more stable and fit for harsh conditions than hydrocarbon surfactants because of the stability of the carbon-fluorine bond. Alternate non-PFAS surfactants, such as silicone and hydrocarbon surfactants, do not perform the stabilizing function to the same degree as PFAS-based surfactants, which is necessary to achieve customer requirements.

E.2.10.2.2. Human health and environmental hazards

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log K_{ow}) and bioconcentration factor (BCF) was assessed. Additionally, it was assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHA's dissemination site.

In relation to transportation, the list of alternatives contained 4 unique CAS numbers. All of these substances were classified according CLP (harmonised classification or self-classification). None of the substances were known to fulfil the PBT or vPvB criteria, since they either did, according to their registration dossier, not fulfil the PBT or vPvB criteria or no data on PBT/vPvB properties were found, or PBT/vPvB properties were not applicable.

The list contained an additional 9 substances with unique substance names for which no CAS numbers were available. One of these substances was classified according CLP (self-classification). No information on PBT and vPvB properties was available. For two substances (Silicone based chemicals, Silicone oils), it was indicated that they may contain residues of D4, D5 and D6, cyclic siloxanes. D4, D5 and D6, and cyclic siloxanes are considered to be PBT/vPvB substances and D4 is considered to be an endocrine disruptor. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.10.3. Environmental impacts

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.10.1, assuming business-as-usual and, consequently, on-going PFAS use and emissions. The analysis of environmental impacts focuses on two restriction options:

RO1, adopting a ban of all PFAS used in the transportation sector;

RO2, adopting a ban on PFAS in combination with use-specific derogations (see Table E.16 below). Regarding the duration of the derogations two variants are distinguished, i.e. a 5-year derogation and a 12-year derogation.

Environmental impacts of RO1 are analysed quantitatively. Likewise, environmental impacts for two of the proposed use-specific derogations (PFAS use in transport refrigeration equipment and mobile air conditioning) relevant for this sector can be assessed quantitatively because emission data are available. Table E.116 below summarizes the characteristics of the restriction options.

Table E.116. Characteristics of restriction options and maximum additional emission scenarios.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---
RO2 (5 years) ^a	Ban with use-specific derogations	(i) Proposed derogation: Refrigerants in mobile air conditioning (MAC)-systems in combustion engine vehicles with mechanical compressors (iii) Proposed derogation: Refrigerants in transport refrigeration other than in marine applications	18 months	5 years
RO2 (12 years)	Ban with use-specific derogations	(ii) Potential derogation marked for reconsideration: Use as refrigerants and for mobile air conditioning (MAC) in vehicles in military applications (iv) Potential derogation marked for reconsideration: Applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods (v) Proposed derogation: Additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry	18 months	12 years

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Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
Maximum additional emission scenarios	Ban with full derogation of entire PFAS species groups	Polymeric PFAS; fluorinated gases	18 months	5 years, 12 years

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, restriction options are expected to be implemented in 2027. All emission estimates represent mean values. Table E.117 shows mean emissions and the expected mean emission reduction for time paths of 30 and 45 years (starting in 2025).

Table E.117. Total mean emissions and emission reduction of RO1 and of maximum additional emission scenarios (transportation sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
	2025-2055		
Baseline	508 839**	---	---
RO1	28 306***	480 533	94
Maximum additional emission scenario `5-year derogation of all fluorinated gases` ^{r*}	95 076	413 763	81
Maximum additional emission scenario `12-year derogation of all fluorinated gases` ^{r*}	195 315	314 524	62
Maximum additional emission scenario `5-year derogation of all polymeric PFAS` ^{r*}	30 568	468 271	94
Maximum additional emission scenario `12-year derogation of all polymeric PFAS` ^{r*}	33 929	474 910	93
	2025-2070		
Baseline	817 430	---	---
RO1	28 306	789 124	96
Maximum additional emission scenario `5-year derogation of all fluorinated gases` ^{r*}	95 076	722 354	88
Maximum additional emission scenario `12-year derogation of all fluorinated gases` ^{r*}	195 315	623 116	76
Maximum additional emission scenario `5-year	30 568	423 748	96

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
derogation of all polymeric PFAS [*]			
Maximum additional emission scenario `12-year derogation of all polymeric PFAS [*]	33 929	427 110	95

* Maximum additional emission scenarios denote worst-case emission scenarios (assuming a full derogation of a particular PFAS group) against which emissions of proposed use-specific derogations are evaluated qualitatively. They do not represent restriction options.

** The estimate provided in the table includes emissions from fluorinated gases. Emission estimates under the baseline without emissions from fluorinated gases would be 49 824 t.

*** The estimate provided in the table includes emissions from fluorinated gases. Emission estimates under RO1 without emissions from fluorinated gases would be 14 202 t.

RO1 achieves a total PFAS emission reduction of about 94% compared to baseline emissions. Furthermore, RO1 is the only restriction option where emissions arising during the PFAS use phase will cease after the 18 months transition period. Environmental impacts of RO2 are discussed below for the proposed derogations.

- (i) *Proposed derogation: Refrigerants in mobile air conditioning (MAC)-systems in combustion engine vehicles with mechanical compressors*
- (ii) *Potential derogation marked for reconsideration: Use as refrigerants and for mobile air conditioning (MAC) in vehicles in military applications*

For (i) a 5-year derogation is proposed after EoF of the restriction and the 18 months transition period. For (ii) a 12-year derogation is proposed after EoF of the restriction and the 18 months transition period.

The proposed restrictions (i) and (ii) address the use of HVCAR fluorinated gases for mobile air conditioning. The discussion of alternatives for this application is included in the section on fluorinated gases (see section E.2.8.2). For the proposed derogation **strong evidence of expected maximum emissions** is available which is derived from tonnage estimates provided in the HVACR sector. Total additional emissions of a 5-year derogation of fluorinated gas use for MAC are 95 076 t, and 194 315 t for a 12-year derogation. Hence, expected additional emissions of both derogations will be substantially higher compared to emissions under a full ban (RO1, see Table E.117), and close to the maximum additional emission scenario (assuming a full derogation of fluorinated gases in the transportation sector, see Table E.117). **No evidence is available** of the fraction of emissions of these two derogations compared to maximum additional emission scenarios. For (i) it is assumed that emissions will be up to 90% of emissions expected under a full derogation of fluorinated gases. For (ii) emissions are assumed to be substantially lower considering that for the UK, for instance, military vehicles on land are equivalent to only 0.035% of the vehicle fleet (14 000 vs 41 million). No data were identified for ships. Assuming further that UK data are broadly representative for other European countries, a worst case estimate of additional emissions arising from (ii) is about 1% of fluorinated gas use for MAC.

- (iii) *Proposed derogation: Refrigerants in transport refrigeration other than in marine applications*

The restriction addresses the use of HVCAR fluorinated gases in transport refrigeration equipment. The derogation is proposed for a time period of 5 years after EoF of the restriction and the 18 months transition period. The discussion of alternatives for this application is

included in the section on fluorinated gases (see section E.2.8.2). For the proposed derogation **strong evidence of expected maximum emissions** is available which is derived from emission estimates in the fluorinated gases sector. Total mean additional emissions of a 5-year derogation of fluorinated gas use for refrigeration are 95 076 t (30-year period), which is an increase of emissions by 30% compared to a full ban (RO1). Though the precise amount of emissions arising from the derogation is not known, it is assumed that it can be up to 100% (worst-case).

- (iv) *Potential derogation marked for reconsideration: Applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods*

A 12-year derogation is proposed. The derogation will cause additional emissions of polymeric PFAS. **No evidence is available** about the precise amount of additional emissions. Assuming a derogation of all polymeric PFAS use, maximum additional emissions will be 33 929 t (30-year period, see Table E.117). This is slightly higher than additional emissions under a full ban (RO1, being 28 306 t). Though the precise fraction of emissions compared to this worst-case reference scenario is not known, it can be assumed it is up to 100% considering that the use is indispensable for a proper functioning of all transportation vehicles.

- (v) *Proposed derogation: Additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry*

A 12-year derogation is proposed. The proposed derogation will likely cause additional emissions of fluoropolymers and probably PFAAs including PFAA precursors. **No evidence is available** about expected additional emissions arising from this derogation. However, additional emissions are assumed to be small as the PFAS use derogated is limited and has only some applications in aviation.

Figure E.18 shows the time path of mean emissions in the transportation sector for the baseline, RO1 and the proposed derogations of uses for fluorinated gases.

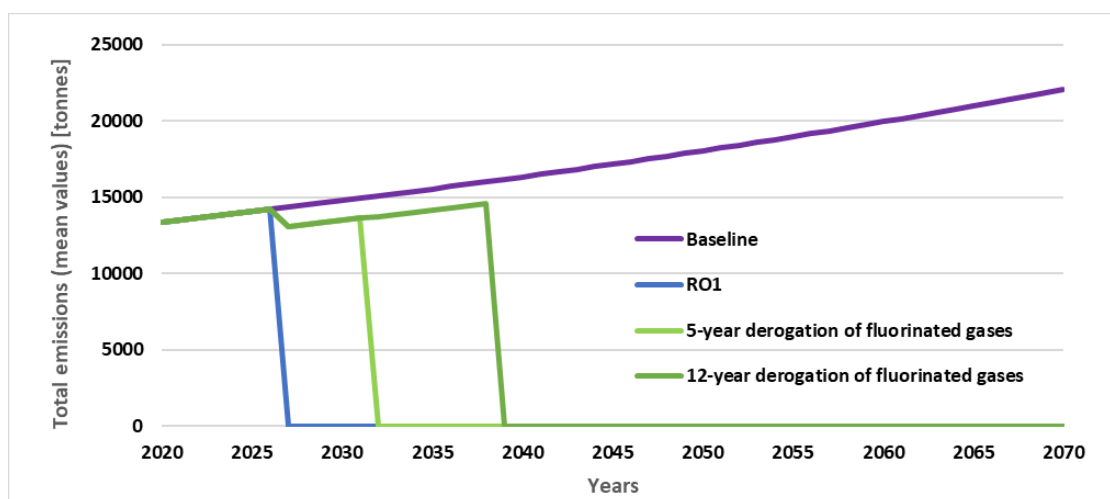


Figure E.18. Time path of mean emissions in the transport sector under the baseline, RO1 and maximum additional emission scenarios (transportation sector, in tonnes)[tonnes].

Source: Own calculations based on market data collated by the Dossier Submitters.

E.2.10.4. Economic and other impacts

E.2.10.4.1. Impacts on companies

The transport sector addressed here covers the production of vehicles for all transport by road

(all motor vehicles), rail, air and sea. Market data for Europe are presented in Table E.118, demonstrating the economic importance of the transport sector. A European focus creates some difficulty given the global supply chains for the industries covered by the sector. The discussion excludes consideration of aspects of the transportation sector that are covered in other sections, for example TULAC (section E.2.2), electronics (section E.2.11), consumer mixtures (section E.2.5) and metal plating and metal goods (section E.2.4).

Table E.118. European transport industry data¹¹⁴.

	Aviation	Automotive	Rail	Shipping
Year for data	2019	2021		2019/2020
Employment (jobs)	405 000	3.7 million (manufacturing) 14.6 million (total)		
Revenues	€130 billion			
Exports	€109 billion			
EU trade data		€76.3 billion trade surplus	46% share of global production of rail equipment and services	Only 5% of European orders are manufactured in the EU
R&D expenditure	€8 billion	€62 billion		

Detailed information on economic impacts is scarce and hence a detailed economic analysis is not currently possible. However, from the evidence gathered it is possible to draw general conclusions regarding the possible impacts of a restriction introduced over different periods for the sector. The level of response to the 2nd stakeholder consultation is shown in Table E.119 (noting that some responses relevant to transport may have been picked up in other sectors such as TULAC).

Table E.119 Levels of response to the 2nd stakeholder consultation for transportation sub-sectors.

Activity	Respondents
Non-electrical components (seals, hoses, tubes, valves, etc.)	54
HVACR (including MAC)	16
Respondents covering several kinds of product	11
Electrical components	9
Miscellaneous (windshield treatments, moulds, etc)	9
Coatings	7
Fire suppression	4
Hydraulic fluids	4
Military applications	4

¹¹⁴ https://defence-industry-space.ec.europa.eu/eu-aeronautics-industry_en, <https://www.acea.auto/publication/economic-and-market-report-state-of-the-eu-auto-industry-full-year-2021/>, <https://www.acea.auto/figure/key-figures-eu-auto-industry/>, (SEA Europe, 2021), date of access: 2023-01-13.

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Activity	Respondents
Distributors and fluorochemical suppliers	3
Batteries and fuel cells	2
Lubricants	2
No data	11

A particularly high level of response is seen from companies using PFASs to manufacture seals, tubes, pipes, gaskets, valves and similar goods. Several of these companies reported that their business was at the present time wholly dependent on the use of PFASs and so they perceived that a restriction could represent a major threat to their business. A large majority of respondents considered that identified alternatives to PFAS were not technically feasible for their products or processes (107 companies to 4). A number of respondents argued that a restriction on the use of PFASs would lead to complete or almost complete loss of business with some providing estimates for loss of business/profits and loss of jobs for their companies. However, it is not possible to extrapolate from these data to provide an overview of impacts for the sector as a whole.

It is worth noting that the 4 respondents who felt that alternatives were technically feasible were from different areas (refrigeration, seals, coatings and one non-specific).

Given the breadth of applications of PFAS across transport there will be a significant burden on manufacturers to undertake the necessary R&D activities as they investigate the use of alternatives, recognising not only the applications covered in this section, but also transport relevant applications covered in other parts of this dossier (e.g. under TULAC, lubricants and electronics). The need for vehicle testing and certification further extends timescales. The necessity for decarbonisation already creates pressure on R&D and design for the sector, though may also provide opportunity to design PFAS out of vehicle systems.

As the preceding text shows, vehicle manufacturers have developed a high dependence on the use of PFAS across a wide variety of applications within the transport sector. The manufacturers are therefore all likely to be in a similar position to one another when it comes to investigating the possible use of alternatives for uses such as seals, gaskets, hoses, pipes, valves, electronics and so on. Based on information gathered in literature review and the responses to the CfE and the 2nd stakeholder consultation it is reasonable to expect that:

1. No vehicle, ship or aircraft manufacturers are currently in a position to make an immediate rapid switch to alternatives for all PFAS applications.
2. Switching will be easier for some components than others. TULAC is one example where alternatives are available for some applications on a 'drop in' basis where modification of mechanics would not be necessary. It is, however, unclear to what extent this will apply in other areas, such as the introduction of alternative polymers for seals and gaskets.
3. It is expected that significant R&D will be required to fully transition away from PFAS.
4. The time taken for alternatives to be fully accepted and pass all necessary certification processes may be long. Transition times reported during consultation ranged from about 1 year to more than 10 years, once a satisfactory alternative had been identified.

Consideration must also be given to component suppliers to the major manufacturers. A risk of business closure or reduction in sales, combined with job losses, was highlighted by companies involved in supplying the major automotive, aviation and rolling stock manufacturers with a diverse range of products:

- Gaskets, seals, hoses and pipes
- Lubricants

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- Coatings
- Friction products
- Moulded products
- MAC and refrigeration systems
- Electronics and electrical insulation
- Hydraulic fluids
- Water repellent coatings for windshields used across transport modes.

Several companies considered business closure a realistic response to a restriction on PFAS, and lost earnings per company ranged from hundreds of thousands to hundreds of millions of €. Few provided evidence to indicate that they expected alternatives to become available on the market in the next 10 years. This may not be surprising given the extent to which PFAS have come to dominate the marketplace in recent decades. Referring back to Table E.118, significant disruption to the transport sector could cause lost earnings in the order of billions of EURO and job losses in the hundreds of thousands or more. However, disruption at this level is not a certainty, and impacts could of course be mitigated through the adoption of derogations providing more time for the sector to adapt.

The extent to which increased costs for producers can be passed on to consumers is unclear. There will be variation in capacity to do this between suppliers at different points in the value chain: manufacturers of some components may have limited competition, whereas manufacturers of cars and goods vehicles aimed at the mass market would likely be prone to higher competitive pressures. A further complication at the moment arises from the economic situation post-COVID, where shortages of components has led to reduced production of vehicles: this may lessen competition between manufacturers, making it easier for them to increase prices to account for additional costs. It is not known how long this situation may persist.

One area where cost data have been identified for transitioning away from PFAS concerns mobile air conditioning (MAC) systems. Controls for this sector are important, given that it is the largest emitter of F-gases, generating 29% of F-gas emissions in the EU/Norway/UK region, despite previous legislation. Some commonly used alternative refrigerants such as hydrocarbons have not been considered for this purpose given their flammability and the potential for them to escape into the passenger compartment. However, an estimate of added cost for CO₂ MAC systems has been identified based on costs of an option offered by one manufacturer (Table E.120), giving a figure of €300 per vehicle (car or small van). Volkswagen has developed a car with CO₂-based air conditioning, which is used by e.g. the German Environmental Protection Agency, UBA (UBA, 2021). As a gas, CO₂ is considerably cheaper than the fluorinated gases (Blumberg and Isenstadt, 2019). However, the higher cost of CO₂ systems arises through:

- Changes in components noting that CO₂ is unsuitable for combustion engine vehicles with mechanical compressors, as the compressor's leak resistance durability is challenging due to high pressures
- Differences in materials used to account for the different physical and chemical properties of the refrigerant gases

Available cost data seem likely to be inflated given that they are taken from one example where CO₂ MAC systems are offered as an option. The resulting low demand suggests that the price given does not reflect the price if such systems were offered as standard and further economies of scale would apply.

Given the estimates of €300 additional cost and 0.6 kg of fluorinated gas per vehicle, a substitution cost of €500/kg gas can be calculated, assuming complete release of this quantity of gas over a vehicle lifetime. For very leaky systems where the full amount of gas is replaced several times over the vehicle lifetime, the price per kg of fluorinated gas avoided would fall, making the restriction more attractive. In contrast, for highly engineered and near leakproof

systems with efficient recovery of fluorinated gas at the end of the vehicle life, the cost per unit of emission would, naturally, be higher. It is assumed that the cost of €300 covers R&D costs, costs of certification and variation in the price of the refrigerant charge. No information on a change in running costs for a CO₂ MAC system has been identified, specifically relating to energy efficiency. However, it is noted that the price of CO₂ is significantly lower than the price of comparable HFCs and HFOs, and so refilling systems with CO₂ would be cheaper than refilling with fluorinated gases. No reason has been identified to indicate that other manufacturers would be unable to switch to new systems. Information from the 2nd Stakeholder Consultation indicates that this is less problematic for hybrid and electric vehicles than for combustion engine vehicles with mechanical compressors.

Table E.120. Summary of information on the costs of a CO₂ based alternative for Mobile Air Conditioning relative to the costs of continued use of fluorinated gases.

Cost element	Commentary
R&D costs of designing equipment to utilise alternative refrigerants.	Assumed to be accounted for in the added price of €300/vehicle.
Costs for certification of new product in some markets.	Assumed to be accounted for in the added price of €300/vehicle.
Difference in the cost of equipment using fluorinated gases and equipment using alternatives.	A single cost estimate of €300/vehicle is available. It is assumed that this is the added cost of a CO ₂ based system compared to one using fluorinated gases.
Variation in the costs of alternative refrigerants.	Assumed to be accounted for in the added price of €300/vehicle, but the price of CO ₂ is significantly lower than the price of comparable HFCs and HFOs. Refilling systems with CO ₂ would thus be cheaper than refilling with fluorinated gases.
Variation in running costs.	No data.
In the event of increased energy losses through the use of technologies that are less energy efficient, additional costs of abatement for greenhouse gas emissions elsewhere in the economy to ensure that climate goals and targets are met.	No data.
Potential for PFAS-dependent operations to cease leading to reduced market share and possible closure of businesses.	No reason has been identified to indicate that existing manufacturers would be unable to switch to new systems.

Other options may be available. Hill (2003) reported on the possible use of R152a as an alternative refrigerant for use in vehicles. R152a has the disadvantage of mild flammability (ASHRAE rating A2) compared to the use of other fluorinated gases, but is markedly less flammable than hydrocarbon alternatives. It also requires a smaller refrigerant charge. Hill considered two systems, one involving a direct expansion option, similar to those used for the dominant systems currently in use with PFAS refrigerants, and another using a secondary loop system. R152a would provide the cooling power in a system separated from the passenger cabin, to which cooling would be delivered through a non-flammable refrigerant contained in a secondary loop. Inflating the original cost estimates from Hill (2003) to 2022 prices indicates an added cost for systems based on R152a of around €22 for the direct expansion system incorporating an additional safety system, and €60 for a secondary loop system, compared to systems using refrigerant R134a, equivalent to a cost of €37 to 100/kg PFAS based on a 0.6 kg charge. The price differential could be considerably smaller (or even

reversed) comparing R152a with HFO R1234yf, given the substantially higher price of the latter, USD 100/g compared to USD 5/kg for automobile OEM bulk wholesale prices (Andersen et al., 2017). There would be some additional costs for manufacturing and servicing for new recovery/recycling equipment and service procedures and additional safety requirements, equipment and training for vehicle assembly plant and service providers. However, the overall costs of the R152a based systems appear, from this evidence, to be significantly cheaper than CO₂ based systems. The direct system proved to be on average 10% more energy efficient than R134a at temperatures ranging from 27 to 46 °C. R152a would also be effective in heat pump mode. Use of a secondary loop system was estimated to give a similar efficiency to R134a. The conclusions of Hill (2003) are supported in more recent works, for example by Andersen et al. (2017) and IEA (2019).

Mobile refrigeration in trucks and reefer (refrigerated) containers has seen businesses switching from refrigerants with high global warming potential to HFOs in response to the requirements of the F-gas regulation. However, there is little indication of switching to other alternatives for this sector: hydrocarbons because of the risk of flammability, ammonia because of toxicity and CO₂ because of concerns over cooling efficiency at higher temperatures (e.g. in southern Europe) and increased space required for active CO₂ refrigeration systems. Information provided in the CfE showed how the distance between tractor and trailer units for articulated lorries was optimised for existing refrigeration systems, to the extent that trailer modifications would be needed to fit a CO₂ unit into the available space. A reduction in the load capacity of trucks to account for a bulkier refrigeration system was cited by some stakeholders as a significant disincentive for fleet operators given the desire to maximise load capacity. There is some penetration of passive systems using CO₂ or other liquefied gases, though there are constraints on the use of such systems (they require an extensive network of refilling stations for liquefied gases). Overall, it is concluded that there are several options that may be cost-effective, though further work to design systems based on non-PFAS gases is clearly necessary and this will take time.

The situation for shipping seems different. As of 2018, 3 shipping lines had placed orders for containers refrigerated using CO₂¹¹². A barrier to introduction of CO₂ is its lower efficiency at medium to high temperatures, though it performs well at lower temperatures (UNEP, 2019a). Limitations on movement of containers as a consequence of the use of CO₂ as a refrigerant can clearly be problematic in an industry that moves goods globally, but less of a problem for goods where movement is more regionalised. There is also research on the use of flammable refrigerants (IIF-IIR, 2016) with safety issues prominent given potential for build-up of gases in enclosed spaces. It is reported that ammonia already has a significant presence in the fishing industry, and also that CO₂ is being used both as cascade and in trans-critical systems for small refrigeration systems (UNEP, 2019a). The fact that these technologies are already finding market opportunity indicates that they are cost-effective.

Overall, the situation for mobile air conditioning and refrigeration with respect to switching from PFAS refrigerants seems promising. Unlike the situation with respect to fluoropolymers there are known alternatives and some already have market share.

Specific operating concerns relating to the use of natural refrigerants in military vehicles were mentioned above, relating to the protection of service personnel. For these reasons it cannot be assumed that cost effective alternatives are already available in the market, and further R&D is needed.

The need to maintain supplies of spare parts for the transport sector could keep PFAS based products in the supply chain for some years to come, particularly for the military market where vehicle lives of 30-50 years were cited by stakeholders to the 2nd stakeholder consultation. The alternative would seem to be to accelerate the redundancy of vehicles. There could be competing effects on prices in the second-hand market if access to spare parts was restricted: Concern over the availability of spare parts could reduce the value of existing assets. However, a lack of spare parts could also reduce the availability of older vehicles which would tend to increase prices. In the event that satisfactory alternatives that could be used

on a 'drop-in' basis are identified, the effect on the second-hand market could be small, but the existence of such alternatives across the range of applications relevant to the restriction is a matter of speculation. The Dossier Submitters have observed the sale of the fluorinated gas R134a to the do-it-yourself (DIY) market for topping up MAC units. It has not been possible to investigate this activity in more detail, but it is noted that DIY repairers are unlikely to be equipped to capture and safely dispose of waste refrigerant. A requirement that only professional and qualified service personnel with access to the correct tools and safe disposal should be permitted to refill MAC units should ensure that leaky systems are repaired and properly maintained.

E.2.10.4.2. Impacts on consumers

As in other sectors, a view expressed by several stakeholders was that due to their comparatively high price, fluoropolymers would not be used unless they offered significant benefits relative to alternatives that are on the market at the present time. This suggests that there could be significant impacts on consumers if PFAS were to be phased out of transportation. However, without precise details and a clear understanding of alternatives in some areas, such impacts are a matter of speculation.

There is clearly potential for an increase in cost from manufacturers given the need for R&D on alternatives and potential redesign of equipment. The extent of such price changes is not estimated here given uncertainty regarding precisely which alternatives would be introduced and the wider consequences of using those alternatives. Demand for road transport as a function of cost ranges from being inelastic (e.g. in relation to commuting) to highly elastic (e.g. for recreation) (Litman, 2022). There is some evidence that demand for purchasing new vehicles is more elastic than previously, in response to a range of factors, including:

- Increased working from home
- The growth of car clubs (where vehicle hire is much simplified)
- Improved provision of public transport in at least some areas
- Improved provision of infrastructure for walking and cycling
- Financial burdens such as the current cost of living crisis.

There may be further impacts on consumers if switching to alternatives reduces the performance of vehicles or vehicle components, for example affecting reliability, comfort, safety features or the overall durability of vehicles. The risk of such impacts should diminish over time given opportunity for further R&D, but cannot be ruled out altogether. Alternatives able to perform at a high level will be available for some applications (the alternatives for MAC coolants are one example) but this cannot be guaranteed for all of the many applications of PFASs across the vehicle industry.

The same general view seems likely to hold for other transport modes. There will be examples where substitution is straightforward and there will be others where it is not, reflecting the broad range of characteristics of PFASs referred to previously for the sector, such as:

- Flexibility
- Resistance to chemical attack
- Resistance to UV
- Electrical properties
- Heat transfer properties
- Performance over a range of operating conditions
- Stain resistance
- Low weight
- Low risk of flammability
- Low risk of toxicity

Several of these characteristics seem likely to be of higher importance for military applications operating in hostile environments given higher risks to life and the associated need for very

high reliability of equipment.

E.2.10.4.3. Impacts on employment

As noted already, there was a widespread view amongst industry respondents to the CfE and 2nd stakeholder consultation that business would reduce in the event of a PFAS restriction leading to job losses. In a number of cases companies are so dependent on PFAS at the present time that they consider business closure or shutdown of certain business units a likely response to restriction. Of the 133 respondents to the transport related questions in the 2nd stakeholder consultation, 37 companies provided estimates of job losses ranging from 4 to 2 500 per company (some included supply chain impacts, some did not), giving a total forecast from respondents of 12 700 jobs lost. This can be translated to an economic estimate of damage from lost employment using a figure per job lost in the order of €100 000 to 130 000, following an approach defined by Dubourg (2016) and used elsewhere in this dossier, to derive an estimate of around €1 billion. This is clearly not a precise estimate for a number of reasons, for example:

- Not all manufacturers, either of final vehicles or in the supply chain, responded to the consultation exercise, and of those that did, many who considered that there were economic risks to their business did not translate that into lost jobs.
- Given a lack of research on alternatives, the true severity of the risk to businesses will not be certain for most companies at this point in time.
- Responses from companies that have alternatives and could benefit from the restriction were limited.

For these reasons it would not be appropriate to assume that these figures are a reliable estimate of job losses and their economic impact under a restriction. However, they demonstrate that there is concern for the future amongst companies in the sector, and associated impacts could be in the order of billions of euros.

E.2.10.5. Summary of cost and benefit assessment

The preceding text demonstrates that there is widespread use of PFAS in the transport sector. However, it is not possible to provide a quantified estimate of economic impacts and benefits. The following tables summarise the outcomes of a qualitative assessment of costs and benefits for the transport sector drawing on information submitted to the CfE and 2nd stakeholder consultation and the literature. Further information can be found in the accompanying text following each table. Reference throughout this section to possible 5- and 12-year derogations is additional to the general transition period of 18 months. Uses considered in the tables below are as follows:

- Use in transport (including automotive, aircraft, rail, marine, and aerospace industries) where the substances are affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods (Table E.121)
- Anti-erosion/anti-corrosion purposes in hydraulic systems in the aviation and aerospace industry (Table E.122)
- Mobile Air Conditioning systems (Table E.123)
- Transport refrigeration (Table E.124)
- MAC and refrigeration in military applications (Table E.125)

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Table E.121. PFAS use in transport (including automotive, aircraft, rail, marine, and aerospace industries) - Summary table on assessment of costs and benefits, based on a general transition period of 18 months where the substances are affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	The transport sector has an extremely high dependence on PFASs, including use in complex products (e.g. seals, O-rings and gaskets in engines). The properties of PFASs can provide input to the design of such products, with the result that drop-in substitutes will not always be available. Even where they are, testing and certification procedures would need to be followed. It is therefore concluded that a full ban is not feasible for the transport sector and that substitution potential is low [sufficiently strong evidence].	Based on available evidence which is considered weak (i.e. not based on referenced data or documented assessments) a full ban of PFAS use in the transportation sector is expected to reduce PFAS emissions by about 94% (assuming a 30-year assessment period, 2025-2055). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a	In the event of a full ban, there would be significant disruption to the industry leading to very high producer surplus losses including business closures, which would also lead to substantial employment losses. In the event that it is possible to produce vehicles, there is also a strong likelihood of consumer surplus losses through the sale of vehicles with limited capabilities and reduced reliability. Disruption to the market could also affect the transition to electric vehicles, with consequences for climate and air quality policies. [sufficiently strong evidence].	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
			result of the restriction are likely underestimated.		
Ban with use-specific derogations: Potential derogation marked for reconsideration: Applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods	5 years	Given the wide variety of PFAS applications in the sector, the potential need for significant re-design of equipment and recertification requirements, it is concluded that 5 years is unlikely to be sufficient to introduce alternatives to PFAS across the sector [sufficiently strong evidence] .	For the proposed derogation total maximum additional emissions of a 5-year derogation of fluorinated gases use for MAC are 95 076 tonnes . Though no evidence is available about the precise fraction of emissions, the fraction of emissions is assumed to be up to 100% (worst-case).	Whilst an additional 5 years would permit some transition from PFAS in the industry it is concluded to be insufficient for a significant number of applications. Introduction of a restriction on this basis could generate risk to many companies in the sector, with potential for substantial job losses and also consumer surplus losses. Both would be reduced compared to the position with no derogation. [sufficiently strong evidence] .	
	12 years	Allowing an additional 12 year period for the development, certification, etc. of alternatives would be sufficient for likely many applications, although in many cases the industry is not advanced in its research on alternatives [weak evidence] .	n/a	The extent of impacts on producers is not estimated, and will be dependent for example on the extent to which drop-in alternatives can be identified without the need for redesign of equipment. A long derogation period provides opportunity to mitigate costs by enabling redesign to be factored into product development cycles [weak evidence] . Given vehicle safety standards and an additional 12 years for development, it is anticipated that safety will not be compromised. Vehicle reliability may	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				however be impacted leading to some consumer surplus loss [weak evidence]. There is no information on the extent to which different parts of the sector are able to pass on added cost to their customers (both the general public and other parts of the motor industry). [no evidence].	
Conclusion	It is often argued by industry that PFASs are only used where absolutely required, given their high cost. However, technical data to prove this point have not been provided. It is accepted that it is likely that there are possibly many applications where PFASs are currently used where substitution with alternatives could be problematic at the present time given the various properties of fluoropolymers. It is concluded that a 12 year derogation could be appropriate for PFAS use in transport (including automotive, aircraft, rail, marine, and aerospace industries) where the substances are affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods. Shorter transition periods would not reflect the current state of the industry with respect to PFAS use, with many uses having no satisfactory identified alternatives at the present time. The rapid introduction of alternatives could lead to consumer losses through reduced reliability of equipment as well as added costs to industry being passed through to customers. There is potential that a 12-year derogations would cause additional PFAS emissions which are likely substantial. In light of the broad use scope and the weak evidence base to narrow down the scope for a derogation, such a derogation is not proposed at this point but marked for reconsideration. A derogation might be proposed at a later stage if additional information on (e.g.) the rationale for continued PFAS use in specific applications and the quantities of PFAS used in those applications is provided.				

The Dossier Submitters consider that the evidence is sufficiently strong that technically and economically feasible alternatives are unavailable in the quantities required for use in transport applications (including automotive, aircraft, rail, marine, and aerospace industries) where the substances are affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods under a full ban (RO1) subject to an 18 month transition period following EiF. This view is based on evidence from the literature, CfE and 2nd stakeholder consultation. Given the extent to which PFAS are embedded in the design of vehicles in many forms (various seals and gaskets, valves, pipes, tubes, electronics, hydraulic fluids and so on) and in many different components, time will be needed to carry out the R&D, etc. and obtain necessary certifications before alternatives can be introduced across the industry. The same also applies to a 5 year derogation, because of the current diversity of PFAS use, and the industry view until now that alternatives were not needed, leaving many alternatives under-researched. There is weak evidence that a 12 year derogation would be required. Improvement of the evidence base will be dependent on further R&D to assess the potential for progress on substitution of alternatives. The opportunity for additional research would clearly improve the substitution potential over time.

RO1 would naturally provide greater benefit in the form of reduced emissions, though there is only weak evidence to support the quantification of those emissions. It seems unlikely that stakeholders have access to the data needed to provide more robust estimates, so improvement of the data would probably require original data collection.

The evidence is strong that the socio-economic costs to both industry and consumers under RO1 would be very high given the diversity of uses of PFAS in the transport sector and the fact that the industry has seen little need to develop alternatives for many of those applications. This creates significant potential for business closures and job losses, especially where companies are currently 100% dependent on the use of PFAS, as is the case with some suppliers of seals, pipes and other components. Costs, and the likelihood of business closures would fall under a 5-year derogation and then further under a 12-year derogation as more time is permitted for research into alternatives and for their introduction to the market. Whilst a 5 year derogation would likely permit some substitution of PFAS applications, it seems unlikely that it would permit complete removal of PFAS from transport without some level of disruption to the market. Further data to identify precisely which current uses of PFASs are problematic, and the quantities of PFASs used in those applications would be beneficial.

The complexity of PFAS use in the sector strongly suggests that a 12-year derogation would be needed in order for the necessary R&D, certification, and other work to be put in place. It is noted that a number of industry commentators to the stakeholder consultation considered even this timescale too short.

Several points should be noted.:

- The conclusions reached here do not apply to specific applications of PFAS in the transport sector that are addressed elsewhere in this dossier, including in the tables that follow. These conclusions are specific to PFAS use in transport (including automotive, aircraft, rail, marine, and aerospace industries) where the substances are affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods.
- The conclusions reached on the benefits of a restriction do not account for changes in emissions at the waste phase, which is dealt with separately.

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Table E.122. Hydraulic fluids for anti-erosion/anti-corrosion purposes in hydraulic systems in the aviation and aerospace industry - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	No acceptable non-PFAS alternatives have been approved for use in the aviation sector and for aerospace industry, where PFASs are used for example for anti-erosion/anti-corrosion purposes in hydraulic systems, including landing gear [sufficiently strong evidence]. Alternatives are not available on a short timescale given the need for approval under various specification schemes [sufficiently strong evidence] .		Not feasible for the aviation and aerospace industry under a full ban given the need to develop, test and certify alternatives [sufficiently strong evidence] .	
Ban with use-specific derogations: Proposed derogation: Additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry	5 years	Information from industry indicates that 5-years would be insufficient to perform the necessary R&D on alternatives and gain approval for their introduction. [sufficiently strong evidence]	n/a	As RO1	
	12 years	Information from the 2 nd stakeholder consultation indicates that a 12 year derogation should give sufficeint time for alternatives to be introduced. [sufficiently strong evidence]	No evidence is available about expected additional emissions arising from this 12-year derogation. However, additional emissions are assumed to be small as the PFAS use derogated is limited and has only some applications in aviation.	Reduced producer surplus loss compared to RO1 particularly given the need for recertification of components using alternative substances in their hydraulic fluid. [sufficiently strong evidence]	
Conclusion	Hydraulic fluids are used in safety-critical applications in the aviation sector such as landing gear. Although only limited evidence has been obtained, a sufficiently strong case has been made that transition to alternatives will take several years. On this basis, and accepting views on the time taken for alternatives to become available and receive the necessary certification, a derogation of 12-years appears appropriate				

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
	for this use.				

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The Dossier Submitters consider that the evidence is strong that technically and economically feasible alternatives would be unavailable in the quantities required for anti-erosion/anti-corrosion purposes in hydraulic systems in the aviation and aerospace industries under a full ban (RO1) subject to an 18 month transition period following EiF. This view is based on a limited number of responses to the 2nd stakeholder consultation. The same position applies to a 5 year derogation, because of the time likely to be needed for R&D on alternatives and certification once an alternative is identified. Substitution potential would increase significantly for a 12-year derogation as this provides sufficient time for testing and certification of alternatives once they have been identified.

RO1 would provide greater benefit in the form of reduced emissions, though there is no evidence to support the quantification of those emissions. Hydraulic fluids containing synthetic oils should be treated as a controlled waste at the end of their service life.

The evidence is sufficiently strong that the socio-economic costs to both industry and consumers under RO1 would be very high given the role played by hydraulic fluids in the sector, though it has not been possible to estimate the size of these costs.

Table E. 123 MAC (Mobile Air Conditioning) systems - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Alternatives are available for electrical and hybrid cars, while not necessarily for combustion engine vehicles with mechanical compressors. Such systems may need to be redesigned by each manufacturer to enable use of alternative refrigerants, for example to address higher pressures of CO ₂ systems and secondary loop systems for R152a. [sufficiently strong evidence]	Based on available evidence which is considered weak (i.e. not based on referenced data or documented assessments) a full ban of PFAS use in the transportation sector is expected to reduce PFAS emissions by about 94% (assuming a 30-year assessment period, 2025-2055).	Alternatives have been identified for combustion engine vehicles, with an estimated cost-effectiveness in the order of €100 to 500/kg PFAS, depending on leakage rates over the service life of vehicles, fate of fluorinated gases at the end of life and the alternative adopted. However, they are not drop-in replacements and systems would need to be redesigned to enable their use [sufficiently strong evidence]. Economic impacts of RO1 related to mobile air conditioning are dependent on the time taken for most manufacturers to design alternative mobile air conditioning systems that can be integrated with existing vehicle designs. This leads to some loss of producer surplus through costs of R&D, capital costs etc. to provide new MAC-systems [sufficiently strong evidence]. There is no reason to expect exports of vehicles from the EU to be affected as systems could be filled with fluorinated gases after export. Lower costs of alternative refrigerants would mitigate costs to consumers in the longer term during servicing. [sufficiently strong evidence].	MAC systems in particular are responsible for significant emissions of gaseous PFAS. The decision on whether or not to apply a derogation period thus needs to reflect the practicalities of introducing alternatives across the industry and the associated environmental burden.
Ban with use-specific derogations: Proposed derogation:	5 years	5 years would provide opportunity for R&D to bring alternatives to the mass market [sufficiently strong evidence] .	For the proposed derogation total maximum additional emissions of a 5- year derogation of fluorinated gases use for MAC are 95 076 tonnes . Though no evidence is available about the precise	Lower producer surplus losses than under a full ban given added time to develop alternative systems and phase out of some non-electric/hybrid models. [sufficiently strong evidence] Low consumer losses, depending on the extent to which manufacturers are able to pass costs	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Refrigerants in mobile air conditioning (MAC)-systems in combustion engine vehicles with mechanical compressors			fraction of emissions, it is assumed that emissions will be up to 90% of emissions expected under a full derogation of fluorinated gases.	onto consumers. [weak evidence] As above, cost effectiveness estimated at €100 to 500/kg PFAS, depending on leakage rates, fate of fluorinated gas at end of life. and the alternative adopted [sufficiently strong evidence]	
	12 years	A 12 year derogation would naturally provide additional time for R&D into alternative systems which could provide efficiency and cost advantages [weak evidence] .	n/a	n/a	
Conclusion	It is concluded that additional time beyond the 18-month transition period would be needed for alternative systems to be introduced, noting that drop-in alternatives are unavailable. A 5-year derogation seems most appropriate for PFAS use in typical transport MAC and refrigeration systems given the likely availability of alternatives at the present time, with the exception of military applications for which a 12-year derogation seems more appropriate. In some sectors alternatives are already widely used, but in others they are not. It is recognised that a derogation of PFAS use in MAC and mobile refrigeration will cause substantial additional emissions, which together account for close to 100% of the use of gaseous PFAS in the transportation sector.				

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The Dossier Submitters consider that based on evidence from the literature, CfE and 2nd stakeholder consultation that the evidence is strong that technically and economically feasible alternatives would be unavailable in the quantities required for use in MAC systems for combustion engine vehicles using mechanical compressors under RO1. This does not apply to electric and hybrid vehicles. Substitution potential is therefore high for some applications but low for others under RO1. Drop-in alternatives have not been identified, and so cooling systems would need to be designed around the use of alternative refrigerants. There is sufficiently strong evidence that a 5 year derogation would provide sufficient time for a transition, given that potential alternatives have already been identified, though further work is needed to integrate these alternatives with vehicles. Evidence on the availability of alternatives strengthens again for a 12 year derogation given both knowledge that there are possible alternatives already on the market and the longer period for undertaking necessary R&D and other activities.

RO1 would naturally provide the greatest benefit in the form of reduced emissions. There is strong evidence supporting the quantification of emissions given submissions made under the F-gas regulation and the UNFCCC (UN Framework Convention on Climate Change). Evidence on the savings made under different derogation periods is weaker given uncertainty on the precise time-schedule for the introduction of alternative systems, but associated error in estimates seems likely to be modest.

Table E.124. Transport refrigeration - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	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 may 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. Overall, it is concluded that there is high substitution potential at EiF for marine applications [sufficiently strong evidence] and low substitution potential at EiF for other applications [sufficiently strong evidence].	Based on available evidence which is considered weak (i.e. not based on referenced data or documented assessments) a full ban of PFAS use in the transportation sector is expected to reduce PFAS emissions by about 94% (assuming a 30-year assessment period, 2025-2055).	Alternative systems have some market penetration indicating that they can be cost-competitive but there remain significant barriers to widespread adoption. There is sufficiently strong evidence that for some parts of the transport sector significant re-design of equipment would be needed, raising questions about the feasibility of substitution under an 18-month transition. This would then cause loss of both producer and consumer surplus, though costs have not been estimated. [sufficiently strong evidence]	
Ban with use-specific derogations: Proposed derogation: Refrigerants in transport refrigeration other than in marine applications	5 years	Given that alternatives are already known, a 5 year derogation would provide opportunity for R&D to better optimise systems, particularly in areas where current options could introduce inefficiencies such as reduced load capacity. [sufficiently strong evidence].	For the proposed derogation total maximum additional emissions of a 5- year derogation of fluorinated gases use for MAC are 194 315 tonnes . Though no evidence is available about the precise fraction of emissions, it is assumed that emissions are substantially lower compared to the maximum emission scenario.	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. [sufficiently strong evidence].	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
	12 years	A 12 year derogation would naturally provide additional time for R&D into alternative systems which could provide efficiency and cost advantages prior to the introduction of alternative systems [weak evidence] .	n/a	Costs to industry would be reduced compared to the above time limits because of increased potential for identifying and certifying alternatives [sufficiently strong evidence] There is also potential for benefits to consumers through reduced costs and systems that are better integrated into vehicle design. [weak evidence] .	
Conclusion	It is concluded that additional time beyond the 18-month transition period would be needed for alternative systems to be introduced, noting that drop-in alternatives are unavailable, although alternatives are known. A 5-year derogation seems most appropriate for PFAS use in typical transport refrigeration systems other than marine, given the likely availability of cost-effective alternatives at the present time. It is recognised that a derogation of PFAS use in MAC and mobile refrigeration will cause substantial additional emissions, which together account for close to 100% of the use of gaseous PFAS in the transportation sector.				

The Dossier Submitter consider based on evidence from the literature, CfE and 2nd stakeholder consultation that the evidence is strong that technically and economically feasible alternatives are unavailable in the quantities required for use in transport refrigeration (including automotive, rail and aerospace industries), and hence that substitution potential is low under RO1. Drop-in alternatives have not been identified, and so cooling systems would need to be designed around the use of alternative refrigerants. It is, however, concluded that there is high substitution potential for marine applications where alternatives already have market share. Some alternatives are being used in road transport also, but their extension to the full market is not straightforward and other alternatives may be preferable in the longer term. There is sufficiently strong evidence that a 5 year derogation would provide sufficient time for a transition for typical uses, given that potential alternatives have already been identified, though further work is needed to integrate these alternatives with vehicles. Evidence on the availability of alternatives strengthens again for a 12 year derogation given both knowledge that there are possible alternatives already on the market and the longer period for undertaking necessary R&D and other activities.

RO1 would naturally provide the greatest benefit in the form of reduced emissions. There is strong evidence supporting the quantification of emissions given submissions made under the F-gas regulation and the UNFCCC (UN Framework Convention on Climate Change). Evidence on the savings made under 5- and 12-year derogations is weaker given uncertainty on the precise time-schedule for the introduction of alternative systems, but associated error in estimates seems likely to be modest.

The evidence is sufficiently strong that the socio-economic costs to both industry and consumers under RO1 would be high given the need to introduce new systems and integrate them into vehicles. Transport operators may bear additional costs if alternative systems are bulkier than those used currently, leading to added weight on vehicles and reduced carrying capacity (though this could be small). There would be some risk of business closures and job losses, though this would be mitigated by continued demand for transport refrigeration. Costs, and the likelihood of business closures would fall under a 5 year derogation and then further under a 12 year derogation as more time is permitted for research into alternatives and for their introduction to the market.

Table E.125. MAC and refrigeration in military applications - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	For specialist military vehicles, including tanks and submarines, concerns have been raised about safety relating to alternatives that are toxic, flammable or require high pressure for operation, recognising that these vehicles can operate under extreme conditions with heightened risk of the failure of MAC and refrigeration systems. Alternative approaches to refrigeration in military transport vehicles may be required, but these are not currently available for the sector. It is concluded that there is low substitution potential [Sufficiently strong evidence] .	No evidence has been found regarding PFAS use specifically in the military applications covered here. Based on available evidence which is considered weak (i.e. not based on referenced data or documented assessments) a full ban of PFAS use in the transportation sector (not specific to military applications) is expected to reduce PFAS emissions by about 94% (assuming a 30-year assessment period, 2025-2055). No account is taken of emissions from the waste phase.	Costs of existing alternatives for military applications would be similar to those for options applying to civilian applications for many routine goods. However, it is likely that goods that are not to be used in higher risk situations that procurement would follow the civilian market simply on price grounds. However, additional design considerations and further R&D would be required to ensure the protection of service personnel in higher risk activities and these will likely be at an increased cost relative to civilian situations. Increased risks to service personnel, reduced comfort, etc. would lead to consumer surplus loss [Weak evidence] .	
Ban with use-specific derogations: Potential derogation marked for reconsideration: Use as refrigerants and for mobile air conditioning (MAC) in	5 years	The lack of clear alternatives at the present time that are capable of providing the performance and safety aspects required for military applications where vehicle users are at high risk makes it unlikely that alternatives could be developed under a 5-year derogation. [Weak evidence] .	n/a	As it is likely that more time would be needed to develop alternatives, the cost impact is considered similar to the case for a full ban. [Weak evidence]	
	12 years	It is envisaged that a 12 year derogation would provide sufficient time for development of alternatives for military applications, given the emergence of new cooling technologies on a	No evidence is available about the precise amount of additional emissions of a 12-year derogation. Assuming a derogation of all polymeric PFAS use, maximum additional	Added time for the derogation provides manufacturers with more opportunity to screen alternative systems to ensure that they can be optimised to the demanding military environment. This is likely to be more cost-efficient for the manufacturers	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
vehicles in military applications		similar timescale [Weak evidence] .	emissions will be 33 929 t . This is slightly higher than additional emissions under a full ban (RO1, being 28 306 t).	and reduce risks of job losses, though cost data for alternative systems have not been identified. It is also likely to facilitate a safer on-vehicle environment for service personnel with associated welfare benefits. It is envisaged that price pressures would mean that this derogation is only used where safety considerations for service personnel are a significant issue: for non-critical applications it is likely that goods supplied as standard to the civilian market would be cheaper. [Weak evidence] .	
Conclusion	The Dossier Submitters accept that military applications need special consideration given the possible extremes of the working environment. It is therefore concluded that additional time beyond the 18-month transition period may be needed for alternative systems to be introduced for military applications, noting that drop-in alternatives seem to be unavailable. A 12-year derogation appears most appropriate, recognising the added hazards encountered in military operations and the possible need for innovative cooling solutions. This will lead to some increase in emissions relative to a full ban, but military applications are concluded to be only a small part of the MAC and refrigeration market. In light of the broad use scope and the weak evidence base to narrow down the scope for a derogation, such a derogation is not proposed at this point but marked for reconsideration. A derogation might be proposed at a later stage if additional information on alternatives becomes available through the Annex XV report consultation, for example concerning the range of applications where a derogation may be appropriate and the quantities of PFAS used in those applications.				

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The Dossier Submitters consider that based on information from the 2nd stakeholder consultation (particularly 3 responses from national defence agencies) that the evidence is strong that technically and economically feasible alternatives are unavailable in the quantities required for use in MAC and refrigeration systems for certain military applications under RO1, and hence that the substitution potential is low. Particular consideration is given to extreme operating conditions for some military applications and their need to operate in hostile environments, which may increase risks associated with natural refrigerants. Drop-in alternatives have not been identified.

RO1 would naturally provide the greatest benefit in the form of reduced emissions. There is limited evidence supporting the quantification of emissions from military applications specifically, though % changes linked to different derogation periods seem likely to be broadly reliable, especially as use-phase emissions for the transport sector are dominated by fluorinated gases from MAC and refrigeration systems.

Given limited time for R&D and certification of alternatives it is likely that there would be significant costs to both producers and consumers under RO1, with potential for business closures and job losses. These would be mitigated through derogations giving additional time for the sector to move to alternatives, increasing the substitution potential. A 5-year derogation is suggested above for MAC and transport refrigeration systems in other transport applications. However, given the harsher operating conditions for military equipment, a longer derogation (12-years) may be appropriate for this sector. Further information to support this is desirable, for example to specify more precisely the applications concerned and the quantities of PFAS involved.

E.2.11. Electronics and semiconductor

E.2.11.1. Baseline

Stakeholders did not provide specific information on a trend in volumes or quantities of PFAS used. It is assumed that in 2022 PTFE is still the dominant fluoropolymer, but PVDF and FEP will have a growing market share. For FEP this is largely because of the **growing electronics market** (FEP is used extensively in cables like LAN cables) as well as solar cell and fiber optic applications.

Stakeholders provided information on expected trend in sales for the next few years. In general, there is no one-to-one relation between sales and the volumes or quantities of PFASs and the data on sales are merely a best guess based on the data at hand. Stakeholders projected increases in annual sales of PFAS containing mixtures and articles in the electronics and semiconductor industry in the EEA to be between 0 and 100 percent. Most stakeholders reported an expected increase of 10% or less (see Annex A.2.13.3).

Additional information from literature and CfE is summarized as follows:

Electrical and electronic equipment (EEE): The Urban Mine Platform indicated that a total weight of 12 500 000 t of EEE was placed on the EEA market in 2020. Stakeholders did not provide specific information on a trend in volumes or quantities of PFAS used in the EEE sectors. However, growth in use of PFASs is expected because of their increasing application in electronics and electrical engineering. In general, annual sales (%) of PFAS containing mixtures and articles in the electronics and semiconductor industry in the EEA is expected to increase by more than 3%/y and in some cases to be growing 100%. No information was provided for relative market share of electronics containing PFASs to the total electronics market in the EEA.

The growth of PFAS use and emissions depends on the growth in the electronics industry (including semiconductors). Precise growth rates are not known. For assessing baseline PFAS use and emissions a mean real growth rate per year of 10% is assumed. To account for the uncertainty of emission estimates, two alternative growth scenarios (5% and 10%/y) are investigated.

The start year of the assessment is 2020. Baseline tonnage and emission estimates for industrial uses of PFASs are projected for a time path of 30 and 45 years (2025-2070) as presented in Table E.126.

Table E.126. Projected yearly PFAS use and emissions in the electronics and semiconductors sector of the EEA between 2020 and 2070 in tonnes (mean values based on market data)*.

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	4 860	7 834	12 617	20 319	32 724	52 703	84 878	220 152	571 017
PFAS emissions	738	1 189	1 914	3 083	4 966	7 997	12 880	33 407	86 648

*Estimates cover industrial and use phase only (thus, not waste phase of products).

Source: Own calculations based on market data collated by the Dossier Submitters.

Emissions were determined by applying standard environmental release categories as provided by ECHA Guidance documents (ECHA, 2016) to available market data of PFAS use in this sector. Hence, emission estimates represent worst case PFAS emissions resulting from industrial manufacture of electronics and semiconductors. The results must be considered as a first tentative estimation with considerable uncertainty because many calculation parameters are based on assumptions with limited underpinning facts. The approach can be used for further refinement when better data become available. Figure E.19 shows expected

mean PFAS emissions between 2020 and 2070 in tonnes.

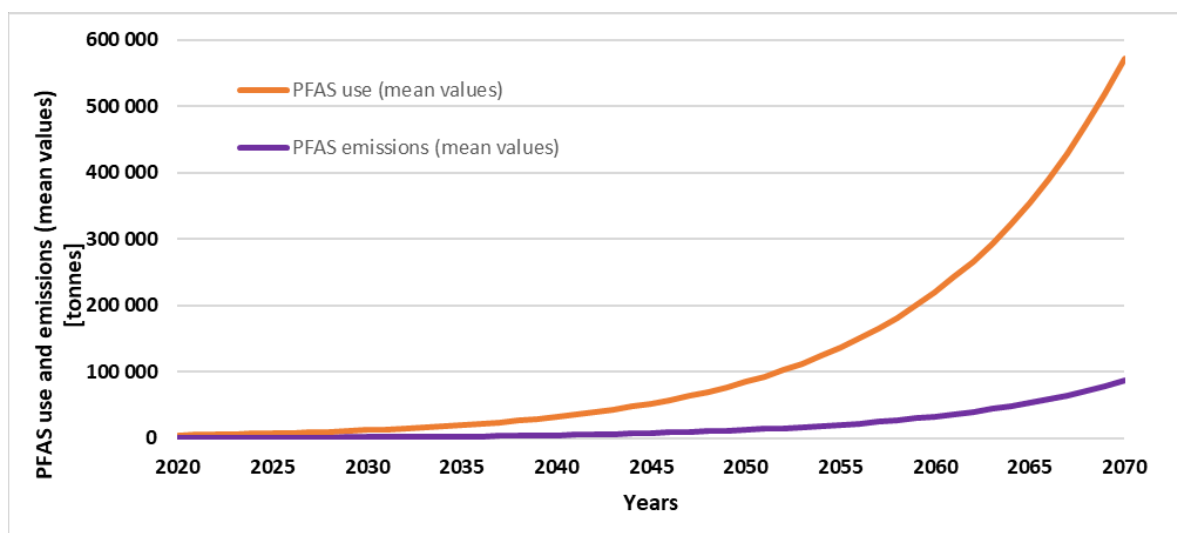


Figure E.19. Expected PFAS use and emissions in EEA under the baseline in the electronics and semiconductor sector (mean values) [tonnes].

Source: Own calculations based on market data collated by the Dossier Submitters.

Based on the assumptions made about market trends for PFAS use, emissions can be expected to increase considerably over time. The latter very much depends on assumed growth rates for the sector, which are highly uncertain but may become adjusted as new and reliable information becomes available. Based on current assumptions, an increase by more than 1000% can be expected in the period between 2025 and 2050. The largest fraction of PFAS emissions are fluoropolymers (including PFPEs) and non-polymeric PFAS (including side-chain fluorinated polymers).

E.2.11.2. Alternatives

E.2.11.2.1. Discussion on availability and quality of information

Information on the alternatives for uses discussed in this chapter and the chapter on energy is difficult to interpret. For a limited number of specific sub-uses information is sufficient to draw conclusions on already available or promising alternatives. The Dossier submitters received a high number of comments from stakeholders. These can be broadly divided into six categories (see Table E.127). For each category stakeholder information is presented.

Note that this tabular listing is intended to document the problems the Dossier Submitters are facing in general and does not differentiate between the uses for electronics, semiconductors and energy as the character of the information is very similar for these uses and in some cases the stakeholder addresses all three uses, and in some cases, it is difficult to understand which specific uses are addressed.

Table E.127 Stakeholder information received in the 2nd stakeholder consultation on availability of alternatives for electronics, semiconductors and energy (all quotes copied directly from stakeholder input).

Broad statements that alternatives are not available. The Dossier Submitters cannot derive generalizable information from generic formulations (Dossier Submitters marked examples in bold)

- **Innovative alternatives** must be found to restrictions in the choice of materials, which are associated with **high development costs**.
- Fluorinated materials, which are quite expensive are **only used for the cases, where no technical/safe alternatives** (cheaper or same price level) are available. For the majority of uses, EPDMs (or NBRs/HNBRs) are used already.
- Most of our applications require oleophobic coating due to customer requirements and application conditions. **In several cases** chemical stability in combination with higher temperature stability is requested, especially for battery and fuel cell venting and in automotive field.
- No other class of polymers do offer **such a balance of properties**; that is to say replacement of fluoropolymer will degrade cable functionality and portfolio use.
- **Non fluorinated agent can't work.**
- Applications where our PFPE based elastic material is used may be able to be replaced by other PFAS material but **we don't think it is technically feasible to replace with non-PFAS alternatives, as far as we know.**
- **As of today** no possible alternative technically suitable is available
- **Maybe in the future ... Maybe with strong drawbacks** (Availability)
- **Where possible**, applications using PTFE-containing materials are replaced with their alternatives already, due to the cost of the PTFE-based materials.
- No other material has **the same low friction and heat resistance** as PTFE.
- Non-fluorinated candidate substitutes cannot be substituted for oil barrier applications, where high oil repellence is an essential property, because it is not possible to ensure **sufficient properties**.
- Even in conformal coating applications, it is very difficult to provide multiple properties such as oil repellence, heat resistance, and corrosion gas resistance at simultaneously using only non-fluorinated materials, and a **significant decrease in properties** compared to fluorinated materials is unavoidable.
- In applications where such multiple properties are required, substitution with non-fluorinated materials is not realistic.
- The proposed solutions are **not suitable for all applications**.
- Non-PFAS alternatives are not technically feasible since they do not provide the functionalities (performance) required by these applications as the PFAS products.
Fluoropolymers (FP) are chosen when the following combination of properties are required: High thermal stability, Non-flammability and high melting-point. Inertness to chemical attack and permeation, Low coefficient of friction, Electrical properties
- PFAS is the only material that fulfils **the functions required by the market**.
- **Most of the applications** require heat resistance and chemical resistance. The materials to be applied have those performances. Only PFAS exists as such the material.
- There is no alternative material that perform high adhesive strength, heat resistance and water resistance for fixing some components to electronics devices.

- There is no alternative material that perform high transparency, antistatic property and easy peeling.
- FAS is only the polymer which has several characteristic performance, the heat resistance, Low dielectric performance, Chemical/UV resistance and others, **any other polymer does not have above performance as a unique polymer.**
- **It is not easy to replace PFAS polymer** to other materials especially Electronic and Energy field, it has wide range application for using PFAS polymer.
- **At present**, there are no alternative materials for PFA in terms of releasability, heat-resistant and chemical resistance.
- We do not have any information on substitutes for PFAS.
- PFASs can provide several excellent functions that only PFASs can impart, e.g. low dielectric constant, low dielectric loss tangent, low refractive index, oil repellence, chemical resistance, corrosion resistance, precursor as very strong organic acid (Photo Acid Generator). These abilities are not in the list and this ability is **difficult to be replaced** with other materials.
- Even before we search non-PFAS alternatives, we firstly need to identify the use. PFAS have neither been regulated nor are listed as SVHCs, so their presence and concentration in articles are not subject to communication in the complex supply chains so far.
- Alternatives would lead to **costly redesign and testing, killing our innovations in the egg.**

Statements on specific uses. That often are too specific to derive a generalizable need for a derogation.

- For Photovoltaic standard polyolefines are not applicable to their lack of UV stability...you would have to exchange photovoltaic panels every 5 years
- We have yet to find an alternative foil that has similar barrier and antifouling properties whilst not impeding Light transmission with a similar life time (20 year)
- the dielectric constant of the PTFE (low density PTFE) used for data cable cannot be reached by the listed alternatives or any other cable insulation: None of the listed alternative can provide all the cumulative benefits of PTFE for most demanding applications, when space cluttering is limited.
- Up to now, no alternative material for membranes is known. Likely it will never be found, as the requirements under the highly corrosive conditions and functionality are quite special. If PFAs cannot be used in our process anymore, this would mean for all clients a downgrading of their technology to old diaphragm or amalgam technology (with much higher energy consumption)
- We have not yet identified a cable insulation material capable of the 200 °C operating required "Solid state batteries" have been discussed as a panacea for several years, but, for most applications, they are a speculative technology with no advanced construction
- For traction batteries, semiconductors and non-semiconductors in vehicles, the proposed substitute materials are not feasible.
- All-solid-state batteries are still under study and even their material systems have not been disclosed.
- For example, In the case of a vent filter, it is necessary to achieve both breathability and waterproofness.
- The requirements of modern semiconductor manufacturing equipment and electronics and energy products, are so demanding that the only technically feasible alternatives are other fluoropolymers. For instance, seals made out of EPDM are being destroyed quickly in a ozone plasma. Silicone is not considered due to contamination concerns in semiconductor

manufacturing. Silicone is not competitive for cable insulation in high-speed data communication. A dielectric constant around 2.5 - 3.6 is for the colour copy and the high speed, the melt temperature of toner will be higher.

- (Alternatives) not competitive to Perfluoropolymers at 1.5 (cellular)
- Unknown for us but we are only downstream users, and we rely on our suppliers to study an alternative. However, due to our specifications required, the substitution would be complicated. If there are any suitable alternatives, they would first have to be tested, evaluated and qualified for each individual application (design modification, validation and repetition in type test), in some cases also at the customer's site (requires >5 y and resources, outcome uncertain).
- Potential alternatives must be photoactive. Up to now no feasible non PFAS based alternative has been invented. In addition, most of the SC manufacturing processes have had robust research conducted over the last 15+ years with no feasible non perfluorinated alternatives found that could be used in high volume manufacturing. So, for these processes, it isn't a matter of when it will [be] feasible to substitute but IF industry can substitute.
- Generally, the technical feasibility will depend on a thorough evaluation process at the different stages of our supply chain. Part validation is key to guarantee a qualitative, durable, safe product on the market, but it is the complete vehicle that ultimately need the final validation (integration of a part into a complex article into an even more complex article). We cannot just rely on a material supplier saying that he found a suitable alternative for a certain substance
- There are no non-fluorinated alternatives available that can withstand the harsh conditions of the chemical wetting processes, which ensure the durability, efficiency and performance of the products

Information that alternatives do not exhibit the required functionalities

- Non of the alternatives listed can be used as corrosion protection
- Specific combination of antiadhesive -, electrical- and mechanical behaviour not replaceable.
E.g. PEEK is ten times more expensive and less antiadhesive and too hard for comparable usage.
- The listed alternatives do not comply with the requirements regarding dissipation factor, insulation performance or temperature requirement
- Can't cope with the required environment to operate.
- Silicone might cause problems in PWIS free products.
- Alternatives like EPDM, Silicons and other Elastomers are already used for decades in section insulators.
- However, for "in contact" applications, the unique combination of hydrophobic, lipophobic, UV & tracking resistance, mechanical properties make fluoropolymers irreplaceable for this kind of application.
- Synthetic oil seems to be difficult for using boiling cooling. because its viscosity and surface tension strongly depends on temperatures. Especially, at low temperate, oils becomes sticky and almost solid.
- In order for this battery to be used for general purposes, several decades are required for its quality and durability to withstand practical use, and after that, it is believed that review of alternative materials will begin. Several alternative materials for the positive electrode binder have been proposed for current lithium-ion batteries, but both of them are lacking in quality and durability at the R&D stage.

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

- Photolithography: no known polymer-based alternatives
- In the cryogenic area there is no other material where the remaining elasticity guaranties safe operation.
- TCE, nPB, PERC, and DCM are the closest alternatives but are extremely toxic and are being phased out.
- Aqueous cleaning agents are also corrosive to metals, have high energy costs, and require extensive wastewater treatment, and there are irregular water disposal practices across end-users.
Organic solvents (HC, alcohols, esters, and ketones) are flammable, some are VOC air pollutants, have limited solvency (low Kb values) and are not suitable for oxygen service cleaning applications. Volatile Methyl Siloxanes are persistent & bioaccumulative.
- There is no alternative to replace PFAS (PFSA, PTFE) in the H2 industry (both EL and FC). Research has evaluated the potential of sulfonated hydrocarbon membranes eg. sulphonated polyetheretherketone (sPEEK) or polysulfone (e.g. seminal work on BPSH polymers by J. E. McGrath). While conduction properties and performance of these materials can be reasonably good, mechanical stability and durability are extremely poor, as oxidation by oxygen radicals, occurs. All non-fluorinated membrane concepts are still highly immature against minimum lifetime requirements of >25 000 hours. In a nutshell, they are not even close to meeting any durability requirements in a lab testing environment
- The listed alternatives are not known to be useful in lithography processes as process chemicals.
- For electronics bought from external suppliers, it is unclear if the mentioned alternatives would be technically feasible.
- No, despite ongoing research and market-exploration, we are not aware of any alternative substance, suitable as anti-drip agent in polycarbonate and PC blends.
- Coils: No substitution materials available which are technically known and tested. High developing costs would be necessary for alternative solution.
- HVS: No substitution materials available to PTFE that can be used for arc extinguishing. The listed fluorine-free alternatives are not technically feasible, as they do not reach the same performance and safety level as fluorochemicals.

General information on non-suitable alternatives

- Conceivable alternatives have huge impact on product design and negative impact on carbon footprint and device availability: PTFE =>no 1/1 alternative; PP, PE, POM not temperature resistant; PEEK, PPS, LCP no dielectric performances or no resistance to fluids; FEP/ETFE =>no 1/1 alternative
PE and PU don't combine the same performances.
- Hydrocarbon elastomers are not resistant against mineral oil used in genset diesel engines as lube oil or fuel. Nitrile rubber has been used before fluorocarbon rubber in diesel engines. But as temperatures increased due to emission requirements and customers requested elongation of maintenance periods nitrile rubber has completely substituted with fluorocarbon rubber.
- To date, their properties like ion conductivity and long term stability is not in the same range.
- Performance of alternative materials regarding proton conduction not competitive at the moment.
- PEEK not an alternative for chemical baths/process basins - will be attacked by solvents or anorganic chemicals in our production processes.

- Reinforcement of PTFE with glass to reduce the wear has been tried, but it trades off with tracking properties.
- Silicon material tears easily. It is nearly impossible to make thin wall insulation using silicone
- Currently, non-PFAS alternatives are lacking sufficient stability under high potentials as they occur in PEW WES (2) and partly during regular operation of PEM FC (1). High potentials cause an oxidation of hydrocarbon based materials which shorten the lifetime considerably. Moreover, above mentioned PEEK materials which are considered for membrane application (1a, 2a) exhibit a high elastic modulus, i.e. they are very stiff and therefore show a low mechanical durability over a long operation period.
low gas permeability of non-PFAS materials which make non-PFAS not feasible as the polymer component in the electrode.
- We cannot use silicone alternatives as the cross-contamination is high.
- it is anticipated that the electric motorization of vehicles in Europe will lag behind other regions by several decades. Even in fuel cells, the proposed alternative materials are not feasible.
- Substitutes are in the Semiconductor production: alternative gasketing materials have too low temperature resistance, chemical resistance and are not pure enough.
- PEM membranes: the described non-PFAS membranes can be used in high temperature fuel cells with a much lower efficiency. These HT-fuel cells need an operating temperature of up to 200 °C and are not suitable for the use in automotive applications.
- Using reformer gas to run HT-fuel cells would also cause CO₂ emission.
- R&D phase and lack quality and durability.
- Because of the poor mechanical and dielectrical properties of Silicone, EPDM and Mica. PEEK is not suitable, because of hardness, stiffness and low flexibility compared to used fluoropolymers
- Photoresist sensitivity and resolution are strongly dependent on the acidity. PFAS structure is necessary to have strong acidity in organic acid. Non-PFAS type PAG can't be applicable. PFAS groups in the polymer can control surface coating uniformity. They are also essential to form hydrophobic top layers for advanced photoresist, such as 193 nm immersion lithography. Low surface free energy of the PFAS group is necessary, and Non-PFAS polymers are not technically feasible.
- The cited NPAs lack necessary durability and features for process chambers and distribution components that contain chemicals in a range of reactivities, temperatures and pressures- and so risk failure and process contamination with substances & micro-particles from degradation, cracking and leachates.
- PEEK is an alternative for fluoropolymers based on temperature resistance but has shortcomings when it comes to electrical or chemical resistance, its stiffness and cannot be colored for identification. Fluoropolymers ensure prolonged lifetime of parts.
- EPDM cannot be used in long lifetime oil and gas applications where (part of) the seal cannot be easily changed, nor where steam and caustic resistance are required.

Information on unsuccessful research

- Research and development 3 - 5 year cycle followed by product qualification and testing.
- First impression is that alternatives do not fulfill all requirements. More investigation is needed for a detailed answer.
- All other alternatives that could be considered in the development process do not lead to a reliable function, which ultimately has to reliably protect material goods as well as people.

Information on possible alternatives (unspecific)

- For process liners other materials might be suitable if the process can be adapted accordingly.
- Some applications can be switched to alternatives, but not all
- **Cable insulation:** For some applications an alternative could be possible, for some not.
- So, the alternative plan in this field is not clear yet, it will be clear depends on the operating environment conditions and the application
- The alternatives provided in the list, and further down in the questionnaire, are all technically feasible alternatives to PFAS that have a proven record.
- The proposed solutions are not suitable for all applications
- Without prior evaluation and listing of all applications an assessment of the substitution possibilities cannot be made accordingly
- Different approaches to solid-state lithium ion batteries are still explored, so it is not clear yet if this kind of batteries will need PFAS to be sufficiently durable.
- The trialled lubricant is currently showing promise because the fluoro based liquids immiscibility with all other liquids. There are no other substances that have similar properties.
- IT&GC: working on a replacement of PTFE components using mentioned alternatives –POM
Over a period of 10 years alternative technology is available. A replacement of PTFE for other applications can be developed but a parallel development of the existing products will delay the ongoing development of green products.
Hydrocarbon membranes are not competitive to PFAS membranes on efficiency and lifetime and have not entered the mass market. PEEK is used but cannot substitute all properties. Looking for better solutions is ongoing
- There are some applications where alternatives may be technically feasible. Sealing with alternatives could be possible when chemical resistance and low friction are not an issue. However, because of the high costs of PFAS they are not used.
For wire insulation silicone materials can provide temperature resistance in some applications. However, the lower mechanical strength might require other design changes.

Considering the listed information on alternatives the Dossier Submitters conclude as follows:

- Only limited information has been submitted on possible alternatives for PFAS uses in the electronics and semiconductors and energy sectors.
- General or at least broadly applicable alternatives may not be available and stakeholders do not foresee any change in the future.
- Some stakeholders therefore conclude that alternatives are not available at all.
- Other stakeholders reported that substitution is possible for some applications.
- Limiting factors are R&D costs, time needed for substitution, uncertainty regarding future success in finding suitable alternatives, assessment of functional losses and the resulting assessment of suitability.
- Some alternatives, notably for uses of polymers, are already available. Nevertheless, stakeholder information on current substitution potential is inconclusive. Some stakeholders agree that users need to analyse all their uses in detail to identify less demanding uses where alternatives suffice. Other stakeholders argue that there is no potential for substitution as PFAS-based materials are more expensive than the available alternatives and therefore are only used when they are indispensable.

Regarding the sub-uses electronics and semiconductors more detailed information on

substitution potential for specific uses is scarce:

Electronics

In general, there are very few alternatives. The alternatives available might not fulfil the requirements e.g. thermal/chemical resistance or durability. Some stakeholders report that it is likely that alternatives can be found for a lot of smaller components, e.g. gaskets, wires, cables etc. as these components are used in many categories. For some uses, e.g. of fluorinated polymers, in electronics alternatives might be available.

Semiconductors

According to industry stakeholders, no non-PFAS technically feasible alternatives are available that can replace the properties necessary for semiconductor manufacturing process chemistries. No single “drop-in” replacement is possible for all semiconductor applications where substitutes exist. Almost every use has to be re-engineered to see if a replacement material will meet the technology requirements. Moreover, even within the semiconductor industry technologies are not consistent. Alternatives that work for one application or one company, will not necessarily work for another application or another company.

The Dossier Submitters identified only a small number of alternatives that can be linked to specific uses, see Table E.128.

Table E.128. List of available non-PFAS substances and technics in Electronics, Semiconductor industry.

Use	Non-PFAS alternatives
Electronics industry	a) Ethylene propylene diene monomer (EPDM) and silicone rubbers as alternatives for fluoroelastomers in sealing. b) Silicone materials, Polyetheretherketone(PEEK), mica, EPDM, Polyvinyl chloride, Polyethylene, ceramic based and one confidential polymer as alternatives for wire insulation. c) Mineral oils, synthetic oils, natural oils, Hydrocarbon fluids as alternatives in heat transfer fluids for immersion cooling (no current but possible future use) d) Cyano group instead of CF₃ for liquid crystal displays (LCD).
Semiconductor industry	e) Aromatic PAG and heteroaromatic PAGs (PAG triphenylsulfonium benzo[b]thiophene-2-sulfonic acid, 4(or 7)-nitro-, ion(1-)) (TPS TBNO) for photolithography (photoacid generators). f) Polyetheretherketone (PEEK) for example for chip manufacturing g) For photolithography (hard and not for all applications): hydrocarbon-based greases, Molybdenum disulfide, graphite h) In semiconductor production Atomic Layer Deposition/Atomic Layer Etching technologies may have potential to reduce the number of photolithography process steps but has not achieved necessary manufacturability to support high volume manufacturing. i) Immersion cooling of semiconductor devices: Mineral oils, synthetic oils, natural oils, Hydrocarbon fluids (Patent: WO2012127342). j) For flame retardancy in plastics: Brominated and chlorinated flame retardants k) One additional confidential alternative for semiconductor manufacturing equipment & infrastructure

E.2.11.2.2. Human health and environmental hazards

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log K_{ow}) and bioconcentration factor (BCF) was assessed. Additionally, it was assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHA's dissemination site.

In relation to the electronics and semiconductor industry, the list of alternatives contained 8 unique CAS numbers. Two of these substances were classified according to CLP (self-classification). None of the substances were known to fulfil the PBT or vPvB criteria due to the fact that no data on PBT/vPvB properties were found.

The list contained an additional three substances with unique substance names for which no CAS numbers were available. None of these substances was classified according to CLP. No information on PBT and vPvB properties was available. For one substance (Silicone rubbers), it was indicated that they may contain residues of D4, D5 and D6, cyclic siloxanes. D4, D5 and D6, and cyclic siloxanes are considered to be PBT/vPvB substances and D4 is considered to be an endocrine disruptor. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.11.3. Environmental impacts

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.11.3., assuming business-as-usual and, consequently, on-going PFAS use and emissions. The analysis of environmental impacts focuses on two restriction options:

- **RO1**, adopting a ban of all PFAS used in the electronics and semiconductor industry;
- **RO2**, adopting a ban on PFAS in combination with use-specific derogations. Regarding the duration of the derogations two scenarios are distinguished, i.e. a 5-year derogation (RO2a) and a 12-year derogation (RO2b).

Environmental impacts of RO1 are analysed quantitatively. Environmental impacts of RO2 are analysed qualitatively. In contrast, for the use-specific derogations emission data were largely lacking. Still, there is information to which PFAS group emissions will belong. Therefore, environmental impacts of RO2a and RO2b are evaluated qualitatively in relation to worst-case environmental benchmark scenarios, i.e. a full derogation of the relevant PFAS groups. Note that these benchmark scenarios do not represent restriction options but are used for comparative purposes only. Consequently, the expected emission reduction Table E.129 below summarizes the characteristics of the restriction options, and the worst-case benchmark scenarios. Table E.129 below summarizes the characteristics of the restriction options.

Table E.129. Characteristics of restriction options and the worst-case maximum additional emission (benchmark) scenarios.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---
RO2	Ban with use-specific derogations	(i) Potential derogation marked for reconsideration: The semiconductor manufacturing process – 12 years	18 months	12 years

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Maximum additional emission scenario	Ban with full derogation of entire PFAS groups	Fluoropolymers incl. PFPEs, fluorinated gases, PFAAs incl. precursors	18 months	12 years

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, restriction options are expected to be implemented in 2027. All emission estimates represent mean values. Table E.130 shows mean emissions and the expected mean emission reduction for time paths of 30 and 45 years (starting in 2025).

Table E.130. Total mean emissions and emission reduction of RO1 and maximum additional emission (benchmark) (electronics and semiconductor sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2020-2055			
Baseline	293 248	---	---
RO1	2 496	290 751	99.1
Maximum additional emission scenario scenario '12-year derogation of all fluoropolymers incl. PFPEs, fluorinated gases, PFAAs incl. PFAA precursors [*]	9 394	283 854	
2020-2070			
Baseline	941 244	---	---
RO1	2 496	938 748	99.7
Maximum additional emission scenario scenario '12-year derogation of all fluoropolymers incl. PFPEs, fluorinated gases, PFAAs incl. PFAA precursors [*]	9 394	931 850	

*Maximum environmental emission scenarios denote worst-case scenarios assuming a full derogation of a particular PFAS group, against which emissions of proposed use-specific derogations are evaluated qualitatively. They do not represent restriction options.

Source: Own calculations based on data collated by the Dossier Submitters.

A full ban achieves an emission reduction of about 99%. Moreover, as can be seen from Figure E.20, due to the expected market growth in this sector (see section E.2.11.3 for further details), emissions are expected to increase over time, which will increase the PFAS pollution burden in the environment if no action is taken. Environmental impacts of RO2 are discussed below for the proposed derogation.

(i) Potential derogation marked for reconsideration: The semiconductor manufacturing process – 12 years

The derogation is proposed for a time period of 12 years after EiF of the restriction and the 18 months transition period and affects emissions from polymeric PFAS, fluorinated gases and PFAAs incl. precursors. Of the uses related to semiconductors that are identified in Annex A all except one would be captured by the derogation. Furthermore, it is the Dossier Submitter's

understanding that within this potential derogation uses related to semiconductor manufacturing equipment & infrastructure would be derogated. Based on current information (i.e. alternatives are available at least for some uses, e.g. some polymeric PFAS uses) a derogation for these uses would not be justified. Of the PFAS uses reported in tables in A.3.12.2, only a fraction would be derogated (7% of PFAAs and precursors; 45% of polymeric PFAS). No information is available about the amount of fluorinated gases used for the manufacture of semiconductors.

The semiconductor production is very technical and requires a controlled environment, where low emissions will occur. As an indication, and based on information on greenhouse gas emissions, the Dossier Submitter assumes that about 5% of PFAS use will be emitted during semiconductor production.

An unknown, but (according to stakeholder information) small amount of PFAAs remains in the manufactured article. No information is available about emissions from polymeric PFAS, but it is expected that a considerably high share of the use quantities remains in the article (i.e. it is not emitted during use). For fluorinated PFAS no information is available about emissions during the use phase of semiconductors, however, only negligible emissions are expected as in general semiconductors are expected to be protected from external stressors. Given these information gaps, it has to be concluded that there is **no evidence about the expected additional PFAS emissions arising from this derogation**. Assuming a full derogation of all polymeric PFAS, PFAAs incl. precursors, and fluorinated PFAS for a duration of 12 years would cause additional emission of **9 394 t** (maximum additional emission scenario, see Table E.125). Given the assumptions and arguments provided above it is reasonable to assume that factual emissions during the production and use phase of semiconductors will be lower.

No information is available about expected emissions during the waste phase. In general, the WEEE (Waste from Electrical and Electronic Equipment) directive requires the separate collection and proper treatment of WEEE and sets targets for their collection as well as for their recovery and recycling. However, the Dossier Submitters assume that especially recovery and recycling of small polymeric PFAS parts is difficult to achieve, meaning that they end up in the shredder light fraction, ultimately being landfilled or incinerated. Therefore, it is expected that **significant emissions will occur during waste phase** resulting from the continued use of polymeric PFAS.

Figure E.20 shows the time path of emissions for the baseline scenario, a full ban of PFAS use in the electronics and semiconductor sector (RO1), and a maximum additional emission scenario.

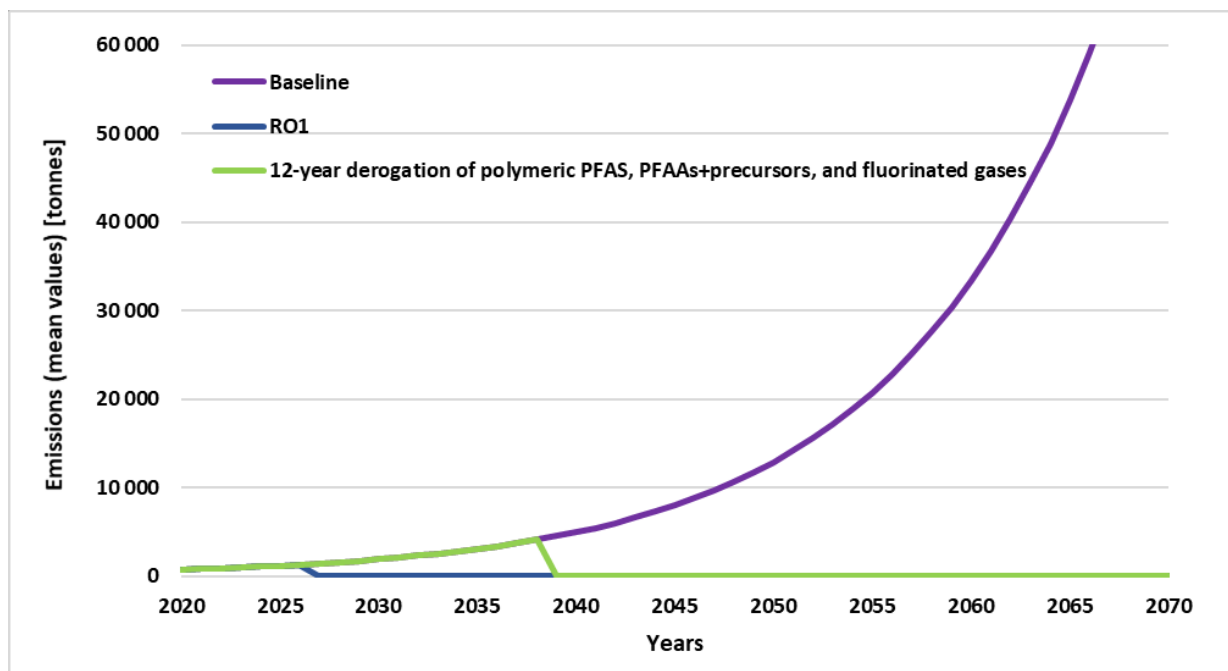


Figure E.20. Time path of mean emissions in the electronics and semiconductor sector under the baseline, RO1 and the maximum additional emission scenario [tonnes].

Source: Own calculations based on data collated by the Dossier Submitters.

E.2.11.4. Economic and other impacts

Detailed information on impacts for European industry could not be obtained during the consultations or from research.

Currently, the semiconductor industry does not see an option to substitute the fluorine chemistry from their processes immediately. It is assumed that this process will take more than five years.

The industry stakeholder consensus is that PFAS alternatives are not available for the electronic industry and if they are available in due time, the expected transition costs on average exceed €100 million and the expected transition times vary but are expected to be considerable (3-15 years).

In general, the industry stakeholder consensus in the semiconductor industry is also that PFAS alternatives are not identified and if they are available, in due time the expected transition costs vary from €20-30 million to more than €100 million and the expected transition times vary per use/component but are expected to be considerable (3-10+ years).

Respondents (from industry) expect loss of competitiveness and innovation for the EEA. They claim that appropriate transition periods and exemptions are necessary due to the lack of alternatives that could guarantee similar performances of affected products. They have also reported that the restriction would have disrupting effects on many technology products/industries and, in turn, on EEA society.

Only five replies (all from the call for evidence) report a precise estimate of the loss in earnings before interest, taxes (EBIT) for electronics including semiconductor:

- €150 million (not clear over which time period because the respondent has not provided the annual turnover);

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- €1 400 million (over 20 years);
- €20 billion (over 20 years);
- €50-100 million (over 20 years);
- €1 000 million (over 1 year).

Only two out of these five replies are from companies based in the EEA. None of the other respondents provide any estimated loss in EBIT.

Qualitative assessments of further possible impacts were given by stakeholders as follows:

Manufacturers of raw materials used in PFAS and manufacturers of PFASs: The main economic impact of a ban of PFASs is downstream and the employment effects are expected to be of a larger magnitude for the specific sectors.

Electronic industry and equipment including semiconductors: FluoroCouncil reports that the industry of electronic applications supports more than 53 000 jobs in Europe. Automotive industry also uses PFAS-based electronic components. FluoroCouncil has previously reported that the use of the fluoro-technology supports more than 72 000 jobs in Europe, though it is not clear how many of these jobs are directly connected to PFAS uses in car-electronics, because fluoro-technology is also used in other automotive solutions (e.g. engines, fuel systems, interiors, transmissions). FluoroCouncil reported that the semiconductor industry involves more than 91 000 jobs in Europe.

The information was insufficient to make a reasonable estimate of what share of employees of each of the wide range of diverse downstream user sectors might be affected in the EEA.

Wider economic impact:

The products are widely used across all industries including IT, government, healthcare, education, entertainment, manufacturing, energy, defense, etc. According to an industry representative "A ban on import of the products would have a severe impact on the economies of the EEA countries."

Some respondents highlight that competitors outside the EEA will immediately gain world market share and the gains for non-EEA competitors (mostly located in Asia) is due to the fact that they can continue to use a technology (using PFAS) that would be restricted for EEA companies.

E.2.11.5. Summary of cost and benefit assessment

E.2.11.5.1. Electronics

As long as no further information is available, the information suggests that the use of PFAS enhances safety and durability of articles and facilitates a more efficient energy consumption. The Dossier Submitters received limited information on alternatives, however, does not fully understand whether these alternatives have the potential to be used broadly or can only be utilized in niche applications. It is the Dossier Submitters' understanding that alternatives are available for some uses in which fluorinated polymers are used currently.

No information on cost-effectiveness and affordability of the alternatives is available, making it impossible to justify a general derogation for all PFAS-uses in electronics. It is also not possible to identify sub-uses for which a derogation is justified as the available information basis is mostly weak or inconclusive.

E.2.11.5.2. Semiconductors

A cost-effectiveness estimate cannot be derived considering the scarce information on impacts of a PFAS ban on this sector. The Dossier Submitters conclude that information on the availability of alternatives is insufficient and therefore characterize it as 'weak' in the summary table below (in accordance with the discussions presented in section 2.4.1.1. of the main report). But there are some indications that substitution to PFAS free alternatives in semiconductors and semiconductor manufacturing across a wide range of applications will not be possible within a transition period of 18 months. Although no quantitative data is available, it is obvious that a potential non-availability of semiconductors would lead to extremely high economic impacts. Semiconductors are used in numerous articles. Not being able to manufacture, use, import or export these articles would lead to high producer surplus losses for manufacturers and employment losses due to business closures and to high socioeconomic costs to customers due to the unavailability of an unknown number of articles. However, for some, most likely smaller, applications substitution is possible and research is ongoing to identify further alternatives and further uses to which the available alternatives are applicable.

Table E.131 summarises the outcomes of the assessment of costs and benefits for electronics. Additional information can be found in the accompanying text following the table.

Table E.131. Electronics - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Fluoroelastomers: Inconclusive evidence on whether technically feasible alternatives (i.e. EPDM and silicone) exist for all sealing applications, Wire insulation: Inconclusive evidence whether technically feasible alternatives (e.g. PEEK, EPDM) exist. Heat transfer fluids for immersion cooling: Sufficiently strong evidence that technically feasible alternatives exist. Liquid Crystal Displays: Weak evidence that technically feasible alternatives exist, i.e. cyano group instead of CF₃, for liquid crystal displays. Other uses: Inconclusive evidence as several stakeholders point out that alternatives are not available. However other stakeholders confirm that it is likely that alternatives are already available or might be found for a lot of components depending on concrete circumstances for each use.	There is sufficiently strong evidence that RO1 will lead to a reduction of emissions of about 99%.	Fluoroelastomers: Sufficiently strong evidence (in the form of stakeholder information) that generally alternatives are cheaper than fluoroelastomer. Wire insulation: Strong evidence that one potential alternative is significantly more expensive (PEEK). Strong evidence that other potential alternatives are cheaper (EPDM, PC). Heat transfer fluids for immersion cooling: No evidence on the economic feasibility of alternatives. Liquid Crystal Displays: No evidence on the economic feasibility of alternatives. Other uses: Inconclusive or no evidence on the economic feasibility of alternatives.	Cost impacts are based on limited and very general information provided by stakeholders.
Ban with use-specific derogations: (i) Potential derogation marked for reconsideration:	5 years	Given the evidence pointing to the existence of technically and economically feasible alternatives at EiF for heat transfer fluid for immersion cooling and liquid crystal displays, in combination with the inconclusive evidence pointing to the non-existence of technically and	n/a	n/a	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
The semiconductor manufacturing process – 12 years		economically feasible alternatives at EiF in all other uses, no derogation is proposed.			
	12 years	Given the evidence pointing to the existence of technically and economically feasible alternatives at EiF for heat transfer fluid for immersion cooling and liquid crystal displays, in combination with the inconclusive evidence pointing to the non-existence of technically and economically feasible alternatives at EiF in all other uses, no derogation is proposed.	n/a	n/a	n/a
Conclusion	High substitution potential at EiF for heat transfer fluids for immersion cooling [sufficiently strong evidence] and liquid crystal displays [weak evidence]. Unclear substitution potential at EiF for fluoroelastomers in all sealing applications, in wire insulation and all other uses [inconclusive evidence]. Given the evidence pointing to the existence of technically and economically feasible alternatives at EiF for heat transfer fluid for immersion cooling and liquid crystal displays, in combination with the inconclusive evidence pointing to the non-existence of technically and economically feasible alternatives at EiF in all other uses, no derogation is proposed.				

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Based on the available limited evidence, no use-specific derogations are proposed for the electronics sector. Several alternatives are available in general, but limited information suggests that users must identify and choose suitable alternatives for a large variety of very different applications. The Dossier Submitters note that the applicability of alternatives often depends on specific use conditions. Sometimes it is not clear whether no alternatives are available at all, or whether users argue that for their specific use and the surrounding conditions no alternative is available. Additionally, most stakeholders do not specify impacts from using alternatives with reduced functionality, e.g. likelihood of material failure, costs for early replacement of materials, etc.

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Table E.132 summarises the outcomes of the assessment of costs and benefits for semiconductors. Additional information can be found in the accompanying text following the table.

Table E.132. Semiconductors - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Weak evidence that technically feasible alternatives exist for: Photolithography (photoacid generators), Fluoroelastomers used for chip manufacturing, Immersion cooling of semiconductor devices, and Flame retardancy in plastics Weak evidence (stakeholder information) suggests the non-existence of alternatives for several uses because of the chemical properties necessary for semiconductor manufacturing process. Weak evidence that alternatives that could be available for one specific use cannot be used for other similar uses.	Sufficiently strong evidence that RO1 will lead to a reduction of emissions of about 99%.	Low/no cost impacts for uses where alternatives are available Stakeholders report that PFAS-based materials are more expensive than alternatives. High producer surplus losses as a result of business closures [strong evidence] due to not being able to manufacture semiconductors (weak evidence) High producer surplus losses as a result of substitution processes, due to costs associated with R&D (weak evidence). High socio-economic costs to customers due to the unavailability of an unknown number of articles using semiconductors (weak evidence). Employment losses as a result of high share of business closures [weak evidence]	
Ban with use-specific derogations: The	5 years	Given the weak evidence that 3-10+ years for transition are needed per component that	n/a	In general, same as under full ban. For a limited number of applications alternatives might be available.	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
semiconductor manufacturing process		needs to be substituted a 5 year derogation is not considered.			
	12 years	Weak evidence that PFAS alternatives will be available in due time (transition times vary per use/component, but are expected to be considerable, i.e. 3-10+ years).	No evidence available about the expected additional PFAS emissions arising from the derogation. Assuming a full derogation of all polymeric PFAS, PFAAs incl. precursors, and fluorinated PFAS for a duration of 12 years would cause additional emission of 9 394 t (maximum additional emission scenario, see Table E.130). Given the assumptions and arguments provided above it is reasonable to assume that factual emissions during the production and use phase of semiconductors will be lower.	Weak evidence on cost impacts: the expected transition costs vary from €20-30 million to more than €100 million per manufacturer and per component (weak evidence). In general, added time for the derogation provides manufacturers with more opportunity to identify and develop cost-effective alternatives whilst limiting loss of producer and consumer surplus and welfare losses.	n/a
Conclusion	High substitution potential at EiF in an unknown number of specific uses for photolithography (photoacid generators), fluoroe lastomers				

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
	used for chip manufacturing, immersion cooling of semiconductor devices and flame retardancy in plastics [weak evidence]. Low substitution potential at EiF for the semiconductor manufacturing process [weak evidence] Given the weak evidence pointing to the non-existence of technically and economically feasible alternatives at EiF, a 12-year derogation in addition to the general 18 months transition period is not proposed at this point but marked for reconsideration for: [the semiconductor manufacturing process] In light of the weak evidence base in relation to alternatives, such a derogation is not formally proposed at this point in the proposed entry text. A derogation might formally be proposed at a later stage if additional information on the availability of alternatives and their technical feasibility becomes available, e.g. information on the R&D efforts that have been undertaken and planned R&D in the future.				

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Based on the available information for semiconductors no generally applicable alternatives are available. However, according to stakeholders for an unknown number of applications, substitution is already, or in the near future, possible and research is ongoing to identify further alternatives and further uses for which the already available alternatives are applicable.

The Dossier Submitters note that the current wording of the derogation marked for reconsideration, ('the semiconductor manufacturing process') is ambiguous in regard to the precise uses and sub-uses that would be covered by the derogation. The wording needs to be adjusted and refined based on additional information. It is the understanding of the Dossier Submitters that a derogation for most uses related to the manufacturing process might be justified (as covered in Table A.49. of Annex A). For immersion cooling a derogation is not justified. For the uses mentioned in the table, the Dossier Submitters need additional information to better understand the potential for substitution (e.g. advanced packaging, semiconductor manufacturing equipment and infrastructure).

Additionally, stakeholders submitted information that it is unavoidable that small amounts of PFAS remain in the manufactured semiconductor article. Therefore, the placing on the market and use of the article must be covered by a potential derogation as well.

E.2.12. Energy

E.2.12.1. Baseline

- a) *Energy sector*: Robust information is not available. However, limited information obtained suggests that PFAS use in the energy sector will increase within the next years: The expected increase in annual sales of PFAS containing mixtures and articles in and outside the EEA is estimated to be more than 15% and, in some cases, up to 100%. However, based on stakeholder comments there is no one-to-one relation between sales and the volumes or quantities of PFASs.
- b) The Urban Mine Platform indicated that a total weight of 12 500 000 t of EEE was placed on the EEA market in 2020. Stakeholders did not provide specific information on a trend in volumes or quantities of PFASs used in the EEE sectors. However, growth in use of PFASs is expected because of their increasing application in electronics (see corresponding chapter), fuel cells and hydrogen technology, rechargeable batteries, electroactive (ferro-, pyro-, and piezoelectric) devices, backsheets for photovoltaics etcetera.
- c) The European Green Deal aims to make the EU's economy sustainable. The EU Chemicals Strategy for Sustainability is part of the European Green Deal and is a first step towards a zero-pollution ambition for a toxic-free environment. According to industry stakeholders, PFASs play an essential role in achieving the EU green deal ambitions of a climate neutral society by 2050 in several industries. Those industries include, amongst others, the semiconductor and fuel cells industries. If no alternatives become available and if the Green Deal continues an increased demand for PFASs in the energy sector can be expected.
- d) *Batteries*: Asia (China, South Korea, and Japan) remains the worldwide leader in the production of Lithium-ion batteries, with many manufacturers able to produce several (up to 100) GWh per year. The European production capacity on this front is expected to grow over time. JRC reports that the 2018 EU share in global production of Lithium-ion batteries was 3% with a slight expected increase to approximately 5% for today. The 2023 forecasts for Europe show a 13.9% worldwide market share in production capacity (expected worldwide production of 658 GWh) (JRC, 2018). Benchmark Mineral Intelligence also reports a steep increase for the EU share in global production of Lithium-ion batteries: They estimate that the EU share as of 2020 was 6.8%. and will increase to 17.8% in 2030.
- e) The total number of battery cells placed on the EEA market in 2020 is close to 6 000 000 000. For additional information confirming strong growth until 2040 see Annex A.
- f) The global fuel cell market is forecasted to grow by a Compound Annual Growth Rate of 18% in the next few years. In particular, the fuel cell market for the automotive industry is expected to grow by 9% by 2021, with increasing demand for fuel cells in material-handling vehicles, light-duty vehicles, buses and the aerospace sector.
- g) The European production of all the fuel cells systems combined is expected to amount to between €500 million and €4 200 million. The same estimates range between €1 500 million and €10 600 million by 2030, corresponding to a value added of €500 million and €3 500 million, respectively.
- h) The market for hydrogen-related machinery, equipment, and components could rise to an annual 200 billion USD by 2050. Fuel cells and electrolyzers offer the largest opportunities for machinery makers. Only fuel cells add up to potential revenue for machinery makers of USD 21-25 billion annually by 2050.
- i) Hydrogen Europe estimated the future need for PFASs in PEM electrolysis, based on the following: To reach the EU's Hydrogen Strategy objective of 40 GW of electrolysis capacity by 2030, a maximum of 500 t of PFSA ionomer (perfluorinated copolymers containing sulfonic acid moieties) most commonly reinforced by PTFE is needed. The estimated volume is an upper bound because it is assumed that all electrolyzers will be PEM technology based and there will be no technological improvements reducing the amount of PFASs.

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- j) *Photovoltaics*: Solar panels are mainly produced in Asia. No data was received on the volume of imports to Europe.
- k) *Immersion cooling* (Most likely no PFAS-use in EEA but potentially in the future): Globally, data centre market is expected to grow by 10% in the coming years. Several factors are driving this growth, including the datafication and the increased needs for computational power and storage drove up by technological trends such as Internet of Things (IoT), Data & Analytics, Artificial Intelligence (AI) and – particularly – blockchain and video streaming. In 2019, data centres immersion cooling market was valued at US\$177 million, but the market is expected to grow at a CAGR of 23.2% in the reference period 2019-2024 and reach an estimated market size of US\$500 million by 2024.

Precise growth rates for the energy sector are not known. For assessing baseline PFAS use and emissions a mean real growth rate per year of 10% is assumed based on information from the second stakeholder consultation. The start year of the projection of tonnage and emission estimates is 2020 as presented in Table E.133.

Table E.133. Projected yearly use and PFAS emissions in the energy sector of the EEA between 2020 and 2070 in tonnes (mean values based on market data)*.

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	3 049	4 911	7 909	12 738	20 514	33 039	53 209	138 101	357 963
PFAS emissions	56	89	144	232	374	602	969	2 513	6 519

*Estimates cover industrial and use phase only (thus, not waste phase of products).

Source: Own calculations by the Dossier Submitters based on market data provided.

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage).

Emissions were determined by applying standard environmental release categories as provided by ECHA Guidance documents (ECHA, 2016) to available market data of PFAS use in this sector. Hence, emission estimates represent worst case emissions of industrial products during their formulation phase. The results must be considered as a first tentative estimation with considerable uncertainty because many calculation parameters are based on assumptions with limited underpinning facts. The approach can be used for further refinement when better data become available. Figure E.21 shows expected mean PFAS tonnage and emissions between 2020 and 2070.

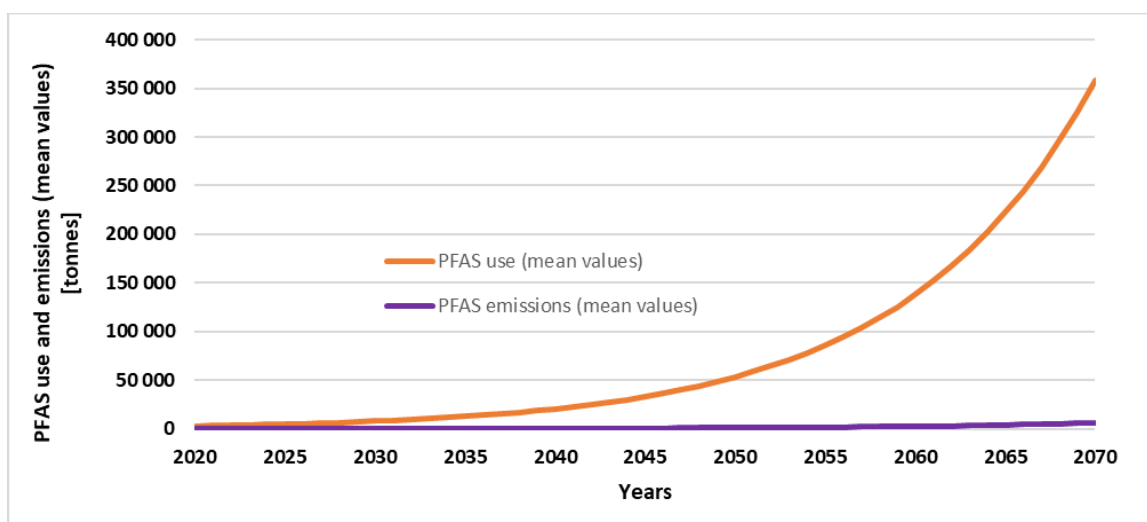


Figure E.21. Expected PFAS use and emissions in EEA under the baseline in the energy sector (mean values) [tonnes].

Based on the assumptions made about market trends for PFAS use, emissions can be expected to increase considerably over time, comparable to the increase in the electronics and semiconductor sectors, though at a lower absolute level. In particular, in the period between 2020 and 2050 an increase by more than 1 000% can be expected. PFAS emissions consist mainly of fluoropolymers and non-polymeric PFASs.

E.2.12.2. Alternatives

E.2.12.2.1. Discussion on availability and quality of information

Information on the alternatives for uses discussed in this chapter is difficult to interpret. For a limited number of specific sub-uses information is sufficient to draw conclusions on already available or promising alternatives. The Dossier Submitters received a high number of comments from stakeholders. These can be broadly divided in six categories. For each category stakeholder information is presented (see corresponding table in section E.2.11.4 combining information available for electronics, semiconductors and energy).

Note that the tabular listing is intended to document the problems the Dossier Submitters are facing in general and does not differentiate between the uses for electronics, semiconductors and energy as the character of the information is very similar for these uses.

Considering the listed information on alternatives the Dossier Submitters conclude as follows:

- Only limited information has been submitted on possible alternatives.
- Generally, or at least broadly applicable alternatives are not available, and stakeholders do not foresee any changes in the future.
- Some stakeholders therefore conclude that alternatives are not available at all.
- However, other stakeholders reported that substitution is possible for some application.
- Limiting factors are R&D costs, time needed for substitution, uncertainty regarding future success in finding suitable alternatives, assessment of functional losses and the resulting assessment of applicability.
- Some alternatives, notably for uses of polymers, are already available. Nevertheless, stakeholder information on current substitution potential is inconclusive. Some

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stakeholders agree that users need to analyse all their uses in detail to identify less demanding uses where alternatives suffice. Other stakeholders argue that there is no potential for substitution, citing that PFAS-based materials are more expensive than the available alternatives and therefore are only used when they are indispensable.

Based on information submitted in various stakeholder consultations, some specific alternatives have been identified that are available for the energy industry but several of them might have limitations regarding properties such as weather resistance, heat resistance or chemical resistance that may cause a decrease in lifetime and/or instability in the systems (see Table E.134).

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Table E.134. List of available non-PFAS substances and technics in Energy sector.

Use category	Sub-use	Potential non-PFAS alternative	Suitability
Solar collector		No information received	
Photovoltaic cells	Film/coating	Polyolefin, polyethylene terephthalate (PET) and/or ethylene vinyl acetate (EVA). Surface coating on top of front sheets covered under construction products	Alternatives are already on the market (OECD, 2022). One stakeholder stated that alternatives have a lack of weather resistance and water vapour barrier properties leading to defects and/or deterioration of the cell (decrease in service life).
	Tape		
Wind energy	Film/coating	No information received	See also chapter on construction where coating of windmill blades and towers are covered.
	and cables		
	Lubricant	No information received	See chapter on lubricants. Note that this also covers lubrication of e.g. gears in windmills.
Coal based power plant	Heat exchanger tubing Filters	No information received	
Nuclear power plant	Infrastructure: Gasket material	Confidential information available	Stakeholder reports that the discussed alternatives are less resistant to higher temperatures, they have limited ability to incorporate components to destroy or capture harmful emissions. Lower chemical resistance results in higher article failures, increased emissions, and more frequent replacement. Other potential alternatives are not expected to perform at the same demanding conditions under which fluoropolymer-based articles can provide reliable operation.
PEM fuel cells	Membrane electrode assemblies (MEA) (including re-enforcement)	Polysulfone, electrospun polybenzimidazole-type materials, hydrocarbon membrane, sulphonated polyetheretherketone (PEEK)	No instant large-scale availability.
	Gas Diffusion Layer (GDL)	No information received	
	Microporous layers (MPL)	No information received	
	Gaskets and seals	Fluorine free elastomers, hydrocarbon elastomers	A stakeholder mentioned that due to the harsh environment in combination with the sensitivity of the Membrane Electrodes Assembly (MEA) for

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Use category	Sub-use	Potential non-PFAS alternative	Suitability
			contamination, very stable sealing materials are required. Fluorine-free-elastomers are under evaluation but contamination of the MEA – limiting its lifetime – as well as oxidative deterioration of the material itself are issues. Some elastomers without fluorine exist and could potentially be used in the future for this function. Those could be cheaper but are, today, not as chemically stable. As for gas-permeability and cost, the alternatives are superior to fluorinated elastomers thus replacement of these materials is desirable when possible. Another stakeholder pointed out issues when using alternatives: Lack of heat resistance, chemical resistance, water vapour barrier and flame-retardant properties. Failure of the seal material to maintain a tight seal due to deterioration. Further they mentioned lack of durability against load fluctuations during power generation. Lack of durability could cause the car carrying the fuel cell to come to a sudden stop. In their view there is also the possibility of short-circuit and ignition.
PEM electrolyser/ PEM fuel cells	Sealing materials; gaskets	Hydrocarbon membrane, sulphonated polyetheretherketone (PEEK), polysulfone (Under development). Ionomers/sulfonated polymers Reinforcement material alternatives: electrospun polybenzimidazole-type materials Hydrocarbon elastomers (seals) One confidential material	According to stakeholders, research work has been ongoing for hydrocarbon membrane and sulphonated polyetheretherketone (PEEK) membrane development. Usually, properties and performance of these materials can be reasonably good whereas the durability is often poor, as oxidation by oxygen radicals occurs. It is expected that it will take ten years or more until a validated alternative material is available in volume. As for the reinforcement material, promising approaches are currently made to replace the PTFE by fluorine-free compounds like electrospun polybenzimidazole-type materials. The commercial use of these reinforcements is expected to begin not before five to ten years from now. Another stakeholder argued that alternatives do not

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Use category	Sub-use	Potential non-PFAS alternative	Suitability
			fulfil the required functions: Lack of heat resistance, chemical resistance, water vapour barrier and flame-retardant properties. Failure of the seal material to maintain a tight seal due to deterioration. Chemical stability, creep resistance, sliding properties, cryogenic properties. It is not clear in which application the "reinforcement" is intended to be used, but if it is intended to be used as a core material in fuel cells, the proposed alternative cannot guarantee the stability, safety and long-term use of the reinforced object. Another stakeholder: While conduction properties and performance of these materials can be reasonably good, mechanical stability and durability are extremely poor, as oxidation by oxygen radicals, occurs. All non-fluorinated membrane concepts are still highly immature against minimum lifetime requirements of >25 000 hours. Although there would be an economic advantage to finding performant fluorine-free materials, there is no alternative today to replace PFASs (PFSA, PTFE) in the hydrogen industry (both electrolyser and fuel cell).
PEM electrolyser		No information received	
Lithium ion batteries	Seals, electrode binders, separator films/coatings, electrolyte additives, thermal management pack/module	hydrocarbon elastomers (seals). Solid state batteries. Lead acid batteries	One stakeholder stated: Lack of heat resistance, chemical resistance, water vapour barrier and flame-retardant properties. Failure of the seal material to maintain a tight seal due to deterioration Stakeholders inform that there may be some non-pfas alternatives for solid state batteries
Batteries	Battery fluid, Compounds for separator films, Binder	No information received	

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Use category	Sub-use	Potential non-PFAS alternative	Suitability
Flow batteries	Ionomer membranes Ion exchange membrane	Solid state batteries	Alternatives such as solid-state batteries are still investigated, but it might take a while before they can replace flow batteries. Stakeholders inform that there is no viable PFAS alternatives as of this moment.
Electrolysis technologies (not PEM)	Equipment: gaskets, tubes, inliner of pipes/tanks	Confidential information on alternatives available	Mentioned alternatives for PTFE-based sealing systems could have satisfactory performance but certainly not at the levels that fluoropolymers provide, particularly in extreme conditions of mechanical strength required, variability of temperatures and chemical conditions. Other elastomers could eventually be used but providing limited mechanical strength and chemical resistance.
Oil and gas application	Equipment: gaskets, tubes, inliner of pipes/tanks. Wires and capacitors.	No information received	For this use see also information in Chapter petroleum and mining
Others	Switchgears High Voltage DC Converter Valves	Sulfur hexafluoride (SF ₆)	Stakeholder information: While conduction properties and performance of these materials can be reasonably good, mechanical stability and durability are extremely poor, as oxidation by oxygen radicals, occurs. All non-fluorinated membrane concepts are still highly immature against minimum lifetime requirements of >25 000 hours.

Literature research did not result in the identification of additional alternatives.

In sum, it is not clear for which uses alternatives are already or within the next 5-10 years available. Stakeholders stressed the functional losses when non-PFAS materials need to be used in the future, however, did not provide specific information on expected impacts regarding direct substitution costs and additional costs for premature failure of articles or additional maintenance.

E.2.12.2.2. Human health and environmental hazards

Not a separate list; see 'Electronics and semiconductors'. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.12.3. Environmental impacts

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.12.3., assuming business-as-usual and, consequently, on-going PFAS use and emissions. The analysis of environmental impacts focuses on two restriction options:

- **RO1**, adopting a ban of all PFASs used in the energy industry;
- **RO2**, adopting a ban on PFAS in combination with use-specific derogations. Regarding the duration of the derogations two variants are distinguished, i.e. a 5-year derogation and a 12-year derogation.

Environmental impacts of RO1 are analysed quantitatively. In contrast, for the use-specific derogations emission data were largely lacking. Still, there is information to which PFAS group emissions will belong. Therefore, environmental impacts of RO2 are evaluated qualitatively in relation to worst-case environmental benchmark scenarios, i.e. a full derogation of the relevant PFAS groups. Note that these benchmark scenarios do not represent restriction options but are used for comparative purposes only. Table E.135 below summarizes the characteristics of the restriction options.

Table E.135. Characteristics of restriction options and benchmark scenarios.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---
RO2	Ban with use-specific derogations	(i) Proposed derogation: Proton-exchange membrane (PEM) fuel cells	18 months	5 years
Maximum environmental emission scenario	Ban with full derogation of entire PFAS groups	Fluoropolymers and PFAAs incl. precursors	18 months	5 years

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, restriction options are expected to be implemented in 2027. All emission estimates represent mean values. Table E.136 shows mean emissions and the expected mean emission reduction for time paths of 30 and 45 years (starting in 2025).

Table E.136. Total mean emissions and emission reduction of RO1 and maximum additional emission scenarios (energy sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2020-2055			
Baseline	16 272	---	---
RO1	188	16 084	99
Maximum additional emission scenario '5-year derogation of all fluoropolymers incl. PFPEs and PFAAs incl. precursors'	607	15 661	96
2020-2070			
Baseline	70 815	---	---
RO1	188	70 627	99.6
Maximum additional emission scenario '5-year derogation of all fluoropolymers incl. PFPEs and PFAAs incl. precursors'	607	70 204	99

*Maximum environmental emission scenarios denote worst-case scenarios assuming a full derogation of a particular PFAS group, against which emissions of proposed use-specific derogations are evaluated qualitatively. They do not represent restriction options. Source: Own calculations based on data collated by the Dossier Submitters.

As illustrated in Table E.136, a full ban on PFAS use in this sector leads to a mean emission reduction of about 99% compared to the baseline scenario. Environmental impacts of RO2 are discussed below for the proposed derogation.

(i) Proposed derogation: Proton-exchange membrane (PEM) fuel cells

The derogation is proposed for a time period of 5 years after EiF of the restriction and the 18 months transition period, and affects emissions from PFAAs incl. precursors and fluoropolymers. Emissions resulting from the proposed derogation are difficult to assess as information on current and future use quantities is scarce and uncertain. A best guess would be that emissions resulting from the production phase are expected to be similar to the emissions expected for electronics, i.e. 5%. During use phase emissions should be negligible as PFAAs and polymeric PFAS are used in enclosed articles. Information on emissions at the end of life of products is sparse, but it is the Dossier Submitters understanding that recycling of PEM fuel cells and electrolyzers is difficult and currently focused on recovering metal. Therefore it is expected that PFAA and polymeric PFAS parts will be landfilled or incinerated, causing emissions during the end-of-life phase. **Evidence** about PFAS emissions during the production and use phase **is lacking**. However, assuming a full derogation of PFAAs and their precursors, and of fluoropolymers used in the energy sector, maximum additional additional emissions will be about 607 t, which is about 3 times higher emissions compared to a full ban (RO1).

Figure E.22 shows the time paths of emissions under the baseline, RO1 and the maximum additional emission scenario.

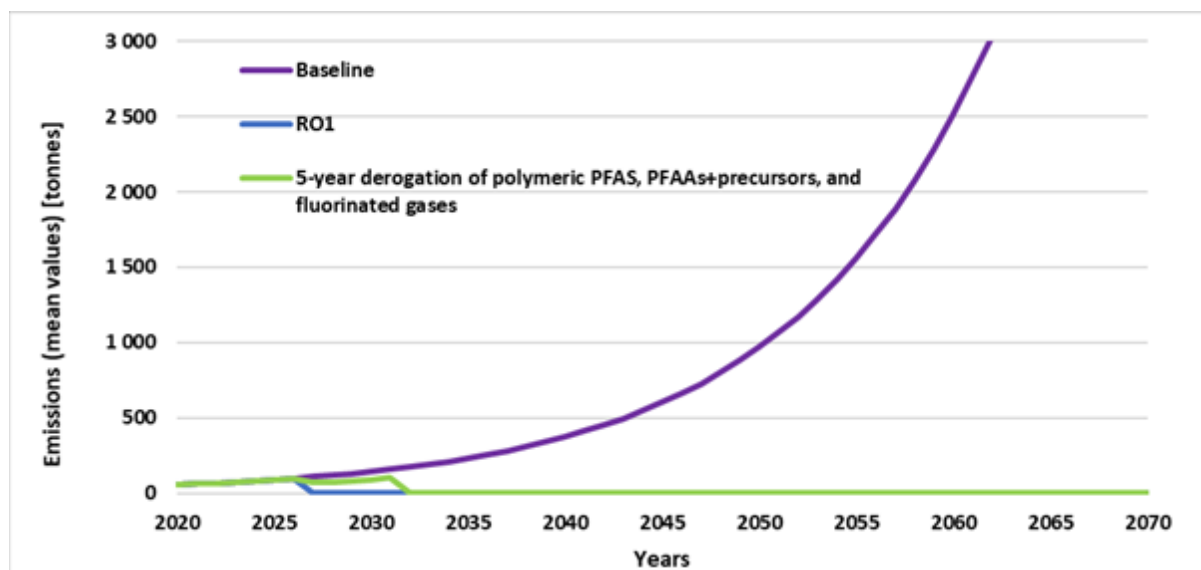


Figure E.22. Time path of mean emissions under the baseline, RO1 and the maximum additional emission scenario (energy sector, in tonnes).

Source: Own calculations based on data collated by the Dossier Submitters.

E.2.12.4. Economic and other impacts

The majority of the replies for the energy industry overlap with the electronics and semiconductor business: Information is available that a very limited number of non-PFAS alternatives are available, more alternatives will be available within the next 5-15 years. Only qualitative information on transition costs is available. Some stakeholder replies indicate the necessary additional transition period within the range 3-15 years when alternatives become available.

Respondents (from industry) expect loss of competitiveness and innovation for the EEA when no equivalent alternatives are available. They claim that appropriate transition periods and exemptions are necessary due to the lack of alternatives that could guarantee similar performance of affected products. They have also reported that the restriction would have disrupting effects on many technology products/industries and, in turn, on EEA society.

Only two replies report some estimates of the loss in EBIT for the energy sector (these are the same respondents for the electronics sectors reporting the same expected EBIT losses):

- €50-100 million (over 20 years); this company is based outside the EEA;
- €1 500 million (over 20 years); this company is based in the EEA.

No hints on the EBIT-sales ratio can be derived from these two replies.

Overall, the restriction of PFASs is likely to affect the workforce in the whole EEA. However, sufficient data was not available to reliably extrapolate impacts to the whole EEA. Stakeholder input suggests that employment would be impacted in the industries that manufacture energy-related articles. But stakeholders also expect significant employment losses in downstream user sectors where the articles are no longer available.

Respondents highlight that competitors outside the EEA will immediately gain market share (on non-EEA-markets) since they can continue to use a technology that would be restricted to EEA companies.

E.2.12.5. Summary of cost and benefit assessment

Table E.137 summarises the outcomes of the assessment of costs and benefits for energy uses. More detailed information can be found in the accompanying text following the table.

Table E.137. Energy - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives exist for: Backsheets for photovoltaic cells (PET, EVA), but also claimed to be less durable. Sufficiently strong evidence for the existence of technically feasible alternatives for membrane applications in PEM fuel cells. Alternatives are reported to be inferior in terms of durability. Evidence points to potential shortages in supply. Sufficiently strong evidence for the existence of alternatives for reinforcement materials for use in PEM fuel cells. Evidence points to alternatives not being commercially available before five to 10 years from 2022. Sufficiently strong evidence that technically and economically feasible alternatives exist for sealing materials used in PEM fuel	There is strong evidence that a ban will lead to an emission reduction of about 99% (assuming a 30-year assessment period).	Not enough information to conclude on costs associated with specific uses. For uses for which substitution is deemed possible, examples of costs that will be incurred include: Costs associated with more frequent replacement, resulting from quicker deterioration and/or more frequent defects, e.g. as a result of the lower weather resistance and inferior vapour barrier properties of alternatives with respect to photovoltaic cells, or lower chemical resistance in the case of nuclear power plants For PEM fuel cells alternatives will not be available in 18 months resulting in closing of business, and resulting producer surplus losses, employment impacts and impacts on customers resulting from the unavailability of PEM fuel cells.	Cost impacts are based on limited and very general information provided by stakeholders.

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		cells These alternatives are claimed to be less durable but available at lower cost. There is weak evidence pointing to lower flame-retardant properties. As such, alternatives might not be technically feasible for applications with particularly high stability, and durability and flame-retardance requirements. Weak evidence, that alternatives for gasket material for nuclear power plants exist but are less durable. Weak evidence that technically feasible alternatives exist for gaskets, tubes, and inliners of pipes/tanks used in relation to non-PEM electrolysis technologies. Weak evidence that alternative batteries, e.g. PFAS-free solid-state batteries could be used as a substitute for lithium-ion and flow batteries: The feasibility of using such batteries as a replacement for flow batteries is still investigated. Inconclusive evidence for uses not mentioned above: Several stakeholders point out that alternatives are not available. However other stakeholders			

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
		confirm that it is likely that alternatives are already available or might be found for several components depending on concrete circumstances for each use.			
Ban with use-specific derogations: Derogations on fluoropolymers and perfluoropolyethers in Proton-exchange membrane (PEM) fuel cells	5 years	Sufficiently strong evidence available, pointing to problems in relation to the availability of validated alternatives (for fluoropolymers and perfluoropolyethers) in sufficient quantities for membranes and significant time requirements for the commercialization of reinforcement materials, (at least 5-10 years are deemed to be required from 2022).	Evidence about PFAS emissions during the production and use phase is lacking . However, maximum additional emissions (assuming a full derogation of PFAAs and their precursors, and of fluoropolymers used in the energy sector) will be about 607 t , which is about 3 times higher emissions compared to a full ban (RO1).	Assuming that alternatives will be available in sufficient quantities in time: No producer surplus losses as a result of business closures [weak evidence] No or low producer surplus losses as a result of substitution [weak evidence] as weak evidence points to lower costs for alternatives. Low or no consumer surplus losses from price changes associated with substitution [no evidence] depending on whether potential additional costs will be borne by producers or consumers. Some additional costs possible, as a result of the earlier disposal of fuel cells due to less durability of alternatives [weak evidence] No employment losses [no evidence]	n/a
	12 years	n/a	n/a	n/a	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Conclusion	A full ban with a transition period of 18 months is proposed for the sector. A use-specific 5-year derogation in addition to the 18 months transition period is proposed for fluoropolymers and perfluoropolyethers in proton-exchange membrane (PEM) fuel cells.				

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No derogations are proposed for the majority of uses at this stage. Evidence is inconclusive and therefore not sufficient to justify additional use-specific derogations. A general derogation for all uses is likely to be not justified, as there are alternatives for some uses. A derogation could (most likely) be justified for specific uses where alternatives are not technically feasible, but this would rely on more detailed information on the specific uses.

No quantitative or more detailed qualitative cost information is available. It seems likely that a full ban on the use of PFAS in the energy sector would result in disproportionate costs. Stakeholders did not argue that alternatives will not be affordable in general but pointed out the technical shortcomings. Therefore, the Dossier Submitters assume that alternative materials will be affordable if they become available.

For some uses alternatives might become available within the next years. No or only limited alternatives will be available within the proposed transition period for an unknown number of sub-uses. The Dossier Submitters do not have enough information to fully assess the impacts of longer transition periods of 5 or 12 years. Considering the information received regarding ongoing R&D and available alternatives, a general transition period of 12 years is likely to be justified (considering the additional emissions). Although uncertainties remain, the Dossier Submitters have no evidence that for the use of PFAS in PEM fuel cells a long transition period of 12 years will result in lower producer or consumer surplus losses and a decrease in supply shortages.

E.2.13. Construction products

This section addresses the use of PFASs in building materials/construction products. Uses and volumes of PFAS-based lubricants is provided in Annex A.3.14 and emission calculations, including assumptions is provided in Annex B.9.14.

E.2.13.1. Baseline

As described in Annex B.9.14., a basic source-flow model has been developed for assessing emissions from building material/construction products containing PFASs under the baseline scenario. The model makes use of the data gathered from stakeholder consultations or estimations based on literature and substance identification in Annex A.3.14. One key caveat here is that on a more general level a large number of substances have been identified as being in use or potentially in use with the quality of data available varying significantly across all substances identified. Therefore, the approach taken has not tried to develop estimates on a substance-by-substance basis, but rather taken a grouping approach. Where availability of data varies significantly on a substance-by-substance basis a key benefit of using a grouping approach is that impacts of varying specific substance data are lessened. The trade-off of using such an approach is that it means the estimates provided will have a higher uncertainty attached to them overall (see Table E.138). However, this approach can still provide useful data to estimate the orders of magnitude for emissions when comparing PFAS groups and different sectors.

The projection of the time path of PFAS use (tonnage) and emissions under the baseline scenario considers expected growth rates for the relevant PFAS groups as shown in Table E.139.

Table E.138. Assumptions for projecting tonnage volumes and emissions.

PFAS groups	Assumption (2020 – 2070)
Polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF)	Continued growth at 5%/y until 2030, after which growth slows to 2.5% between 2030 and 2040 and slows further to 1%/y between 2040-2050.
Ethylene tetrafluoroethylene (ETFE)	Growth rate of 8%/y until 2025, after which growth slows to 5% (in line with PTFE) until 2030. The growth pattern then mirrors PTFE as growth of 2.5% annually between 2030 and 2040 and 1%/y thereafter between 2040-2050.
Other fluoropolymers	Growth rate of 2.5%/y between 2020 and 2040, after which it falls in line with the other fluoropolymers as a rate of 1%/y between 2040 and 2050.
Non-polymeric PFAS	Use is assumed to have a flat increase of 1%/y from 2020 to 2050, assuming the market continues to be suppressed by the existing restrictions on a number of PFAS.

Based on the information provided in Table E.138, for the baseline scenario of PFASs use and emissions in the building/construction sector a declining growth rate is assumed for all PFAS groups. A yearly real growth rate for all PFASs groups of 5% is applied from 2020-2030, which declines to 2.5% from 2030-2040, and to 1% for the remaining years of the assessment period assuming that the growth rate of 1% will also apply in the period from 2050 to 2070. For non-polymeric PFASs the market growth is 1% during the entire assessment period. The start year of the projection of tonnage and emission estimates is as presented in Table E.139.

Table E.139. Projected yearly PFASs use and emissions in the building / construction sector in the EEA between 2020 and 2070 in tonnes (mean values based on market data)

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	8 984	11 465	14 633	16 556	18 732	19 687	20 691	22 856	25 248
PFAS emissions	2 489	3 026	4 055	4 588	5 190	5 455	5 733	6 333	6 996

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during formulation and the use phase (thus not the waste stage).

In Annex B.9.14.2. PFASs emissions from building materials/construction products were determined by applying standard environmental release categories to the range of tonnages (low and high) provided by stakeholders (Annex A.3.14.2.). Emission estimates represent low and high worst case emissions during formulation, application (for mixtures only) and use-phase of building material/construction products containing PFASs. The results must be considered as a first tentative estimation with considerable uncertainty because many calculation parameters are based on assumptions with limited underpinning facts. In Annex B.9.14.2. emission estimates of building material/construction products is divided between articles and mixtures. Mixtures (such as architectural paints and coatings, coil coating, wind turbine blade coating and top coating for composite architectural membranes) account for approximately 98% of the emissions and application of mixtures accounting for 90% of the total emissions. The in-use phase for both articles and mixtures, as well as the application phase for mixtures can be split between indoor and outdoor use. Emissions is in the model dominated by the outdoor use and especially by application of mixtures outdoor, as the in-use phase outdoor for articles and mixtures only account for around 1% and 2%, respectively.

Primary degradation for the in-use phase outdoor is likely to be through a combination of weathering and abrasion depending on the specific application. For emissions associated with indoor applications, the rate of emission is likely heavily influenced by the specific application. For example, architectural membranes used in roof spaces may lie undisturbed many months or years, with a single significant release during maintenance or removal. Conversely, coatings used on flooring may emit on a steady basis over the working life due to abrasion from footfall and cleaning activities. This makes applying emission factors at a high-level (i.e., all indoor articles) challenging. It also means that use itself can be both within public buildings and domestic properties, which also affects the potential rates of emission, pathways, and exposure. No further efforts have been made to try and disaggregate between articles used in public and private buildings.

In terms of substance groups, emission calculations in Annex B.9.14.2 is dominated by polymeric PFASs (fluoropolymers) that account for approximately 94% whereas non-polymeric PFASs/PFAAs and precursors (including side-chain fluorinated polymers) only account for approximately 6%.

Figure E.23 shows expected PFASs use and emissions (all PFASs) for the construction sector as a whole, based on available market data (Annex A.3.14.2.) and assumptions on growth rates shown in Table E.138. Growth rates adopted for PFAS use were also applied to emission projections.

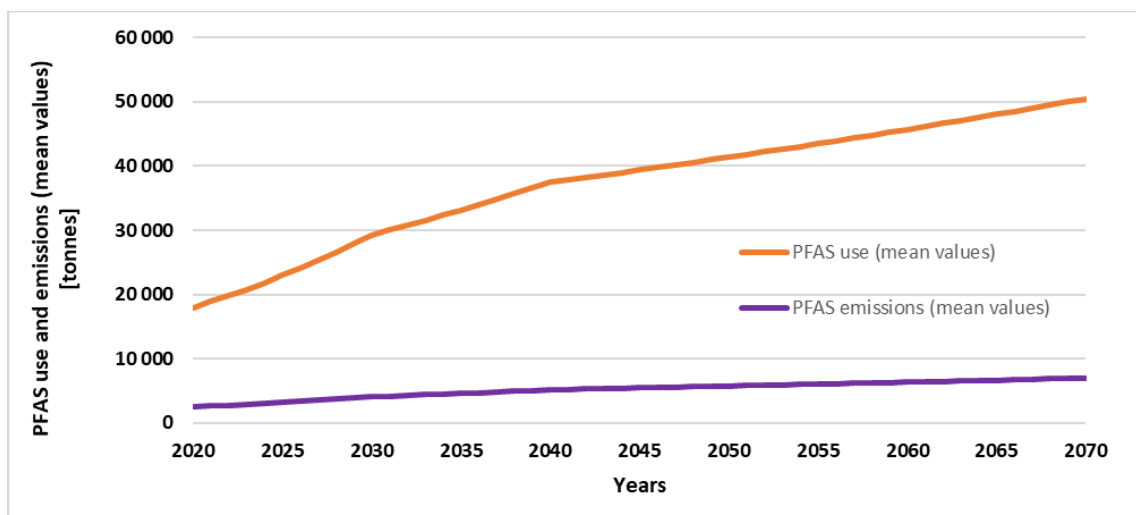


Figure E.23 Expected PFASs use and emissions in EEA under the baseline in the building/construction sector (mean values) [tonnes].

Based on the assumptions made about market trends for PFAS use in construction products, emissions can be expected to increase over time. Under the baseline, PFAS emissions will likely double between 2020 and 2050.

E.2.13.2. Alternatives

E.2.13.2.1. Description of the use and function of the restricted substance(s)

Uses of PFASs in building material/construction products is described in Annex A.3.14. In this section further descriptions are given for uses where evidence on alternatives and/or economic impact has been provided or identified. For other uses, including some of the uses in Annex A.3.14, no evidence on alternatives and/or economic impacts has been provided or identified and there is, as a result, no evidence indicating that a derogation might be needed. These uses will not be discussed any further.

Wires and cables used in the building and construction sector are included under the sections on electronic and semiconductors (see section E.2.11). The same goes for the foam blowing agents which is included under Heating, ventilation, air conditioning and refrigeration (HVACR) and other applications of fluorinated gases (see section E.2.8).

The section is divided into three sub-sections: Fluoropolymer and PFPEs, side-chain fluorinated polymers and non-polymeric PFASs.

E.2.13.2.2. Fluoropolymers and PFPEs – description of function and use in building materials/construction products

Architectural coatings and paints, coil coating and coating of wind turbine blades

A coating is a covering that is applied in a thin film to the surface of an article (substrate) to add specific function(s) to the substrate. Paints (and lacquers) are coatings that are decorative and that can also add function(s) to the substrate. In fluoropolymer coatings, the fluoropolymer is usually considered to be part of the binder. Many fluoropolymer top coatings in protective paint systems are nearly pure fluoropolymers, whereas primers and one-coats are generally blends of high temperature organic polymers or inorganic polymers with fluoropolymers. In coating and paint for building material/construction products, here considered as architectural paint and coating (painting/coating the exteriors and interiors of buildings and other building structures like e.g. bridges), coil coating (coated steel and

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aluminum coils, that can be formed into exterior building panels and roofs) and wind turbine blade coating, fluoropolymer binders can be used for protection against harsh (environmental) conditions and provides chemical/corrosion resistance, durability, weather and UV resistance. Especially for the interior use of architectural paint and coating under harsh conditions (e.g. industrial use), fluoropolymers can also provide thermal stability and flame resistance.

According to OECD (2022) the most commonly used fluoropolymer (binders) in coating and paint for building material/construction products is PVDF, ECTFE, FEVE, PTFE and FEP. Functionalised PFPEs can also be used as binders in paints and coatings

Micro-powder PTFE can be used as additives in coating in low levels to impart fluoropolymer like properties such as reduced wear rate and friction.

Architectural membranes (composite membranes with top coating) and architectural membranes (pure fluoropolymers)

Architectural membranes/structural membranes/tensile fabrics are used for light weight roofing, facades and building envelopes. Fluoropolymers used for this application and are either used as a composite or as a pure fluoropolymer membrane. Composites can e.g. be fiberglass fabric with a topcoat of e.g. PTFE, PFA, FEP or PVDF. Another example is polyester coated with PVC (base coat) and a topcoat of e.g. PVDF or PTFE. Such top coatings are mixtures comparable to the coatings and paints described above. Pure fluoropolymer membranes can be ePTFE, PVDF or ETFE foil/film. Fluoropolymers are used especially for protection against harsh environmental conditions (weathering and UV radiation). They are also durable, chemical resistant, water- and oil/dirt repellant and require low maintenance. In general, they have a long service life.

ETFE foil/film for greenhouses

Pure ETFE foil/film can be used for covering greenhouses to make them self-cleaning, durable, weather and chemical resistant while allowing the full spectrum of solar light to pass through.

PTFE thread sealing tape

PTFE tape (100% PTFE film) is self-welding and used to seal applications e.g. pipe connections for liquids and gases. PTFE tapes have high tensile strength and by using PTFE tape the sealings becomes durable, water- and heat resistant. PTFE tape can also be used in the manufacturing and installation of windows, doors etc.

Polymeric PFASs used as processing aids for production of non-PFAS polymers/plastics

PFAS polymer processing aids (PPAs) (fluoroelastomers, PVDF (and also PFPEs)) are added to resins of non-PFAS thermoplastics (e.g. PE and PP), thermosetting plastics and elastomers used as building materials/construction products. The PPAs is added to eliminate of melt fracture (shark-skin effect), improve wear and abrasion resistance, reduce coefficients of friction (COF), make surfaces easier to clean, increase melt tension and strength, and improve processability and mold release, reduce of die build-up, improve of the surface finish with high gloss levels, increase production start-up, reduce pressure, increase output at constant die pressure and temperature, lower energy consumption.

Bridge and building bearings

Fluoropolymers (PTFE) are used in bridges and building bearings to lower friction. This allows one end of the bridge to slide when the bridge expands or shrinks due to temperature differences. In buildings sliding allows movement in case of earthquakes.

Window frames

Fluoropolymers (PVDF) films are used for laminating PVC and high-pressure laminate (HPL) window frames. PVDF is added because it is transparent and for protecting the PVC frame against chemicals, weathering and UV-radiation.

E.2.13.2.3. Side-chain fluorinated polymers – description of function and use in building materials/construction products

Side-chain fluorinated polymers used for surface protection/sealants

PFAS-containing sealants are, as described in Annex A.3.14.1, used to create a water and soil/oil-resistant barrier that protects surfaces of building materials/construction products from stains, mold and physical damage. Acrylate-, urethane- and silane/siloxane-based side-chain fluorinated polymers can be used for sealing of porous materials such as stone, grout, unglazed tile, and concrete in e.g. kitchen and bathroom tilework, and stone, tile or concrete flooring. Also used in exterior applications such as patios, staircases, foundations, parking garages, bridges, old buildings, churches etc.

The same substances can (in slightly different formulations) be used for surface protection of non-absorbing substrates (e.g. glass, enamel, ceramics, metal, stone, concrete and linoleum, laminated plastic floor).

E.2.13.2.4. Non-polymeric PFASs – description of function and use in building materials/construction products

Fluorosurfactants as wetting/levelling agents in e.g. coating, paints and adhesives

Non-polymeric PFASs (fluorosurfactants) are used at low levels in the formulation of building/construction products such as coatings, paints, lacquers and adhesives. The fluorosurfactants lower the surface tension, improve wetting, levelling and anti-blocking in (especially water-based) paints and coatings. Defoaming and avoidance of surface defects such as cratering and orange peel is also mentioned as important surfactant properties. For adhesives the fluorosurfactants also enhance the penetration in the substrate and thereby increase adhesion strength. Some types of fluorosurfactants also provide water and oil/dirt repellency.

Non-polymeric PFAS as processing aids:

Non-polymeric PFASs are used as processing aids for production of certain types of non-PFAS construction products (articles). The processing aids are not part of the final product (or do not serve a function in the final product).

Window film manufacturing

Fluorosurfactants are used as coating additives and dispersants to create low resurface energy in window film manufacturing

E.2.13.2.5. Availability of alternatives

All alternatives considered below have been identified because they are currently marketed products. Very limited specific quantitative data on the relative levels of productions, sales or use of alternatives have been provided in this assessment, however.

E.2.13.2.6. Identification of potential alternative substances and techniques fulfilling the function

This section is divided into three sections: Fluoropolymer and PFPEs, side-chain fluorinated polymers and non-polymeric PFASs.

E.2.13.2.7. Alternatives to fluoropolymers and PFPEs in building/construction mixtures and articles

Architectural coatings and paints

According to OECD (2022), the overall global market penetration for PFASs in architectural protective coatings is approximately 1%. In architectural paints and coatings fluoropolymers are used as top coating for protection against harsh (environmental) conditions and provides chemical/corrosion resistance, durability, weather and UV resistance as well as thermal stability and flame resistance OECD (2022). Similar technical functions are described for functionalised PFPEs (e.g. urethane acrylate or amido-silane PFPEs) (Solvay, 2013; Wang et al., 2020).

In the 2nd stakeholder consultation, the same technical properties of fluoropolymers as mentioned above and the long service life of especially PVDF and FEVE-based (30 to 50+ years mentioned) coatings were highlighted.

Corrosion resistance of non-PFASs-based architectural paints and coatings: Fluoropolymer paints and coatings are said to be corrosion-resistant and can withstand harsh weather conditions such as on bridges near oceans where the salt content is high. According to OECD (2022) epoxy and polyurethane coatings both provide suitable corrosion resistance due to their stability to various chemicals. No further information was received on this in the CfE or the 2nd stakeholder consultation. It should be noticed that non-PFASs architectural paints and coating systems are already widely used on bridges across the world (Hempel, 2022a). As an example, Hempadur Avantguard epoxy primer series contains zinc and hollow glass spheres for corrosion resistance (Hempel, 2022c).

Durability, weather and UV resistance of non-PFASs-based architectural paints and coatings: According to OECD (2022) e.g. polyurethane, polyester, polysiloxane, and epoxy coatings are durable and weather resistant. The report also compares efficacy and performance of these coatings compared to PVDF and FEVE-based coatings used as topcoat. Specifically, the gloss retention (a measure of degradation by UV light) was compared. The conclusion was that FEVE performed slightly better than PVDF and that both these fluoropolymer-based coatings perform much better (have a higher gloss retention) than acrylic urethane (a type of polyurethane), polyester and polysiloxane. OECD (2022) also refers to a case example where painting of a bridge with a fluoropolymer-based paint (FEVE) is compared to a non-PFAS alternative (polyurethane). For the total cost calculations over 100 years, a lifetime of 20-25 years for FEVE-paint seems to be assumed, whereas it is only 5-10 years for the polyurethane paint.

The OECD (2022) report states that epoxy coatings degrade in sunlight. It should be noted that the Hempadur Avantguard epoxy primers mentioned above are used in a coating system (often 3-coat system) and that the topcoat is often based on polyurethane. According to Hempel different qualities of polyurethane exist (Hempel, 2022b). Hempel offers paint systems that do not contain fluoropolymers, with a very high estimated service life (>25 years) even at high humidity, aggressive atmosphere and inshore areas of high salinity (Hempel, 2020).

In the 2nd stakeholder consultation, a product called Tetrashield (a polyurethane top coating) was also mentioned, and it is stated by the stakeholder that *"preliminary studies showcase that Tetrashield resins technically perform comparably to FEVE"*. Tetrashield is also mentioned in OECD (2022).

According to OECD (2022) non-fluoropolymer alternatives used for thermal stability include epoxy-based coatings. These can resist temperatures up to 200 °C, which is lower than fluoropolymer coatings, which can resist temperatures up to 230 °C (OECD, 2022). However, according to the product data sheet on Hempel Silicone Aluminium 56914 this product, that is based on aluminium pigmented polysiloxane, is heat resistant and has a service

temperature up to 600 °C (Hempel, 2022e). The product is intended for painting of hot pipelines, exhaust pipes, smokestacks and other hot surfaces.

Non-fluoropolymer alternatives also exist for fire protection. E.g. Hempafire Pro 400 for protection of structural steel against cellulosic fires (Hempel, 2022d) or Hempafire XTR 100 for protection of structural steel against hydrocarbon passive fire (Hempel, 2022g).

In the 2nd stakeholder consultation, no stakeholders mentioned the use of micro-powder PTFE (PTFE wax) as an additive in alternatives to architectural paints and coatings based on fluoropolymer binders. The Hempel products mentioned in this section do not contain micro-powder PTFE (Hempel, 2022b).

According to OECD (2022) household paints and coating products are not based on fluoropolymer binders.

Coil coating

According to OECD (2022), the PFAS-based coil coating market penetration is 3-12% in EU and for paint market penetration is 8% in EU, Asia and North and South America.

In the 2nd stakeholder consultation, it is stated that coil coatings can be formulated to give the metal a very attractive surface finish and the coated metals have a long durability (guaranteed for 25 years). One stakeholder state that durability is >30 years and another states that it is >40 years. In the OECD (2022) report it says that the durability of coils coated with PVDF is 25-30 years. In the 2nd stakeholder consultation, it is further stated that the ease of removing and separating pre-painted metal cladding (including PVDF/FEVE coated) from other building waste facilitates very high rates of recycling 89% and reuse 10% with only 1% going to landfill.

In the 2nd stakeholder consultation, it is stated that general alternatives identified in the CfE and targeted stakeholder consultation for paints and coatings (polyurethane, polyester powder, wax emulsions, silicones/silanes/polysiloxanes, and hydrocarbon polymer technologies) is not suitable replacements for PVDF coil coatings, as they are not as durable (have the same lifetime).

According to stakeholder input in OECD (2022) polyester melamine (durability 15 years) is the best alternative to PVDF (durability 25-30 years). No further information was given in the report.

On their webpage Wanzhi steel¹¹⁵ compares binders in Polyester, Silicone Modified Polyester (SMP) and High Durability Polyester (HDP) topcoats for coil coatings to PVDF binders in terms of hardness, strength, weather resistance corrosion resistance, cost and service life. Polyester has the lowest cost and lowest service life (7-8 years) since UV and corrosion resistance is poor compared to PVDF. SMP and HDP is more expensive than polyester but costs less than PVDF. SMP and HDP is comparable in terms of hardness, strength, weather resistance corrosion resistance to PVDF. However, service life of SMP (10-12 years) and HDP (up to 15 years) is shorter than the 20-25 years mentioned for PVDF.

Other alternatives are available on the EEA market. E.g. one product described in Mäder (2021) who claims that their ultra-high durable polyester-based coil coating product Durovern UHD “meets the most stringent requirements in metal construction and can be considered as an alternative to standards PVDF”.

In the 2nd stakeholder consultation, it was also commented that PTFE waxes (micro-powder PTFE) is used in non-PFAS paint systems for coil coating e.g. polyester and polyurethane paint

¹¹⁵ <https://wzppqi.com/what-is-the-best-paint-for-steel/>, date of access: 2023-01-13.

to optimise the formulations for application on the coil coating line and improve the scratch resistance of the end products. Without mentioning specific alternatives, it is stated in one reply to the 2nd stakeholder consultation, that: *"some alternatives for the PTFE waxes exist; they do not allow for like-for-like substitution. Their performance in forming processes and resistance against scratches will be affected. The use of these alternatives in coil coating paints would require extensive assessments to validate their performance."*

No other information on alternatives for the use of micro-powder PTFE as an additive in coil coating mixtures was identified.

Coating of wind turbine blades

Fluoropolymers (FEVE and ETFE) are as described in Annex A.3.14.1 used for protection of wind turbine blades under harsh conditions. The main function is to resist environmental damage such as weathering and rain erosion of the blades.

According to Hempel the impact from rain may cause significant coating erosion or even composite damage. In severe cases the erosion may lead to a 2-3% drop in annual energy production (Hempel, 2022f).

The CfE and 2nd stakeholder consultation did not provide any information on surface protection of wind turbine blades. Neither on the use of fluoropolymers as binders or on alternative binders.

In OECD (2022) epoxy and polyurethane coatings have been identified as alternatives to PFAS formulated coatings. However, three examples given in the report may not be an alternative for wind turbine blades as one of the products seems to contain PFASs and the Hempel products Hempadur 4774D and Hempathane HS 5561 B seems to be for steel constructions (including wind turbine towers).

Since OECD (2022) did not provide useful information on alternatives, a quick internet search was conducted in order to find out if any non-PFAS coatings for wind turbine blades are available in the EEA market. This search showed that Hempel in 2022 launched non-PFAS top coating based on polyaspartic ester and titanium dioxide for wind turbine blades called Hempablade Edge 171. At the Hempel webpage it is stated that the coating has exceptional rain erosion protection performance and strong UV resistance (Hempel, 2022f). No data have been identified that compares the efficacy of Hempablade Edge 171 with fluoropolymer-based coating for wind turbine blades.

In personal communication with Hempel (Hempel, 2022b) they said that to the best of their knowledge fluoropolymers is currently not used for wind turbine blade coating in Denmark. Similar information is available in the Danish press. In a quote the wind turbine producer Siemens Gamesa said: "PFAS is not used in our products" (translated from Danish) (TV2, 2022) and the branch organisation Green Power Denmark is quoted for saying: *"We do not have information that shows that PFAS is used in Danish wind turbines"* (translated from Danish) (Rønberg, 2022). This information, involving some of the largest wind turbine producers in the world, indicates that non-fluoropolymer-based coating for wind turbine blades is used in EEA.

Architectural membranes (composite membranes with top coating) and architectural membranes (pure fluoropolymers)

In this section alternatives for composite architectural membranes with a fluoropolymer based top coating and pure fluoropolymer architectural membranes is described together, even though, top coatings for composite membranes are considered to be mixtures and pure fluoropolymer membranes are considered to be articles.

Llorens (2015) describes typically used fabrics and coated fabrics for composite architectural

membranes/structural membranes/tensile fabrics and their technical performance:

- Cotton and other natural fibres: High UV resistance but in general low technical performance. Feasible only for light-duty applications (service life of 4-5 years).
- Polyamide (PA or nylon): High strength, stiffness and tenacity and low weight, but not dimensionally stable when wet, poor UV resistance and stretches considerably (therefore not commonly used in architecture).
- Polyester: Very commonly used in architecture. Good tensile strength and elasticity, but mechanical properties degrade with UV light, and it is subject to ageing. Can be coated or laminated with PVC to provide UV protection. A top coating is commonly applied on top of polyester/PVC. Both fluoropolymer and non-fluoropolymer based top coatings can be used. Fluoropolymers (e.g. PVDF) provide (further) UV resistance, durability and water/dirt resistance. The technical performance of the non-fluoropolymer top coatings is:
 - Acrylic lacquer: Poor UV resistance
 - PVF film (fluoropolymer not in scope of this restriction proposal): UV resistance, durability and water/dirt resistance
 - Titanium dioxide (TiO₂): UV resistance, hydrophobic (self-cleaning) and high light reflectance
- Fiberglass: Very commonly used in architecture. High tensile strength (although decreasing when wet) and long lifetime, but brittle and low elastic strain. Can be coated with silicone to enhance properties such as UV resistance and water protection (not soil resistance). The translucency for silicone coated fiberglass can be as high as 25%.
- Aramid (Kevlar®, Twaron): High strength (except compressive strength), low weight, good abrasion/chemical/thermal resistance. Can degrade slowly from UV exposure. Can be coated with PVC or silicone to provide UV protection (only used when other materials are inadequate).
- Carbon fibers: Less detail provided than on the other materials. Used for high-tech products, low expansion coefficient, non-combustible.

Llorens (2015) also compared the technical performance of some of the above described materials with fluoropolymers (PTFE and PVDF). This is shown in Table E.140 below that is a remake of table 3.2 in Llorens (2015).

Table E.140. Comparison of fabric performance (table 3.2 in Llorens (2015)).

	Polyester				Fiberglass fabric		PVDF fabric	
Coating	PVC	PVC	PVC	PVC	PTFE	Si	Uncoated	PVDF
Top coating	Weldable PVDF merging	Non-weldable PVDF merging	TiO ₂ merging	Crosslink PVDF				
Expected lifetime	15 years	>20 years		>25 years	>25 years	>20 years	>30 years	>25 years
Soiling protection	Average	Good	Good	Good	Very good	Average	Very good	Very good

	Polyester				Fiberglass fabric		PVDF fabric	
Tranparency	5-15%	8-14%			8-20%	25-30%	20-40%	35%
Fire behaviour	Flame retardant	Flame retardant	Flame retardant	Flame retardant	Non-combustible	Flame retardant	Non-combustible	Non-combustible
Tolerance to folding	Very good	Good		n.a.	Little	Medium	Very good	Very good

Table E.140 does not include performance of polyester/PVC with PVF top coating (film). According to Seaman Corporation (2020) it has a service life of >20 years and resist UV radiation better than PVDF. On other parameters (durability, fire resistance etc.) performance seems to be comparable to PVDF.

Questions on the use of non-fluoropolymer based architectural membrane fiber materials mentioned above, cotton and other natural fibers, polyamide, polyester and polyester/PVC, fiberglass and fiberglass/silicone, aramid, aramid/PVC and aramid/silicone, was included in the 2nd stakeholder consultation.

In response to the 2nd stakeholder consultation stakeholders generally stated that none of the mentioned alternatives can provide the unique combination of properties provided by fluoropolymers (thermal resistance, chemical resistance, exceptional anti-stick performance, UV- and weather resistance, light weight, shockproof and flame retardancy) and consequently, it lowers significantly environmental impacts over the service life of the membrane (50 years). For the moment, there are no alternatives offering such requested performances. Stakeholders further commented that natural fibers, polyester, nylon and aramid fibers are all degraded by ultraviolet light from outdoor exposure and that fiberglass, aramid, carbon and fluoropolymer fabrics are substrates to be coated by PTFE or PFA – coating with PVC will not allow for chemical resistance.

One stakeholder stated that they, during the last 20 years, have been working in R&D on silicone coating but without any success to provide similar performance as fluoropolymers.

Regarding fire safety, one responded to the 2nd stakeholder consultation commented, that cotton and other natural fibers is very flammable whereas another stakeholder commented that cotton, natural fibers, polyester and polyamide do not provide fire resistance equivalent to PTFE coated glass fiber fabrics.

One stakeholder highlighted that the mono-material solutions ETFE foil/film (100% PFAS), that is frequently used in membrane applications for roofs and facades, is fully recyclable and have a long service life (>40 years).

Overall, the responses from the 2nd stakeholder consultation are in line with Llorens (2015), however, no specific comments were received for the materials that has performance characteristics that is comparable to fluoropolymer coated fabrics - polyester/PVC with PVF or TiO₂ containing top coating and silicone coated fiberglass fabric.

No other alternatives were identified via the 2nd stakeholder consultation.

ETFE film/foil for greenhouses

One stakeholder mentioned in the 2nd stakeholder consultation that ETFE foil/film is used for greenhouses as it is light weight, break/shockproof, flame retardant and anti-stick

performance (leading to easy cleaning). The stakeholder did not mention any alternatives. However, glass and polyethylene foils are used for the same application in greenhouses.

PTFE thread sealing tape

Four stakeholders gave input on the use of PTFE tape in the 2nd stakeholder consultation. In general, the stakeholders agreed that there are no useful alternatives available that meet the requirement of natural gas fittings and connections and aggressive media such as oxygen and nitric acid). One stakeholder commented that tow, as a potential alternative to PTFE thread sealing tape, is now heavily restricted due to microbial development. Another stakeholder mentioned that hemp sealant will dry out in natural gas service and causes leaks which is a safety risk.

According to Fernández et al. (2021), silicone-based thread-seal tapes are available but less common. However, it does not seem like the silicone-based products referred to is actually thread sealing tape (like PTFE tape), as LeakSeal® Self-Fusing Tape is referred to as: *"silicone repair tape that is used for fixing leaky pipes and hoses"*. PTFE can also be used as a temporary short-term solution to help seal plumbing leaks until further work can be carried out. LeakSeal® seems to be an alternative for this use. Sharkbite® Silicone Wrap is used for *"brass fittings that requires the fitting be wrapped in an impermeable material to protect the connection from ground contaminants"* and does not seem to be an alternative for PTFE thread sealing tape.

Fernández et al. (2021) also states that *"liquid/paste pipe thread sealants without PFAS are available"* and that *"such products can be stronger and more durable alternatives to PTFE tape and are thus preferred by plumbers for permanent seals"*. It should, though, be noted that PTFE tape is used for non-permanent seals. Fernández et al. (2021) refers to a product called Hercules® Megaloc® that is described as *"a multi-purpose thread sealant made with DuPont™ Kevlar® for use on metals, including steel, stainless steel, brass, copper, aluminium and plastic."*

According to Fernández et al. (2021) PTFE tape is not only used for sealing applications for e.g. pipe connections, it can also be used in the manufacturing and installation of windows, doors, vents, skylights and other structural openings. The report states *"during manufacturing, fluorinated tape is employed to hold PVC frames together and prevent physical deformities during welding"*. No information on these uses of PTFE tape was received in CfE or 2nd stakeholder consultation. Therefore, for the use of PTFE tape for manufacturing and installation of windows, doors etc. no evidence has been provided or identified to indicate that a derogation is needed.

Polymeric PFASs used as processing aids (PPAs) for production of non-PFAS polymers/plastics

Polymeric PFASs are used as processing aids (PPAs) in the production of non-PFAS polymers/plastics e.g. such as polyethylene and polypropylene. As the processing aid is added to the resin, it is incorporated into the final building material/construction product.

Seven stakeholders gave input on this use in the 2nd stakeholder consultation. It is, though, not clear if all uses of non-PFAS polymers/plastics referred to by stakeholders are building material/construction products or industrial equipment like films, pipes and tubing. The types of polymer/plastic mentioned by stakeholders are mostly thermoplastics but also a few that are (or could be, depending on the exact type) thermosets.

As described in Annex E.2.3.4.1, on technical feasibility of alternatives to PFASs in thermoplastic packaging film for food packaging, boron nitride is identified as an alternative processing aid. In this section it is described that boron nitride powder has been shown to be effective in the production of films including polyethylene and m-LLDPE films.

One stakeholder in the 2nd stakeholder consultation stated that in pipe applications, hard

foreign particles like boron nitride can result in premature pipe failure due to stress concentrations. No other stakeholders commented on the use of boron nitride.

Another stakeholder in the 2nd stakeholder consultation replied that siloxanes might be an alternative. It is, though, not specified in the reply which type of polymer/plastics were siloxanes can be used as processing aids instead of polymeric PFASs. No other stakeholders commented on the use of siloxane, but two stakeholders stated that there are no commercially available alternatives that meet the technical requirements.

DuPont manufactures the thermoplastics additive series Multibase™. According to the datasheet (DuPont, 2021) these siloxane-based additives can be used to enhance polymer processing of thermoplastics such as polyolefins, thermoplastic polyurethanes, styrenics, polyester, polycarbonate, polyamide and polyoxymethylene. The described properties of using Multibase™, e.g. improved processing and flow, mold release, faster throughput, internal lubrication, improved dispersion of fillers, reduced energy demand, improved scratch resistance, surface properties and greater abrasion and mar resistance, is comparable to the properties described from using polymeric PFASs as PPAs.

Bridge and building bearings

One stakeholder gave input on the use of PTFE in bridge and building bearings in the 2nd stakeholder consultation. The stakeholder stated that the only known alternative are steel rollers, which require significantly more space in the constructions. The Dossier Submitters identified no other information on this use.

Window frames (laminated with fluoropolymers)

One stakeholder gave input on the use of PVDF film for laminating PVC and high-pressure laminate (HPL) window frames in the 2nd stakeholder consultation. The stakeholder states that: "the polymer needs to be transparent and must be UV-stable for >20 years and needs to provide a high chemical resistance" and that to their knowledge there is no alternative.

As no other stakeholders gave input on this use, the Dossier Submitters do not know if other producers of PVC and HPL window frames also use PVDF (or other fluoropolymers) for laminating the frames. According to a market analysis (MarketResearch, 2020) PVC accounted for 31% of the global market window and door frames market in 2019. Wood, metal and other (e.g. fiberglass, glass and composite) accounted for the remaining part.

E.2.13.2.8. Alternatives to side-chain fluorinated polymers in building/construction products

Side-chain fluorinated polymers used for surface protection/sealants

Side-chain fluorinated polymers are used for making surfaces resistant to water- and soil/oil. According to the 2nd stakeholder consultation surfaces can be protected without changing the natural appearance of the substrate. Other functionalities mentioned in the 2nd stakeholder consultation are UV durability and breathability. It is further stated that that these substances can be used for anti-graffiti applications. Without mentioning any alternatives it was stated in the 2nd stakeholder consultation that alternatives do not provide the same combination of effects.

It is not clear from the three responses received in the 2nd stakeholder consultation on the use of side-chain fluorinated polymers for building material/construction products precisely which types of side-chain fluorinated polymers they refer to in their replies. However, based on these stakeholders' webpages it cannot be excluded that they all refer to side-chain fluorinated polymers based on 6:2 fluorotelomer chemistry (with different types of reactive groups) as they have raw materials with these substances in their portfolio.

6:2 fluorotelomers are considered to be PFHxA-related substances. According to the RAC and SEAC Opinion on the Annex XV dossier proposing a restriction on “Undecafluorohexanoic acid (PFHxA), its salts and related substances” (ECHA, 2021a), which is currently under deliberation, no derogation for building materials and construction products is suggested. If the EU commission follows this opinion, it will be the primary reason for substituting 6:2 fluorotelomers in building material/construction products.

The non-fluoropolymer alternatives described under architectural paints and coatings, epoxy, polyester, polyurethane etc. does also provide protection of surfaces and can therefore for some applications be seen as alternatives to side-chain fluorinated polymers.

According to ECHA (2017) non-PFAS side-chain polymers based on silane/siloxane chemistry are commercially available for building protection. In this background report properties of PFAS side-chain polymers based on silane/siloxane is compared to non-PFAS side-chain polymers based on silane/siloxane chemistry. The comparison is from a 2004 technical datasheet from Bayer Silicones who manufactured/formulated some of the alternatives. In the background report it says: *“The mixtures containing polyfluorosilanes, are according to the comparison, outstanding as concern stain resistance on concrete, terracotta and claybrick, but have less water repellence than some of the alternatives and are relative expensive. The differences are reflected in the fact that the mixtures containing polyfluorosilane are mainly marketed for applications where oil and stain resistance (including anti-graffiti) is required. Mixtures based on silicones/siloxanes (without fluor) are efficient in water repellence and are today the mixture of choice for applications where water repellence is the main property required. For oil-repellence, mixtures based on PFAS-technology (with silane or carbon backbone) are the most efficient.”.*

SiSiB Silicones via their webpage offers a range of non-PFAS side-chain polymers based on silane/siloxane chemistry for protection of building material/construction products such as concrete, bricks, ceramics, roof tiles, perlite, vermiculite, gypsum, sand-lime bricks, natural sandstone, mineral plasters etc. The actual formulation (crème based, water based or solvent based) determines the level of penetration into the substrate. According to SiSiB Silicones, silanes are smaller than the pores of mineral building materials and when applied they react with themselves (e.g. via a sol-gel reaction) and hydroxyl groups within the substrate to create (sidechain) siloxane network. This formation of strong chemical bonds provides the durability characteristic of silicone treatments. When cured, external liquid water is kept from entering the pores, while water vapour generated from within the structure can still escape. The structure remains breathable. Because they are inside the pores, water repellent treatments are not affected by UV radiation (SiSiB, 2015). Other companies e.g. Dow Corning and Evonik produce similar products as SiSiB Silicones.

Side-chain fluorinated polymers can be used for permanent anti-graffiti coating (coating that usually only has to be applied once). Other permanent anti-graffiti coating on the market are nanoparticles(silica)-based coating, silicon, acrylic-siloxane copolymers, and polyurethanes (including polyurethane acrylate) (Amrutkar et al., 2022). Semi-permanent anti-graffiti coating is also on the market. Semi-permanent anti-graffiti coating is typically based on acrylics or epoxies and can sustain two or three cleaning cycles, after which reapplication is required. Sacrificial anti-graffiti coating (removed during the graffiti removal) that includes waxes, polysaccharides, and polysiloxane have to be re-applied after the cleaning process (Amrutkar et al., 2022). In the paper by Amrutkar et al. (2022) a number of commercially available permanent, semi-permanent and sacrificial anti-graffiti coatings is identified.

Some surface protection products are also available as DIY products for consumers.

E.2.13.2.9. Alternatives to non-polymeric PFASs in building/construction products

Fluorosurfactants as wetting/levelling agents in e.g. coating, paints and adhesives

Of the six stakeholders providing answers to the 2nd stakeholder consultation three specifically

mentioned C6, fluorotelomer surfactants and/or C6 fluorotelomers (two manufactures of PFASs and one downstream user). One stakeholder (manufacturer) specifically referred to C4 side-chain polymeric fluorosurfactants. The remaining two stakeholders (downstream users) who responded to the 2nd stakeholder consultation, did not specify the type of fluorosurfactant that they referred to in their responses.

To the question in the 2nd stakeholder consultation *"Are in your view the listed non-PFAS alternatives technically feasible in your product(s)/processes?"* the following responses were received:

- The two PFAS manufactures who referred to C6, fluorotelomer surfactants and/or C6 fluorotelomers: *"Fluorotelomer surfactants reduce surface tension while providing excellent wetting and leveling, oil repellency and chemical resistance. No alternative has this combination."* and *"Different potential alternatives have been tested but do not provide the same level of combined water, oil and stain repellency than C6. Downstream users have reported that only C6 fluorotelomers can provide a high level of performance to the construction products and a low environmental impact."*
- The downstream user referring to C6, fluorotelomer surfactants and/or C6 fluorotelomers: *"The PFAS substances currently used have unique technical properties, however being expensive. Equivalent PFAS-free alternatives still remain to be developed by our raw materials suppliers and would thereafter need to be thoroughly tested by our R&D team on a product-by-product basis, all the way from manufacturing to application in the customer specific production line. There is no readily available alternative that can easily substitute the fluorinated surfactants, so it will take considerable time for the suppliers to first develop the alternatives and then for us, being the coating formulator, to test and evaluate the alternatives in application uses."*
- The PFAS manufactures referring to C4 side-chain polymeric fluorosurfactants: *"silicone or hydrocarbon alternatives do not deliver reduction in surface tension required for wetting and leveling of hard to coat surfaces. Technically feasible alternatives are also PFAS-containing additives"*
- The two downstream users that did not specify the type of fluorosurfactants they referred to: *"No, reason being that fluorinated material has outstanding properties which allows them to use in small quantities. Alternatives need to be used in much higher concentration consequently leading to jeopardizing other paint properties"* and *"To my knowledge, there is no alternative chemistry that can provide same level of performances as surfactants (extremely low surface tension/high contact angle), and resistance/repellency to water/oil/grease all together"*

The Alliance for Telomer Chemistry Stewardship (ATCS) in a response to ECHAs consultation on the restriction proposal of Undecafluorohexanoic acid (PFHxA), its salts and related substances, states that: *"Paints and varnishes in which C6 fluorosurfactants are used as additives are mainly intended for building materials. These products must display, amongst other properties, high durability. Downstream users have reported that alternatives based on C4 fluorotelomers are available, but that they display a lower performance and raise similar concerns regarding persistence."* (ATCS, 2020). Furthermore, in the RAC and SEAC Opinion on the Annex XV dossier proposing a restriction on Undecafluorohexanoic acid (PFHxA), its salts and related substances (ECHA, 2021a), which is currently under deliberation, no derogation for building material/construction products is suggested. If the EU commission follows this opinion, it will be the primary reason for substituting C6 fluorotelomer surfactants in building material/construction products.

The stakeholder that referred to C4 side-chain polymeric fluorosurfactants in the 2nd stakeholder consultation in December 2022 announced that they will *"Exit all PFAS manufacturing by the end of 2025"* and *"Work to discontinue use of PFAS across our product portfolio by the end of 2025"* (3M, 2022). This announcement can very well be the primary reason for substituting C4 side-chain polymeric fluorosurfactants in building material/construction products.

No manufacturers of non-PFAS surfactants replied to the 2nd stakeholder consultation.

Based on responses to the CfE and literature some non-PFAS wetting and levelling agents were identified. Evonik e.g. offers a range of non-PFAS wetting additives for paints and coatings (Evonik, 2017a) under the trade names such as TEGO®, SURFYNOL® and DYNOL™. These wetting and levelling agents are based both on siloxanes (e.g. polyether siloxane copolymers, siloxane-based gemini surfactant or modified polyether siloxane) and hydrocarbon surfactants (e.g. non-ionic organic surfactants). Another type of hydrocarbon surfactants used as wetting and levelling agents that is commonly mentioned in the literature (e.g. in OECD (2022)) is based on sulfosuccinates like Hydropalat® (BASF, 2019).

DYNOL™ is by the manufacture Evonik referred to as superwetting surfactants (Evonik, 2017b). The DYNOL™ products is available for a number of different applications related to building material/construction products e.g. adhesives, wood, plastics, industrial and architectural coatings. Surface tension behavior of the DYNOL™ surfactants is claimed to be comparable to fluorosurfactants (DYNOL™ has better dynamic surface tension behavior whereas fluorosurfactants has slightly better equilibrium surface tension behavior) (Evonik, 2017b). The Evonik products can also be used on difficult to wet substrates like metal and glass (Evonik, 2022). Via their webpage Evonik also offers a Webinar called "*Substrate wetting - the future beyond fluorosurfactants*".

It should also be noted that the solvent-based paints and coatings from Hempel mentioned above under architectural coatings and paints and coating of wind turbine blades does not contain fluorosurfactants as wetting and levelling agents.

According to OECD (2022) domestic/household paints and coatings usually don't contain fluoropolymer binders, they may, however, contain fluorosurfactants as wetting and levelling agents. It should be noted that in the EEA there are Ecolabeled indoor household paints and varnishes are available, labelled with the Nordic Swan. According to the most recent criteria document such products must not contain PFASs (Nordic Ecolabelling, 2022).

Non-polymeric PFASs as processing aids

In the 2nd stakeholder consultation one stakeholder described the use of non-polymeric PFASs as processing aids for production of certain types of non-PFAS architectural membrane-like building material/construction product. The processing aids are not part of the final product. The stakeholder described that no non-PFAS processing aids are available for the production of the specific use. However, the stakeholder describes the architectural membrane-like product as niche product in the market, which is dominated by alternatives.

Another stakeholder in the 2nd stakeholder consultation described the use of non-polymeric PFASs (fluorosurfactants) as processing aids for production of acrylic foam tape. According to the stakeholder, the fluorosurfactant does not serve a function in the performance of the final product. The stakeholder further states that the fluorosurfactant is used because no alternatives have been identified that enables the performance needed in these foam tape applications. R&D to identify alternatives is ongoing. The stakeholder in December 2022 announced that they will "*Exit all PFAS manufacturing by the end of 2025*" and "*Work to discontinue use of PFAS across our product portfolio by the end of 2025*" (3M, 2022). Therefore, the information on the use of fluorosurfactants as processing aids for production of acrylic foam tape is considered to be uncertain, as manufacturing will either have to be stopped or the R&D process to identify, test and re-qualify alternatives is already at an advanced stage.

Window film manufacturing

In the 2nd stakeholder consultation one stakeholder stated that fluorosurfactants are used as coating additives and dispersants to create low resurface energy in window film manufacturing. According to the stakeholder there are no known PFAS-free alternatives that provide the same performance. No other producers of window film replied to the 2nd

stakeholder consultation.

The stakeholder that gave input on window film manufacturing in the 2nd stakeholder consultation in December 2022 announced that they will “Exit all PFAS manufacturing by the end of 2025” and “Work to discontinue use of PFAS across our product portfolio by the end of 2025” (3M, 2022). Therefore, the information on window film manufacturing is considered to be uncertain, as manufacturing will either have to be stopped or alternatives will have to be identified within a short timeframe.

E.2.13.2.10. Risk reduction, technical and economic feasibility of alternatives

This section is divided into three sections: Alternatives to fluoropolymer and PFPEs, alternatives to side-chain fluorinated polymers and alternatives to non-polymeric PFASs.

The following section engaged with risk reduction, technical and economic feasibility of alternatives to PFAS-containing products within the construction and building sector. The section has been divided into three sub-sections: Alternatives to fluoropolymer and PFPEs, alternatives to side-chain fluorinated polymers and alternatives to non-polymeric PFASs, as presented below each describing the technical and economic feasibility of alternatives.

The section covering technical and economic feasibility alternatives to fluoropolymer and PFPEs are divided into two sub-sections covering respectively alternatives to mixtures containing fluoropolymers or PFPEs, and alternatives to articles consisting of or containing fluoropolymers or PFPEs.

The first section, on mixtures, includes architectural paints and coatings, coil coating, wind blade coating, and top coating for composite architectural membranes. The second section on articles, includes architectural membranes (pure fluoropolymers), ETFE film/foil for greenhouses, PTFE thread sealing tape, polymeric PFASs used as processing aids for production of non-PFAS polymers, bridge and building bearings and window frames (laminated with fluoropolymers).

Alternatives to mixtures containing fluoropolymers or PFPEs in building material/construction products

Technical feasibility of alternatives

Architectural paints and coatings, wind turbine blade coating, and coil coating

As can be seen from section E.2.13.2.3 alternative binders for top coatings are available for architectural paints and coatings, coil coating and wind turbine blade coating. For architectural paints and coatings and coil coating these alternatives dominate the market. In general alternative binders exist that provides technical properties that are comparable to the fluoropolymers, though, especially for architectural paints and coatings and coil coating stakeholders commented that service life of alternatives will be shorter under harsh (environmental) conditions.

Micro-powder PTFE may be used in low levels as additives in coil coating mixtures of alternative-based (non-fluoropolymer) binders. No information on specific alternatives or performance has been provided or identified.

Architectural membranes (composite membranes with top coating

PVF is in use as top coating on polyester/PVC composite architectural membranes under the

brandnames such as Shelter-Rite® with Tedlar® film by Seaman Corporation, however, it is not clear to the Dossier Submitters, if PVF is marketed for this use in EEA. According to Seaman Corporation (2020) performance of polyester/PVC with PVF top coating is comparable to polyester/PVC with PVDF in terms of protection against harsh environmental condition (weathering and UV radiation) and it has a service life of >20 years. On other parameters such as durability, fire and chemical resistance, water- and oil/dirt repellency performance of PVF is at least as good or better than PVDF (Seaman Corporation, 2020). PVF as top coating is therefore considered to be technical feasible alternative for composite architectural membranes. However, to the best of the Dossier Submitters' knowledge PVF is still being manufactured with PFAS polymerization aids.

By adding TiO₂ on top of a polyester/PVC architectural membrane the photocatalytic effect of adding TiO₂ can absorb natural sunlight (UV) and decompose organic matter, making the membrane self-cleaning (TiO₂ can also be added to PVDF and PTFE). According to Llorens (2015) performance of polyester/PVC membranes with TiO₂ is comparable with PVDF in terms of soiling and fire resistance. Llorens (2015) did not provide any information on expected service life and transparency. No other information on expected service life of polyester/PVC membranes with TiO₂ was identified. Based on the available information polyester/PVC membranes with TiO₂ is, therefore, considered to be a technical feasible alternative for composite architectural membranes, though, service life may be shorter than the 15 years for fluoropolymers as indicated by Llorens (2015) and stakeholders. It should be noted that such polyester/PVC membranes with TiO₂ is available on the EEA market (Taiyo Europe, 2021).

According to Llorens (2015) silicone is more flexible than PTFE which gives fiberglass fabric coated with silicone a higher tolerance to folding. Furthermore, fiberglass fabric coated with silicone can be made more translucent than fiberglass fabric coated with PTFE. Silicone is water resistant whereas dirt/soil resistance is by Llorens (2015) described as 'average' compared to soil resistance of PTFE which is described as 'very good'. It seems, though, like there is ongoing research on the use of TiO₂ for self-cleaning properties – e.g. the use of the TiO₂ in combination with silane/siloxane (Khan et al., 2020). Besides self-cleaning properties, laboratory test also showed promising results to maintain the superhydrophobic durability against mechanical abrasion, chemical exposure and UV radiation (Khan et al., 2020). For the key performance parameter 'lifetime/service life', that is related to weathering and UV-radiation, Llorens (2015) states that it is >25 years for fiberglass fabric coated with PTFE, and >20 years for fiberglass fabric coated with silicone. Stakeholders stated that fluoropolymer coating (PTFE, FEP, PVDF) on top of fiberglass fabric can reach 40-50 years durability and that silicone coating does not provide the same performance. It should, though, be noted that fiberglass fabric architectural membranes coated with silicone are available in EEA e.g. under the brand name Atex® textile membranes (service life 20 years).

Based on the available information fiberglass fabric coated with silicone is considered to be a technical feasible alternative for fiberglass architectural membranes, though, service life may be shorter than fluoropolymer coated fiberglass fabric and dirt/soil resistance will not be as good.

Economic feasibility of alternatives

Architectural coatings and paint

In the CfE and 2nd stakeholder consultations stakeholder input has been received, but it has not been possible to gain quantifiable, economic data on the use of fluoropolymer binders.

In a reply to the 2nd stakeholder consultation, one stakeholder who uses fluoropolymer based architectural paint and coatings, emphasized that they have not been able to find an alternative to replace the fluoropolymer binders currently used, but they are aware of the high price of fluoropolymers. Though the use of fluoropolymer coatings is rather expensive, and likely significantly more expensive than potential alternatives, the use is, according to

stakeholders, still favored due to the chemical properties. Three stakeholders reasoned in reply to the 2nd stakeholder consultation how potential alternatives have lower lifetime, and requires higher concentrations of the alternative substances, more frequent reapplication, and/or an increased need for replacement of the coated elements. This would in the end lead to higher costs e.g. increased labour costs, despite the unit price of alternatives being cheaper.

According to OECD (2022), the overall global market penetration for PFASs in architectural protective coatings is approximately 1%.

A producer of alternatives noted, however, in the 2nd stakeholder consultation, that their alternative, Tetrashield, not only is favorable in terms of cost, but that the technical performance is comparable to FEVE - and even exceeds FEVE in some ways.

Coil coating

With respect to coil coating, two stakeholders argue, in the 2nd stakeholder consultation, that PVDF prepainted metal, used for large external surfaces of buildings, is a cost effective, sustainable and recyclable material. They state over 90% of the prepainted metal is recycled at end of life and as such the material is positive for the circular economy. According to these stakeholders, replacing the fluoropolymer top coating with alternatives would lead to significant cost increases, as panels would have to be repainted or replaced to be equivalent to metal painted with PVDF. Additionally, one stakeholder argued that a restriction scenario would lead to decreased quality of European coil coated products and thus reduce the competitiveness in the market.

According to OECD (2022) approximately 90% of the coil coatings are used for roofing and building panels in the EU market. In 2011, the EU coil coating market shares were distributed with 88-91% being non-fluoropolymer materials, while 3-12 % were estimated as containing fluoropolymers such as PVDF and FEVE (OECD, 2022).

The alternative binders for topcoats coil coating includes Silicone Modified Polyester and High Durability Polyester, where the cost per unit prices, according to the webpage of Wanzhi steel is lower than for PVDF.

Wind turbine blade coating

For wind turbine blade coating quantitative estimates on comparative unit costs between fluoropolymers and fluorine-free alternatives is generally lacking in the public domain, and no information has been provided by suppliers or downstream users in the 2nd stakeholder consultation. Non-fluoropolymer-based coatings are available on the EEA market from e.g. Hempel.

Architectural membranes (composite membranes with top coating)

Polyester coated with PVC and TiO₂ composite architectural membranes is in use in the EEA and is claimed to be a cost-effective alternative to traditional roofing systems (Taiyo Europe, 2021). Fiberglass fabric architectural membranes coated with silicone are available in EEA e.g. under the brand name Atex®. According to Llorens (2015), with regards to cost and handling, silicone-coated fiberglass can be positioned somewhere between PVC-coated polyester and PTFE-coated fiberglass.

Quantitative estimates on comparative unit costs between composite architectural membranes with a fluoropolymer topcoat and non-PFAS architectural membranes are generally lacking in the public domain. Despite requesting more information from CfE and 2nd stakeholder consultations, it has not been possible to gain quantifiable, economic data on fluoropolymers and fluorine-free architectural membranes. In the 2nd stakeholder consultation four stakeholders have, however, provided their viewpoint on the cost of

alternatives compared to fluoropolymers within their uses and productions.

It has thus been emphasized by the stakeholders how the unit cost of non-PFAS alternative top coating might be cheaper than the costs of fluoropolymer top coating, but as the alternatives among other things require more cleaning and frequent reapplication, the end costs are likely to be higher when applying alternatives. Increased costs of labor, maintenance, compliance, qualification, and general development and adaptation throughout the supply chain is also likely to be of significance, though no specific data has been submitted in the 2nd stakeholder consultation.

Stakeholders highlighted moreover, that while the unit cost of most fluoropolymers is likely to be higher than other materials, the use is still favored as it ensures functionality, and overall cost saving can be made over the full working life of the product. Therefore, transitioning to alternatives might have potential knock-on implications for the operations where the fluoropolymers are used.

Stakeholder input on transition periods

Input on transition periods was received via the 2nd stakeholder consultation on architectural coatings and paints, coil coating and composite architectural membranes. No stakeholders commented on wind turbine blade coating. Stakeholder replies can be seen below.

- Architectural coatings and paints:
 - There are no legal requirements, but customers expect coatings to meet certain specifications. Approval time 3-4 years.
 - Flame spread testing (EN ISO 13501) 8-12 months for certain uses and 5-10 years of accelerated real world exposure testing is also mentioned.
- Coil coating:
 - Coil coated steels are subjected to extensive weathering studies, to develop the appropriate technical information that is used to satisfy national building regulations and technical accreditations. Approval will take 5-6 years from the start of weathering studies.
 - Assessment of alternatives to micro-powder PTFE (PTFE waxes) in coating formulations will have to be followed by extended weathering studies.
- Composite architectural membranes:
 - No legal requirements but various approval schemes exist by public authorities, by third parties, and by customers. There are time consuming weathering tests under multiple conditions and flame retardancy tests which need to be carried out, estimated testing time is 12-24 months.
 - No suitable alternatives have been found so far. The transition period might vary between 3 and 10 years, depending on the application.

Concluding remarks

Architectural coatings and paints

Available data indicates that alternative binders in top coatings, such as polyurethane in architectural paints and coatings, might have a shorter lifetime under harsh (environmental) conditions than fluoropolymer binders. However, this does not seem to have an impact on the global market that according to OECD (2022) is dominated heavily by alternatives binders. The Dossier Submitters, therefore, conclude based on information from CfE, literature review and stakeholder consultations, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use in architectural paints and coatings and that the substitution potential is high.

Coil coating

Available data indicates that alternative binders in top coatings, such as high durability

polyester in coil coatings, might have a shorter lifetime under harsh (environmental) conditions than fluoropolymer binders. This does not seem to have impact on the market, that according to OECD (2022) is heavily dominated by alternative binders. However, two stakeholders state that micro-powder PTFE is used as an additive in coil coating mixtures containing alternative binders. No information on alternatives to the use of micro-powder PTFE was identified. There is hence weak evidence that available alternatives might contain micro-powder PTFE as an additive. The Dossier Submitters conclude based on information from CfE, literature review and stakeholder consultations, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use in coil coatings and that the substitution potential is high.

Wind turbine blade coating

Information shows that alternative binders to fluoropolymers are available on the EEA market for top coating of wind turbine blades. Available information further indicates that these alternatives already are in use by some of the largest wind turbine producers in the world. The Dossier Submitters, therefore, conclude based on information from literature review and stakeholder consultations, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use in wind turbine blade coatings and that the substitution potential is high.

Architectural membranes (composite membranes with top coating)

Information shows that alternative top coating of composite architectural membranes is available on the market. PVF is not considered a useful alternative since it is likely still being manufactured with PFAS polymerisation aids. Lifetime of polyester/PVC membranes with TiO₂ and fiberglass fabric coated with silicone will likely be shorter, than composite architectural membranes with a fluoropolymer based top coating. Further, fiberglass fabric coated with silicone will be less dirt/soil repellent. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. The Dossier Submitters, therefore, conclude based on information from CfE, literature review and stakeholder consultations, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use in composite architectural membranes and that the substitution potential is high.

E.2.13.2.11. Alternatives to articles containing fluoropolymers or PFPEs in building material/construction products

Technical feasibility of alternatives

Architectural membranes (pure fluoropolymers)

Composite architectural membranes (polyester/PVC with TiO₂ containing top coating and silicone coated fiberglass fabric) can to some degree be seen as alternatives to pure fluoropolymer architectural membranes of ePTFE, PVDF or ETFE foil/film. It is indicated in Llorens (2015) and by stakeholders in the 2nd stakeholder consultation that the pure fluoropolymer architectural membranes have a (much) longer service life than the alternative composite membranes described in the previous section. Furthermore, fiberglass fabric is not flexible and can therefore, in many cases not be used directly for the same applications as the pure fluoropolymer membranes (another design is required). Silicone coated fiberglass fabric is less soil/dirt resistant. It was pointed out by one stakeholder in the 2nd stakeholder consultation that ETFE is fully recyclable.

ETFE film/foil for greenhouses

As ETFE film/foil in greenhouses in some cases have replaced glass and polyethylene they can be considered as alternatives. Compared to ETFE film/foil in greenhouses polyethylene has a shorter service life before the greenhouse has to be re-sheeted. Glass has a long service

life but is less flexible and has a weight that is approx. 100 times higher than ETFE.

PTFE thread sealing tape

Tow, hemp, silicone and liquid/paste pipe thread (based on e.g. Kevlar®) is mentioned as potential alternatives to PTFE thread sealing tape. As described in the previous section tow and hemp are by stakeholders considered not to be technical feasible alternatives. No information has been identified that challenges this. The silicone-based tape LeakSeal®, described in the previous section, seems to be a technical feasible alternative to PTFE tape for fixing leaky pipes until further work can be carried out. LeakSeal® does not seem to be an alternative to PTFE thread sealing tape. Non-PFAS liquid/paste pipe thread is considered to be a technical feasible alternative PTFE thread sealing tape. However, liquid/paste pipe thread is used for permanent seals whereas PTFE thread sealing tape is used for non-permanent seals.

Polymeric PFASs used as processing aids for production of non-PFAS polymers/plastics

Boron nitride and siloxanes were identified as potential drop-in alternatives to the use of polymeric PFASs as processing aids (PPAs) in the production of non-PFAS polymers/plastics. As described in Annex E.2.3.4.1 boron nitride is considered to be a technical feasible alternative for the production of PE films. However, as indicated by one stakeholder, boron nitride might not be a technical feasible alternative for all applications exemplified by the stakeholder comment that: *"hard foreign particles like boron nitride can result in premature pipe failure due to stress concentrations"*.

The properties of using siloxanes (Multibase™) are comparable to the properties described from using polymeric PFASs as PPAs (DuPont, 2021). However, no information has been identified that describes potential loss of functionality from substituting polymeric PFASs PPAs with siloxanes.

Bridge and building bearings

Steel rollers are expected to be technical feasible alternatives to PTFE in bridge and building bearings. However, it is the understanding of the Dossier Submitters that the use of steel rollers will require that the bridges and buildings will have to be designed differently as the steel rollers require significantly more space in the constructions.

Window frames (laminated with fluoropolymers)

The stakeholder that gave input on the use of PVDF film for laminating PVC and HPL window frames in the 2nd stakeholder consultation stated that to their knowledge there is no alternative. However, other types of window frames such as wood and metal frames have a significant market share (MarketResearch, 2020). These alternative materials are considered technical feasible alternatives to PVC and HPL laminated with PVDF. Furthermore, given the limited number of stakeholder input on this use, the Dossier Submitters do not know if it is common for producers of PVC and HPL window frames to laminate the frames with PVDF film.

Economic feasibility of alternatives

Architectural membranes (pure fluoropolymers)

No quantitative estimates on comparative unit costs between pure fluoropolymers architectural membranes and non-PFAS composite architectural membranes has been identified. However, polyester coated with PVC and TiO₂ composite architectural membranes are in use in EEA, and it is claimed to be a cost-effective alternative to traditional roofing systems (Taiyo Europe, 2021). Fiberglass fabric architectural membranes coated with silicone are available in EEA e.g. under the brand name Atex®. According to Llorens (2015), with regards to cost and handling, silicone-coated fiberglass can be positioned somewhere between

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PVC-coated polyester and PTFE-coated fiberglass. The unit cost of non-PFAS composite architectural membranes is, therefore expected to be lower than pure fluoropolymers architectural membranes.

The comment received in the 2nd stakeholder consultation on economic feasibility of alternatives to composite architectural membranes with a fluoropolymer top coating in general also applies to pure fluoropolymers architectural membranes. These comments are reflected in the section on economic feasibility of alternatives to mixtures containing fluoropolymers and PFPEs.

ETFE film/foil for greenhouses

No comment was received in the 2nd stakeholder consultation on the economic feasibility of alternatives to ETFE greenhouses and no quantitative estimates on comparative unit costs have been identified. However, more frequent reapplication must be expected for polyethylene foils as they have a shorter lifetime than ETFE film/foil. Glass is much heavier than ETFE and it therefore requires more material (e.g. wood or metal) for construction. Glass has a long lifetime but is not self-cleaning. Even if ETFE has a higher unit cost, these things will raise the overall cost of polyethylene and glass. Unit costs of recycling of ETFE compared to polyethylene and glass have not been identified.

PTFE thread sealing tape

The only comment received in the 2nd stakeholder consultation on the economic feasibility of alternatives to PTFE tape, is that there is no alternative material.

PFASs used as processing aids (PPAs) for production of non-PFAS polymers/plastics

In a response to the 2nd stakeholder consultation one stakeholder indicated that alternatives are cheaper than polymeric PFAS PPAs. The same stakeholder, however, also states that the alternatives do not live up to the technical requirements. Three other stakeholders also stated that the alternatives do not live up to the technical requirements and that the question of economic feasibility is therefore not relevant.

Bridge and building bearings

The stakeholder that gave input to the 2nd stakeholder consultation stated that steel rollers as alternative to PTFE containing bridge and building bearings "*are economically on a much higher level*".

Window frames (laminated with fluoropolymers)

The stakeholder that gave input to the 2nd stakeholder consultation on lamination of PVC and HPL window frames with PVDF film, did not provide information on economic feasibility of alternatives, likely because they stated that to their knowledge no alternatives are available.

Stakeholder input on transition periods

Pure fluoropolymer architectural membranes

In a response to the 2nd stakeholder consultation one stakeholder stated that: "*Flammability test and studies have to be performed according to DIN, EN and ASTM standards. Long term test on weathering and durability have to be carried out to prove the suitability of the alternative products.*" The same stakeholder stated that the average approval time is >10 years for the intended use in roofing.

ETFE film/foil for greenhouses

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

No information received on transition periods.

PTFE thread sealing tape

EN751-3 describes the use of PTFE tape in sealing materials for metallic threaded joints used for family gases (fuel gases), natural gases, liquefied petroleum gases and for hot water of heating systems. No information on expected transition period was provided by stakeholders in the 2nd stakeholder consultation.

Production of non-PFAS polymers used as building materials/construction products

In a response to the 2nd stakeholder consultation one stakeholder mentioned a need for a 3-5 year transition period without specifying why.

Bridge and building bearings

No information received on transition periods.

Window frames (laminated with fluoropolymers)

No information received on transition periods.

Concluding remarks

Architectural membranes (pure fluoropolymers)

Non-PFAS composite architectural membranes are available on the market as alternatives to pure fluoropolymer architectural membranes. The lifetime of polyester/PVC membranes with TiO₂ and fiberglass fabric coated with silicone is shorter than pure fluoropolymer architectural membranes. Further, fiberglass fabric coated with silicone is less flexible and less dirt/soil repellent. No evidence is available to the Dossier Submitters pointing to a shortage in the supply of alternatives. The Dossier Submitters, therefore, conclude based on information from literature review and stakeholder consultations, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use in architectural membranes currently made of pure FP and that the substitution potential is high.

ETFE film/foil for greenhouses

Glass and polyethylene are technically feasible alternatives to the use of ETFE in greenhouses. Polyethylene has a shorter lifetime and glass requires more material (e.g. wood or metal) for construction. The alternatives might also require more frequent cleaning. Polyethylene and glass are common materials, and the capacity is expected to be high. The Dossier Submitters, therefore, conclude based on information from stakeholder consultations, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use in greenhouses covered by ETFE and that the substitution potential is high.

PTFE thread sealing tape

Liquid/paste pipe thread (based on e.g. Kevlar®) is an alternative to PTFE thread sealing tape for permanent pipe seals. There is no evidence pointing to a shortage in the supply of alternatives available to the Dossier Submitters. The Dossier Submitters, therefore, conclude based on information from CfE, literature review and the 2nd stakeholder consultation that the evidence is weak that technically feasible and economically feasible alternatives are available for the quantities required for use as PTFE thread sealing tape and that the substitution potential is high.

For non-permanent pipe seals no alternatives have been identified and technical feasibility is uncertain. The Dossier Submitter, therefore, conclude based on information from CfE, literature review and 2nd stakeholder consultation, that the evidence is inconclusive that technically feasible and economically feasible alternatives are available for the quantities required for use as PTFE thread sealing tape and that the substitution potential is unclear.

For the use of PTFE tape for manufacturing and installation of windows, doors etc. no evidence has been provided or identified to indicate that a derogation is needed.

Polymeric PFASs used as processing aids (PPAs) for production of non-PFAS polymers/plastics

Available data indicates that alternative for polymeric PFASs used as processing aids for production of non-PFAS polymers such as boron nitride and siloxanes is commercially available. However, limited information has been identified that describes potential loss of functionality of building material/construction products from substituting to alternatives. No evidence is available to the Dossier Submitters pointing to a shortage in the supply of alternatives. The Dossier Submitters, therefore, conclude based on information from CfE, literature review and the 2nd stakeholder consultation that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use as processing aids and that the substitution potential is high.

Bridge and building bearings

Only one stakeholder gave input in the 2nd stakeholder consultation on PTFE in *bridge and building bearings*. Steel rollers are expected to be technically feasible alternatives, however, they are more expensive and are not considered to be drop-in alternatives as bridges and buildings will have to be designed differently as the steel rollers require significantly more space in the constructions. No evidence is available to the Dossier Submitters pointing to a shortage in the supply of alternatives. The Dossier Submitters, therefore, conclude based on information from stakeholder consultations, that the evidence is weak that technically feasible and economically feasible alternatives are available for the quantities required for use as bridge and building bearings and that the substitution potential is high.

Window frames (laminated with fluoropolymers)

Only one stakeholder gave input in the 2nd stakeholder consultation on the use of PVDF film for laminating PVC and HPL window frames. Other types of window frames such as wood and metal frames have a significant market share and are considered technically feasible alternatives. The Dossier Submitters, therefore, conclude based on information from, literature review and stakeholder consultations, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use in window frames and that the substitution potential is high.

E.2.13.2.12. Alternatives to side-chain fluorinated polymers in building material/construction products

Technical feasibility of alternatives

Without mentioning any alternatives, it was stated in the 2nd stakeholder consultation, that alternatives do not provide the same combination of effects of side-chain fluorinated polymers when used for surface protection/sealing. As mentioned in the previous section, it cannot be excluded that the three stakeholders that replied to the 2nd stakeholder consultation all refer to side-chain fluorinated polymers based on 6:2 fluorotelomer chemistry.

Based on non-exhaustive desktop research non-PFAS side-chain polymers based on silane/siloxane chemistry for protection of porous surfaces was identified to be commercially available. The non-PFAS side-chain polymers based on silane/siloxane chemistry for

protection of porous surfaces provides good water repellence, the structure remains breathable, and the water repellent treatments are not affected by UV radiation. However, oil/dirt repellence is not good compared to side-chain fluorinated polymers. Overall, the non-PFAS side-chain polymers based on silane/siloxane chemistry is considered to be technically feasible for protection of porous surfaces, though, with loss of functionality in terms of oil/dirt repellence compared to side-chain fluorinated polymers.

According to Amrutkar et al. (2022) sacrificial (e.g. waxes, polysaccharides), semi-permanent (e.g. acrylics and epoxides applied in several layers) and permanent (e.g. nanoparticles-based coating, silicon/siloxane, and polyurethanes) anti-graffiti coatings are on the market as potential alternatives to side-chain fluorinated polymers.

In the review paper by Amrutkar et al. (2022) advantages and disadvantages of the different types of anti-graffiti coatings are given. The described advantages of permanent nanoparticles-based coating (e.g. nano-silica): "*corrosion prevention, chemical and thermal stability, hardness, UV resistance, transparency, improved self-cleaning capability and antibacterial efficiency*" is comparable to the advantages described for PFAS-based anti-graffiti coatings. Some of the nanoparticles-based coating in Amrutkar et al. (2022), though, seems to be based on PFAS-based binders. This is, however, not the case in Moura et al. (2014), where the performance of a permanent nano-silica anti-graffiti product is compared to an anti-graffiti product based on side-chain fluorinated polymers. Both products are considered to be suitable for anti-graffiti solutions on inorganic porous materials when comparing water vapour permeability, colour change, hydrophobicity, durability and resistance to weathering (Moura et al., 2014).

According to Moura et al. (2014) sacrificial anti-graffiti coatings are generally preferred for historic and heritage buildings where the appearance of the building cannot be altered. Sacrificial coatings based on polysaccharides is compatible with most surfaces, including metals, exterior walls, or painted surfaces (Amrutkar et al., 2022) and is therefore not limited to historic and heritage buildings.

The non-fluoropolymer alternatives described under architectural paints and coatings, epoxy, polyester, polyurethane etc. does also provide protection of surfaces and can therefore for some applications be seen as alternatives to side-chain fluorinated polymers.

Economic feasibility of alternatives

Quantitative estimates on comparative unit costs between side-chained fluorinated polymers and non-PFAS alternatives are lacking. Despite requesting more information through CfE and 2nd stakeholder consultation, it has not been possible to gain quantifiable economic data. Two stakeholders in the 2nd stakeholder consultation refer to the issue of alternatives not providing the same effects, while one finds it possible that alternatives could be economically feasible, but that this would require totally revised processes.

Sacrificial anti-graffiti coating is according to Amrutkar et al. (2022) more cost-effective than another category of anti-graffiti coating products (semi-permanent and permanent).

Stakeholder input on transition periods

The stakeholders find that an implementation of alternatives will involve elements such as development of products, market launch, and commercialization, which is likely to take approximately 5 years according to one stakeholder, while another expects it to take at least 6 years. A third stakeholder refers to the quality and effectiveness of the process but estimates it to be possible within 1 to 3 years.

Concluding remarks

Alternatives to side-chain fluorinated polymers used for surface protective coating/sealing are

available on the market, and there is no evidence available to the Dossier Submitters pointing to a shortage in the supply of alternatives. Many of the alternatives have been on the market for a long time and the Dossier Submitters consider these to be technically feasible, and many can be considered as drop-in alternatives. However, there can be a loss of functionality, as alternatives do not provide the same level of soil/dirt repellence as side-chain fluorinated polymers. The Dossier Submitters, therefore, conclude based on information from literature review, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use in protective coating/sealants and that the substitution potential is high.

E.2.13.2.13. Alternatives to non-polymeric PFASs in building material/construction products

Technical feasibility of alternatives

Fluorosurfactants as wetting/levelling agents in e.g. coating, paints and adhesives:

The solvent-based paints and coatings from under architectural coatings and paints and coating that do not contain fluorosurfactants may for some applications be considered as drop-in alternatives.

According to the six stakeholders that replied to the 2nd stakeholder consultation (three referring C6 and/or fluorotelomer surfactants, one referring to C4 side-chain polymeric fluorosurfactants and two didn't specify the type of fluorosurfactant that they referred to in their responses) no alternatives have the same combination of properties as fluorosurfactants and alternatives cannot match the low surface tension of fluorosurfactants, even at higher doses.

Many non-PFAS-based surfactants are available on the market. It has not been possible for the Dossier submitters to prepare a full survey of this market. However, examples of non-PFAS-based surfactants that can be used in building materials/construction products such as water-based coatings, paints and adhesives are provided in the previous section.

These wetting and levelling agents are based both on siloxanes (e.g. polyether siloxane copolymers, siloxane-based gemini surfactant or modified polyether siloxane) and hydrocarbon surfactants (e.g. non-ionic organic surfactants and sulfosuccinates).

Non-PFAS alternatives to fluorosurfactants used in building material/construction products such as TEGO®, SURFYNOL® and DYNOL™ and Hydropalat® is available on the market. The manufacture of DYNOL™, Evonik, claims that the surface tension behavior of the DYNOL™ superwetting surfactants is comparable to fluorosurfactants. Furthermore, Evonik also offers a Webinar called "Substrate wetting - the future beyond fluorosurfactants".

It is the understanding of the Dossier Submitters that alternatives should in general not be considered as drop-in alternatives to fluorosurfactants but rather that in many cases re-formulation will be needed in order for the non-PFAS surfactant system to fulfill properties comparable to the fluorosurfactants, e.g. wetting, levelling, defoaming and anti-cratering.

Even if no alternatives on their own have the same combination of properties as fluorosurfactants, as stated by stakeholders, it seems based on information from Evoniks webpage, that it is possible to reformulate and use (combinations of) non-PFAS surfactants to obtain (some of) the properties of the fluorosurfactants. Especially compared to the fluorosurfactants that are restricted in the EU (PFOS, PFOA and their related substances) or those that are about to be restricted (PFHxS, C9-C14 PFCAs (and likely also PFHxA) and their related substances).

One property that can likely not be matched by non-PFAS surfactants is oil/dirt repellency that is provided by some specific types of fluorosurfactants.

Processing aids

According to one stakeholder reply in the 2nd stakeholder consultation no non-PFAS processing aids are available for the production of the specific use. However, the stakeholder describes the architectural membrane-like product as niche product in the market, which is dominated by alternatives. In terms of technical feasibility the stakeholder states that all alternatives have their trade-offs in performance, but that they are able to meet building regulations. It must, therefore, be assumed that downstream users see the alternatives as technically feasible.

Another stakeholder in the 2nd stakeholder consultation stated that alternatives to fluorosurfactants as processing aids for production of acrylic foam tape are available but that R&D to identify alternatives is ongoing. The stakeholder in December 2022 announced that they will *"Exit all PFAS manufacturing by the end of 2025"* and *"Work to discontinue use of PFAS across our product portfolio by the end of 2025"* (3M, 2022). No other producers of acrylic foam tape replied to the 2nd stakeholder consultation and no other information has been identified.

Window film manufacturing

In the 2nd stakeholder consultation, one stakeholder there are no known PFAS-free alternatives that provide the same performance. The stakeholder in December 2022 announced that they will *"Exit all PFAS manufacturing by the end of 2025"* and *"Work to discontinue use of PFAS across our product portfolio by the end of 2025"* (3M, 2022). No other producers of window film replied to the 2nd stakeholder consultation and no other information has been identified.

Economic feasibility of alternatives

Fluorosurfactants as wetting/levelling agents in e.g. coating, paints and adhesives

Quantitative estimates on comparative unit costs between fluorosurfactants and non-PFAS alternatives are generally lacking. Despite requesting information through CfE and 2nd stakeholder consultation, it has not been possible to gain quantifiable, economic data on fluorosurfactant and non-PFAS alternatives, as several stakeholders note how, due to the lack of alternatives, they cannot comment on whether there are economically feasible ones. It should be noted that no manufacturers of non-PFAS surfactants responded to the 2nd stakeholder consultation. Two stakeholders mention how potential alternatives might require more frequent reapplication and higher concentrations of the alternative substance, which could lead to higher costs. Two stakeholders, who in the 2nd stakeholder consultation specifically mentioned C6 and C6 fluorotelomers in their replies, expect moreover a transitioning to alternatives to be likely to have knock-on effects on the operations where fluorosurfactants traditionally are used, as there will be a need for developing and testing the alternatives.

In the 2nd stakeholder consultation, two stakeholders responded that the use of fluorosurfactants is rather expensive, and likely significantly more expensive than potential alternative surface-active substances, but the use is still favored as it ensures functionality, which stakeholders believe is the reason that paint manufacturers and end-users are willing to pay the higher price. Therefore, according to one stakeholder, the C6 fluorotelomer surfactants are used only if low surface tension and other functional properties are required, which cannot be achieved with a fluorine-free alternative. Another stakeholder, referring to fluorosurfactants in general, further added that fluorosurfactants provide unique properties, there are no technical alternatives, so not so much a question of formulation costs. Paint manufacturers and end-users are ok to pay a higher price as long as this chemistry is the right technical solution. Economically, they state, that they may find some lower cost alternatives but for water repellence only, not allowing to reach overall properties, not matching the most demanding applications.

Processing aids

No specific information on economic feasibility of alternative architectural membrane-like products (not produced with non-polymeric PFAS processing aids) was provided or identified.

For the use of fluorosurfactants as processing aids for production of acrylic foam tape it was mentioned in the 2nd stakeholder consultation that *"Non-fluorinated alternatives' material costs are not significantly different than PFAS-based surfactants used in acrylic foam tape applications; however, non-PFAS alternatives do not meet the technical requirements"*.

Window film manufacturing

In the 2nd stakeholder consultation, one stakeholder there are no known PFAS-free alternatives that provide the same performance. The stakeholder in December 2022 announced that they will *"Exit all PFAS manufacturing by the end of 2025"* and *"Work to discontinue use of PFAS across our product portfolio by the end of 2025"* (3M, 2022). No other producers of window film replied to the 2nd stakeholder consultation and no other information has been identified.

Stakeholder input on transition periods

Fluorosurfactants as wetting/levelling agents in e.g. coating, paints and adhesives

In response to the 2nd stakeholder consultation stakeholders stated that there currently are no suitable alternatives available to fluorosurfactants, with the same combination of properties. Based on responses from two downstream users the proposed estimations of the necessary time for a transition varies between *"up to several years"*, *"3 to 10 years"* though stakeholders underline how a fitting alternative is yet to be found. The stakeholder that mentioned *"3 to 10 years"* specifically referred to C6.

Processing aids

For the final architectural membrane-like product, where non-polymeric PFASs is used as processing aids, one stakeholder states that CE certification takes 6-12 months and on top of that national certification takes 1-2 years for the testing of one product.

For the use of fluorosurfactants as processing aids for production of acrylic foam tape one stakeholder mentioned in the 2nd stakeholder consultation that *"the R&D timeline to seek another option is five years. It will take an additional three years for product testing, re-qualification and full-scale operational manufacturing capability across all industries and customers impacted"*. It should be noted that this stakeholder has announced that they will *"Exit all PFAS manufacturing by the end of 2025"* and *"Work to discontinue use of PFAS across our product portfolio by the end of 2025"*.

Concluding remarks

Other factors than this restriction proposal do likely have a big impact on substitution of non-polymeric PFASs in building materials/construction products. One factor being the 3M announcement that they will *"Exit all PFAS manufacturing by the end of 2025"* and *"Work to discontinue use of PFAS across our product portfolio by the end of 2025"* another factor is the restriction proposal on undecafluorohexanoic acid (PFHxA), its salts and related substances which is currently under deliberation. For PFHxA no derogation of building material/construction products is suggested by RAC and SEAC (ECHA, 2021a).

Fluorosurfactants as wetting/levelling agents in e.g. coating, paints and adhesives

The solvent-based paints and coatings, mentioned under architectural coatings and paints and coatings that do not contain fluorosurfactants may for some applications be considered

as drop-in alternatives. For other applications alternatives are available on the market, however not as drop-in alternatives. Re-formulation is likely possible for most applications, however, there may be some loss functionality (no or lower oil/dirt repellency) for some applications. No evidence is available to the Dossier Submitters pointing to a shortage in the supply of alternatives. The Dossier Submitters, therefore, conclude based on information from CfE, literature review and stakeholder consultations, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use of surfactants as wetting/levelling agents in e.g. coating, paints and adhesives and that the substitution potential is high.

Non-polymeric PFASs as processing aids

Technically feasible alternatives are available to architectural membrane-like building materials/construction products produced by non-polymeric PFAS processing aids (not included in the product). The alternatives dominate the market, and no evidence is available to the Dossier Submitters pointing to a shortage in the supply of alternatives. The Dossier Submitters, therefore, conclude based on information from stakeholder consultations, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are available for the quantities required for use as processing aids in building material/construction products and that the substitution potential is high.

Specifically, for the use of non-polymeric PFAS processing aids for production of acrylic foam tape the evidence on available alternatives is inconclusive. One stakeholder highlighted in the 2nd stakeholder consultation that no alternatives are available, but that R&D is ongoing for replacing fluorosurfactants as processing aids for production of acrylic foam tape. The stakeholder in December 2022 announced that they will "*Work to discontinue use of PFAS across our product portfolio by the end of 2025*". Either production will, therefore, have to be stopped or another solution (alternatives) will have to be identified within a short timeframe. The Dossier Submitters, therefore, conclude based on information from 2nd stakeholder consultation, that the evidence is inconclusive that technically feasible and economically feasible alternatives are available for the quantities required for use as [non-polymeric PFAS processing aids for production of acrylic foam tape and that the substitution potential is unclear.

Window film manufacturing

There is uncertain evidence for the use of fluorosurfactants for window film manufacturing. One stakeholder highlighted in the 2nd stakeholder consultation that there are no alternatives available for this use. The stakeholder in December 2022 announced that they will "*Work to discontinue use of PFAS across our product portfolio by the end of 2025*". Either production will, therefore, have to be stopped or another solution (alternatives) will have to be identified within a short timeframe. The Dossier Submitters, therefore, conclude based on information from 2nd stakeholder consultation, that the evidence is inconclusive that technically feasible and economically feasible alternatives are available for the quantities required for use as window film manufacturing and that the substitution potential is unclear.

E.2.13.2.14. Human health and environmental hazards

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log K_{ow}) and bioconcentration factor (BCF) was assessed. Additionally, it was assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHAs dissemination site. Non-chemical alternatives are also listed in the table.

In relation to building material/construction products, the list of alternatives contained twenty-eight (28) unique CAS numbers. Twenty of the substances with unique CAS was

classified according to CLP (harmonised classification or self-classification). One of these substances (fiberglass) is self-classified as Carc. 1B in its fiber/solid state. None of the substances with unique CAS is identified as having PBT or vPvB properties. Sixteen (16) of the substances may contain D4, D5 and/or D6 as residues. D4, D5 and D6 have been identified by ECHA's Member State Committee as SVHC substances with PBT/vPvB properties (ECHA, 2019).

The list contained an additional six (6) substances with unique substance names for which no CAS numbers were available. For these substances, no information on classification or PBT and vPvB assessments were available. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.13.3. Environmental impacts

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.13.3., assuming baseline and, consequently, on-going PFAS use and emissions. The analysis of environmental impacts focuses on one restriction option:

- **RO1**, adopting a ban of all PFAS used in the building/construction sector;

Environmental impacts of RO1 are analysed quantitatively. Table E.141 below summarizes the characteristics of RO1.

Table E.141. Characteristics of RO1.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---

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 is expected to be implemented in 2027. All emission estimates represent mean values. Table E.142 shows mean emissions and the expected mean emission reduction for a time path of 30 and 45 years (starting in 2025).

Table E.142. Total mean emissions and emission reduction of RO1 (building/construction sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	152 555	---	---
RO1	6 513	146 042	96
2025-2070			
Baseline	250 522	---	---
RO1	6 513	244 009	97

As illustrated in Table E.142, a full ban on PFAS use in this sector leads to a mean emission reduction of about 96% compared to the baseline scenario, depending on the length of the timeline.

E.2.13.4. Economic and other impacts

It has not been possible to identify much information in literature, associated with potential costs related to the substitution of PFASs within the areas of building material/construction products. A brief literature review did, however, reveal some potential alternatives for the

main uses of PFASs in building material/construction products. To assess more information on the potential effects of a restriction and economic impacts, CfE, and targeted stakeholder consultations have been carried out. Despite these efforts, very little specific information to quantify the potential costs of a restriction on the use of PFASs in building material/construction products is available. The collected information on the main types of costs is patchy and covers only some of the many applications of PFASs in building material/construction products.

The impacts of a ban on PFASs use in the building/construction sector varies considerably depending on the use and types of PFASs covered. Therefore, the assessment here is separated into fluoropolymers & PFPEs and non-polymeric PFASs, respectively. The section on fluoropolymers and PFPEs is further sub-divided in to building/construction mixtures and building/construction articles.

As the side-chained fluorinated polymers degrade to PFAAs, the economic impacts related to the side-chain fluorinated polymers are included under non-polymeric PFASs.

E.2.13.4.1. Fluoropolymers and PFPEs

For fluoropolymer and PFPE in building/construction mixtures some alternatives are available. The economic implications for downstream users are summarized in Table E.143 below.

Table E.143. Overview of economic impacts of a ban of polymeric PFASs (fluoropolymers and PFPEs) used in mixtures in building/construction applications.

Product category	Substitution costs	Transitional costs	Loss of functionality
Architectural coatings and paints	No comparison between FP top coating and alternatives (polyurethane, polyester, polysiloxane) has been possible in this assessment. It is indicated that FP top coatings is the most expensive	Likely to be limited, as alternatives are available and dominates the EEA market.	Possible negative impacts on the lifetime under harsh environmental conditions (weathering/UV-radiation) when substituting FP top coating with e.g. polyurethane
Coil coating	No comparison between FP top coating of coil and alternatives (silicone modified polyester and high durability polyester) has been possible in this assessment. Indicated that FP top coatings are of the highest cost.	Likely to be limited, as alternatives are available and dominates the EEA market. However, stakeholders state that alternatives may contain micro-powder PTFE as additive. If this is the case reformulation will be needed.	Possible negative impacts on the lifetime harsh environmental conditions (weathering/UV-radiation) when substituting FP top coating with different polyester types
Wind turbine blade coating	No comparison between FP top coating of wind turbine blades and alternatives (e.g. coating based on polyaspartic ester and titanium	Likely to be limited, as alternatives are available on the EEA market.	No loss of functionality identified. It can be speculated if there are possible negative impacts on the lifetime under harsh environmental conditions (weathering/UV radiation and rain erosion) when substituting FP top coating with alternatives

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Product category	Substitution costs	Transitional costs	Loss of functionality
	dioxide) has been possible in this assessment.		
Architectural membranes (composite membranes with top coating)	No comparison between FP top coating and alternatives (silicone for fiberglass and TiO₂ for polyester/PVC) has been possible in this assessment. Indicated that FP top coatings are the most expensive.	Likely to be limited, as alternatives are available and currently on the market.	Possible negative impacts on the lifetime of the polyester/PVC membrane under harsh environmental conditions (weathering/UV-radiation) when substituting FP top coating with TiO₂ Possible negative impacts on the lifetime of the fiberglass fabric under harsh environmental conditions (weathering/UV-radiation) when substituting FP top coating with silicone Less soil/dirt repellence of the fiberglass fabric when substituting FP top coating with silicone (unless made self-cleaning with TiO₂)

For architectural coatings and paints and coating of wind turbine blades drop-in alternatives are available. For architectural coatings and paints the alternatives are available at a lower cost, but the alternatives are likely to have a shorter lifetime under harsh environmental conditions. This is also the case for coil coating. However, information from two stakeholders indicate that alternative formulations based on e.g. polyester or polyurethane, contain low levels of micro-powder PTFE. If this is correct for all or most of the alternative formulations, reformulation is required - which will increase the costs. On the other hand, if only a limited number of alternative formulations contains micro-powder PTFE as an additive, transitional costs will be low as no shortage in supply of drop-in alternatives is expected.

For composite architectural membranes less expensive alternatives composite membranes with non-PFAS top coating (e.g. silicone for fiberglass fabric and TiO₂ for polyester/PVC membranes) are available on the market, though, with some loss of functionality, which might induce higher maintenance costs. As no evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters, substitution costs are expected to be limited.

For fluoropolymer and PFPE in building/construction articles, there are some available alternatives. The economic implications for downstream users are summarized in Table E.144 below.

Table E.144. Overview of economic impacts of a ban of polymeric PFASs (fluoropolymers and PFPEs) used in articles in building/construction applications.

Product category	Substitution costs	Transitional costs	Loss of functionality
Architectural membranes (pure fluoropolymer)	No comparison between pure FP membranes and composite alternatives (silicone for fiberglass and TiO ₂ for polyester/PVC) has	Likely to be limited, as alternatives are available and currently on the market.	Negative impacts on the lifetime when substituting pure FP membranes with composite membranes with non-FP top coating (TiO ₂ or silicone).

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Product category	Substitution costs	Transitional costs	Loss of functionality
	been possible in this assessment. Indicated that the cost of pure FP membranes are higher than the cost of alternatives.		Fiberglass fabric is less flexible than pure FP membranes. Less soil/dirt repellence of the fiberglass fabric when substituting FP top coating with silicone (unless made self-cleaning with TiO₂).
ETFE film/foil for greenhouses	No comparison between ETFE and alternatives (glass and polyethylene) has been possible in this assessment.	Likely to be limited, as alternatives are available and currently on the market.	Negative impacts on the lifetime when substituting ETFE with polyethylene. Glass is less flexible than ETFE film/foil and the weight is approx. 100 times higher. Alternatives require more cleaning
PTFE thread sealing tape	No comparison between PTFE thread sealing tape and alternatives (liquid/paste pipe thread) has been possible in this assessment.	Uncertain, as liquid/paste pipe thread may only partly be an alternative. If this is the case, some R&D costs may also be expected	Liquid/paste pipe thread can (likely) only be used for permanent pipe seals.
Polymeric PFASs used as processing aids (PPAs) for production of non-PFAS polymers	No comparison between polymeric PFASs and alternatives (boron nitride and siloxane) has been possible in this assessment. Indicated that pure polymeric PFAS processing aids is the most expensive	Likely to be limited, as alternatives are available and currently on the market. Uncertain if there are drop-in alternatives. If there are no drop-in alternatives, reformulation and/or adaption of existing systems will be needed.	In general, limited information available. Potential premature pipe failure when using boron nitride instead of polymeric PFASs as processing aid for production of pipes
Bridge and building bearings	No comparison between PTFE bridge and building bearings and alternatives (steel rollers) has been possible in this assessment. Stakeholder state that alternatives are much more expensive	Uncertain, as it is unknown if alternatives are available and currently on the market (as drop-in). The use of steel rollers will likely require that the bridges and buildings will have to be designed differently.	Steel rollers require significantly more space in the construction
Windows frames	No comparison between PVDF film for laminating	Likely to be limited, as alternatives are available	Window frames made of wood

Product category	Substitution costs	Transitional costs	Loss of functionality
(laminated with fluoropolymers)	PVC and HPL window frames and alternatives (other types of window frames like wood or metal) has been possible in this assessment.	and currently on the market.	may require more maintenance

No shortage of supply of alternatives to ETFE film/foil for greenhouses and for PVC and HPL window frames laminated with PVDF are expected, as alternatives already have large share of the market. Substitution costs for these uses are, therefore, expected to be limited.

For pure fluoropolymer architectural membranes there are less expensive alternatives, in the shape of architectural composite membranes with non-PFAS top coating, available on the market. But these alternatives entail, however, some loss of functionality. The capacity of alternative top coatings for composite architectural membranes is unclear. No evidence is available to the Dossier Submitters pointing to a shortage in the supply of composite architectural membranes with non-PFAS top coating. This is also the case for polymeric PFASs used as processing aids for production of non-PFAS polymers. If the capacity of alternatives for these two uses is high enough, substitution costs are expected to be limited.

For PTFE thread sealing tape, liquid/paste pipe thread is considered a technically feasible alternative for permanent pipe seals, but the technical feasibility is uncertain for non-permanent seals. There is no evidence pointing to a shortage in the supply of alternatives available to the Dossier Submitters, and the substitution costs are hence expected to be low.

According to a stakeholder, using steel rollers as alternatives to bridge and building bearings, will be much more expensive. This alternative might also result in bridges and buildings having to be designed differently. Though there is no evidence pointing to a shortage in the supply of alternatives available to the Dossier Submitters, there might hence be high socio-economic costs associated with substitution.

E.2.13.4.2. Non-polymeric PFASs

For non-polymeric PFASs in building material/construction products, there are some available alternatives. The economic implications for downstream users are summarized in Table E.145 below.

Table E.145. Overview of economic impacts of a ban of non-polymeric PFASs (PFAAs and PFAA-precursors) in building/construction applications.

Product category	Substitution costs	Transitional costs	Loss of functionality
Side-chain fluorinated polymers (PFAA-precursors) used for surface protection/sealants	No comparison between SCFP and alternatives (e.g. non-PFAS side-chain polymers) has been possible in this assessment. Indicated that SCFP is the most expensive.	Likely to be limited, as alternatives are available and currently on the market.	Less soil/dirt repellence when substituting SCFP with alternatives.
Fluorosurfactants as wetting/levelling agents in e.g. coating, paints and adhesives	No comparison between fluorosurfactants and alternatives (silicone and hydrocarbon surfactants) has been possible in this assessment. Fluorosurfactants are significantly more expensive. In some cases, higher levels of alternatives might be needed.	Likely limited, as alternatives are available and currently on the market, but not as drop-in alternatives (apart from products without fluorosurfactants). Reformulation is required for e.g. waterbased paints and coatings using fluorosurfactants as wetting and levelling agents. Reformulation might to some extent be driven by the PFHxA restriction proposal and 3M announcement to end manufacturing and use of PFASs. Products (e.g. solvent based architectural paints and coatings) without fluorosurfactants are available on the market.	Possible negative impacts on surface tension substituting fluorosurfactants with alternatives. However, superwetting surfactants are claimed to be comparable to fluorosurfactants in terms of surface tension. Less or no soil/dirt repellency when substituting specific types of fluorosurfactants with alternatives.
Non-polymeric PFAS as processing aids (not included in the final non-PFAS article)	No comparison between final products produced by processing aids and alternative final products has been possible in this assessment.	Likely to be limited, as alternative final products (not produced with PFAS processing aids) are available and currently on the market as drop-	Stakeholder indicated possible loss of functionality of alternative final products (without further specifications), however this stakeholder also

Product category	Substitution costs	Transitional costs	Loss of functionality
		in alternatives. Alternative final products dominate the market.	stated that the alternative final products meet building regulations.

There is no evidence pointing to a shortage in supply of alternatives to side-chain fluorinated polymers used for surface protection/sealants are expected, as alternatives have been on market for several years. The socio-economic costs for these uses are, therefore expected to be limited. However, loss of functionality is to be expected for some applications as alternatives provides less soil/dirt repellence.

For fluorosurfactants used as wetting/levelling agents there are less expensive alternatives available, though these are not drop-in alternatives. Increased concentrations might be required when applying the alternatives, and there might be some loss of functionality. There are however also products (e.g. solvent based architectural paints and coatings) without fluorosurfactants available on the market. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters, and substitution costs are likely limited.

With regards to non-polymeric PFAS processing aids, there are manufactured alternatives to replace the final products (without PFAS), and as there is no evidence pointing to a shortage in the supply of alternative final products available to the Dossier Submitter, the costs are expected to limited.

Besides the uses of non-polymeric PFASs listed in Table E.145, uses of fluorosurfactants for window film manufacturing and for the use of fluorosurfactants as processing aids for production of acrylic foamtape were also mentioned by stakeholders:

- There is uncertain evidence for the use of fluorosurfactants for window film manufacturing and for the use of fluorosurfactants as processing aids for production of acrylic foam tape. One stakeholder highlighted in the 2nd stakeholder consultation that there are no alternatives available for these two uses, but that R&D is ongoing for replacing fluorosurfactants as processing aids for production of acrylic foamtape. The stakeholder in December 2022 announced that they will “*Work to discontinue use of PFAS across our product portfolio by the end of 2025*”. Either production will, therefore, have to be stopped or another solution (alternatives) will have to be identified within a short timeframe.

E.2.13.5. Summary of cost and benefit assessment

E.2.13.5.1. Fluoropolymers and PFPEs

Table E.146 summarises the outcomes of the assessment of costs and benefits for polymeric PFASs (fluoropolymers and PFPEs) in mixtures used as building materials/construction products.

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Table E.146. Polymeric PFASs in mixtures used as building materials and construction products – Summary table on assessment of costs and benefits, based on a general transition period of 18 months (fluoropolymers and PFPEs).

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban					
Architectural coatings and paints	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives exists. No evidence points in the direction of shortages in the supply of alternatives. Conclusion: High substitution potential at EiF [sufficiently strong evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Sufficiently strong evidence that substitution costs are expected to be limited; alternatives are available and dominating the EEA market. No evidence on reformulation costs, one-off capital costs or administrative costs related to the transition have been identified. The economic implications for downstream users are expected to be limited; possibly some loss of functionality (lifetime), under harsh environmental conditions (weathering/UV radiation). There is sufficiently strong evidence that a ban on polymeric PFASs in architectural coatings and paints is likely to have low socioeconomic costs.	Not applicable

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Coil coating	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives to replace fluoropolymer binders in coil coating exist. No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. Weak evidence that available alternative formulations might contain micro-powder PTFE as additive. Further information is needed to understand to which extent existing alternatives contains micro-powder PTFE as additive. Conclusion: High substitution potential at EiF [sufficiently strong evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	The existence of alternatives to fluoropolymer binders in coil coating is not doubted, as they dominate the market (even with some potential changes to the lifetime). Cost impacts are uncertain as a result of the uncertainty associated with the content of micro-powder PTFE in (some) alternative formulations. The substitution costs depend on the number/volume of alternative formulations without micro-powder PTFE as additive. If this number is high, costs will be low as drop-in alternatives then are available (with some potential changes to the lifetime). If the number is low, reformulation is needed, and new weathering studies may also be needed, and costs will be higher. As a result, the socio-economic costs of a full ban are uncertain.	Not applicable

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Wind turbine blade coating	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives exist. No evidence points in the direction of shortages in the supply of alternatives. Conclusion: High substitution potential at EiF [sufficiently strong evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Sufficiently strong evidence that substitution costs are expected to be limited. No evidence on reformulation costs, one-off capital costs or administrative costs related to the transition have been identified, and the economic implications for downstream users are expected to be limited. There is sufficiently strong evidence that a ban on polymeric PFASs in wind turbine blade coating is likely to have low socioeconomic costs.	Not applicable
Architectural membranes (composite membranes with top coating)	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives to replace fluoropolymers in composite membrane top coating exists – but with some loss of functionality (less soil repellence for some types) and reductions in lifetime. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Some alternatives are available on the market and likely at a lower unit cost than fluoropolymer top coating. Substitution costs are expected to be limited, if alternatives are available in sufficient quantities. The available alternatives might have negative impacts on the lifetime of polyester/PVC membrane and fiberglass fabric under harsh environmental conditions. Siloxane has less soil/dirt repellence. As a result, higher maintenance costs are expected. As such, there is sufficiently strong evidence that a ban of PFASs in architectural membranes (composite membranes with top coating) will likely be associated with moderate socio-economic costs.	Not applicable

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Conclusion	A full ban of polymeric PFASs (FPs and PFPEs) in architectural coating and paints with a transition period of 18 months is proposed. A full ban of polymeric PFASs (FPs and PFPEs) in wind turbine blade coating with a transition period of 18 months is proposed. A full ban of polymeric PFASs (FPs and PFPEs) in coil coating with a transition period of 18 months is proposed. A full ban of polymeric PFASs (FPs and PFPEs) in architectural membranes (composite membranes with top coating) with a transition period of 18 months is proposed.				

Table E.147 summarises the outcomes of the assessment of costs and benefits for polymeric PFASs (fluoropolymers and PFPEs) in articles used as building material and construction products.

Table E.147. Polymeric PFASs in articles used as building materials and construction products - Summary table on assessment of costs and benefits, based on a general transition period of 18 months (fluoropolymers and PFPEs).

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban					
Architectural membranes (pure Fluoropolymers)	Not applicable	Sufficiently strong evidence technically and economically feasible alternatives to replace pure fluoropolymer architectural membranes with non-PFAS composite membranes exists, but with some loss of functionality (less soil repellence for some types) and reductions in lifetime. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EoF [sufficiently strong evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Some alternatives are available on the market and likely at a lower unit cost than pure fluoropolymer membranes. Substitution costs are likely to be limited, if alternatives are available in sufficient quantities. The available alternatives composite architectural membranes (polyester/PVC membrane with TiO2 and fiberglass fabric coated with siloxane) will have negative impacts on the lifetime under harsh environmental conditions, and fiberglass fabric coated with siloxane have less soil/dirt repellence. As a result, higher	Not applicable

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				maintenance costs are expected. As such, there is sufficiently strong evidence that a ban of PFASs will likely be associated with moderate socio-economic costs.	
ETFE film/foil for greenhouses	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives to replace ETFE film/foil in greenhouses exist. No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential [sufficiently strong evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Sufficiently strong evidence that substitution costs are likely to be limited, following the availability of alternatives (traditional products: glass and polyethylene foil), that likely dominate the market. The economic implications for downstream users are expected to be moderate, as functional losses and reductions in lifetime will lead to higher maintenance costs (polyethylene foil has a shorter lifetime and glass is less flexible, requires more construction material (e.g. wood or metal) and not is self-cleaning). There is sufficiently strong evidence that a ban on ETFE film/foil for greenhouses is likely to have moderate socioeconomic costs.	Only one stakeholder has responded to the request for information

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
PTFE thread sealing tape	Not applicable	Weak evidence that technically and economically feasible alternatives to replace PTFE thread sealing tape exist. Liquid/paste pipe thread is considered technically feasible alternative for permanent seals but the technical feasibility is uncertain for non-permanent seals. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF in relation to permanent seals [weak evidence] and unclear substitution potential at EiF for non-permanent seals [inconclusive evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	The magnitude of capital costs associated with substitution is unknown and liquid/paste pipe thread may only partly be an alternative. If this is the case, some R&D costs may also be expected. There is weak evidence that substitution costs are low, following the availability of alternatives and no indication pointing to significant capital costs or significant changes to operating costs.	Not applicable
Polymeric PFASs used as processing aids (PPAs) for production of non-PFAS polymers/plastics	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives to replace polymeric PFASs as processing aids for the production of thermo- and thermoset plastics in use in the building/construction sector exist. But there is weak evidence on the extent to which existing systems would need to be adapted. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Substitution costs are likely to be limited as alternatives (e.g. boron nitride and siloxanes) are available and likely of a lower cost. There is however uncertainty on whether alternatives can be considered drop-in alternatives or if reformulation or adaptations to existing systems would be needed. The economic implication for downstream users depends on whether alternatives can be considered to be drop-in alternatives. There is weak evidence that	Not applicable

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				substitution costs are low, following the availability of alternatives, evidence pointing to lower costs of alternatives and no indication pointing to significant capital costs.	
Bridge and building bearings	Not applicable	Weak evidence that technically and economically feasible alternatives are available to replace fluoropolymers (PTFE) in bridge and building bearings exist. Steel rollers are considered technical feasible but are more expensive and will likely require redesign. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EoF [weak evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	The magnitude of capital costs associated with substitution is unknown, as it is unknown if steel rollers are available as drop-in alternatives. Steel rollers are stated to be significantly more expensive by stakeholders. The economic implications for downstream users could be high, as alternatives require more space in constructions. Bridges and buildings will therefore likely have to be designed differently, which might also be associated with additional costs. If the higher costs of alternatives are passed on to downstream users, downstream users will also face consumer surplus losses. There is weak evidence that a ban of PFASs in bridge and building bearings could be associated with high socio-economic costs.	Only one stakeholder has responded to the request for information

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Windows frames (laminated with fluoropolymers)	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives to replace PVC and HPL window frames laminated with fluoropolymers (PVDF) exist. No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential at EIF [sufficiently strong evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Sufficiently strong evidence that substitution costs are likely to be limited, following the availability of alternatives. Alternatives to PVC and HPL frames include traditional materials for window frames such as wood and metal. These alternatives have a high market share. The economic implications for downstream users are expected to be limited. Window frames made of wood will likely require more maintenance, but they also have a long lifetime if maintained properly. There is sufficiently strong evidence that a ban on fluoropolymers (PVDF) for laminating PVC and HPL window frames is likely to be associated with low socioeconomic costs.	Only one stakeholder has responded to the request for information
Conclusion	A full ban of pure fluoropolymer architectural membranes with a transition period of 18 months is proposed. A full ban of ETFE film/foil for greenhouses with a transition period of 18 months is proposed. A full ban of PTFE thread sealing tape with a transition period of 18 months is proposed. A full ban of polymeric PFASs used as processing aids for production of thermo and thermosetting plastics with a transition period of 18 months is proposed. A full ban of fluoropolymers in bridge and building bearings with a transition period of 18 months is proposed. A full ban of PVC and HPL windows frames laminated with fluoropolymers with a transition period of 18 months is proposed.				

E.2.13.5.2. Non-polymeric PFASs

Table E. 148 summarises the outcomes of the assessment of costs and benefits for non-polymeric PFASs in building materials and construction products. Because the side-chain fluorinated polymers degrade to non-polymeric PFAS (PFAAs) these are included in the table below.

Table E. 148 Non-polymeric PFASs in building materials and construction products - Summary table on assessment of costs and benefits, based on a general transition period of 18 months (including PFAA-precursors).

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban					
Side-chain fluorinated polymers (PFAA-precursors) used for surface protection/sealants	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives to replace side-chain fluorinated polymers for surface protection/sealants exist. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential [sufficiently strong evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Sufficiently strong evidence that substitution costs are limited, following the availability of (though not always drop-in) alternatives. The alternatives are likely of lower costs. The economic implications for downstream users are expected to be moderate, as functional loss will lead to higher maintenance costs due to lower soil/dirt repellence which can be relevant for some applications. There is sufficiently strong evidence that a ban on side-chain fluorinated polymers used for surface protection/sealants is likely to have moderate socioeconomic costs.	Not applicable

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Fluorosurfactants as wetting/levelling agents in e.g. coating, paints and adhesives	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives to replace non-polymeric PFASs (fluorosurfactants) exist. No evidence pointing to a shortage in the supply of alternatives is available to the Dossier Submitters. Conclusion: High substitution potential [sufficiently strong evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Sufficiently strong evidence that substitution costs are likely to be limited, following the availability of alternatives. The alternatives are likely of lower costs but might require higher amounts. There are no drop-in alternatives, except products (e.g. solvent based architectural paints and coatings) without fluorosurfactants that are available on the market and can be seen as alternatives for certain applications. Reformulation might be required for some uses, however the costs are to some extent likely to be absorbed by the PFHxA restriction proposal and the 3M announcement to end manufacturing and use of PFASs. Potentially some welfare losses following lower functionality, as some specific types of fluorosurfactants provide dirt/soil repellence, which is not the case for alternatives. There is sufficiently strong evidence that a ban on PFAS is likely to have low socio-economic costs in relation to fluorosurfactants as wetting/levelling agents in products such as coatings, paints, and adhesives.	Not applicable

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Non-polymeric PFASs as processing aids	Not applicable	Sufficiently strong evidence that technically and economically feasible alternatives to replace the final products (architectural membrane-like product) manufactured with a non-polymeric PFAS processing aid exist. No evidence pointing to a shortage in the supply of alternative final products is available to the Dossier Submitters. Conclusion: High substitution potential at EiF [sufficiently strong evidence]	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Sufficiently strong evidence that substitution costs are limited, following the availability of alternative final products (not produced with non-polymeric PFAS processing aids) as drop-in. Alternative final products dominate the market According to a stakeholder, alternative final products also meet building regulations (not further specified). There is sufficiently strong evidence that a ban on PFASs is likely to have low socio-economic costs in relation to processing aids for production of an architectural membrane-like product.	Not applicable

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
	Not applicable	Inconclusive evidence on whether technically and economically feasible alternatives exist for replacing non-polymeric PFAS processing aids for production of acrylic foam tape. Conflicting information - one stakeholder stated that no alternatives are available. However, later the stakeholder announced to end manufacturing and use of PFASs. Conclusion: Unclear substitution potential [inconclusive evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Not assessed due to unclear substitution potential	Not applicable
Window film manufacturing	Not applicable	Inconclusive evidence on whether technically and economically feasible alternatives exist for replacing non-polymeric PFASs (fluorosurfactants) for manufacturing of window film . Conflicting information - one stakeholder stated that no alternatives are available. However, later the stakeholder announced to end manufacturing and use of PFASs. Conclusion: Unclear substitution potential [inconclusive evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 96% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	Not assessed due to conflicting information	Not applicable
Conclusion	A full ban of side-chain fluorinated polymers used for surface protection/sealants with a transition period of 18 months is proposed. A full ban of non-polymeric PFASs (fluorosurfactants) as wetting/levelling agents in e.g. coatings, paints and adhesives with a transition period of 18 months is proposed. A full ban of non-polymeric PFASs used as processing aids with a transition period of 18 months is proposed. A full ban of non-polymeric PFASs used for window film manufacturing with a transition period of 18 months is proposed.				

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

A ban on the use of non-polymeric PFAS in the building materials/construction products are indicated to have limited consequences.

E.2.14. Lubricants

This Section addresses the use of PFASs in lubricants. Uses and volumes of PFAS-based lubricants are provided in Annex A.3.15. and emission calculations, including assumptions, are provided in Annex B.9.15.

E.2.14.1. Baseline

As described in Annex B.9.15.2. a basic source-flow model has been developed for assessing emissions from the use of PFAS-based lubricants under the baseline scenario. One key caveat here is that 38 different PFASs (both polymeric and non-polymeric) have been identified as being in use or potentially in use with the quality of data available varying significantly across all substances identified. Therefore, the approach taken did not aim to develop estimates on a substance-by-substance basis, but rather taken a grouping approach. Where availability of data varies significantly on a substance-by-substance basis a key benefit of using a grouping approach is that impacts of varying specific substance data are lessened. The trade-off of using such an approach is that it means the estimates provided will have a higher uncertainty attached to them overall. However, this approach can still provide useful data to estimate the orders of magnitude for emissions when comparing PFAS groups and different sectors. The projection of the time path of PFAS use (tonnage) and emissions under the baseline scenario considers expected growth rates for the relevant PFASs groups as shown in Table E.150.

Table E.149. Assumptions for projecting tonnage volumes and emissions for PFAS-based lubricants.

PFAS groups	Assumption (2020 – 2070)
Perfluoropolyethers (PFPEs)	A market research report by Grandview expects the demand for synthetic oils to grow by 5% annually between 2019 and 2025 (Grand View Research, 2021b). Specifically, for PFPEs a market research report by MarketResearch (2019) expects demand to grow by 4.2% annually between 2018 and 2027 driven by the aerospace, chemical sector, electronics sectors and other sectors (e.g. automotive and food sector). Industry feedback from CfE was that demand for fluorinated lubricants is expected to grow by 1 – 15% per annum in the short to medium term (next 10 years).
Polytetrafluoroethylene (PTFE)	Based on the CfE the sectors that use the highest volume of lubricants containing micro-powder PTFE are automotive, industrial and aerospace. Consumer use accounts for approximately 7%. According to the definition of synthetic polymer microparticles in the restriction proposal of synthetic polymer microparticles, micro-powder PTFEs are synthetic polymer microparticles. At the implementation of the proposed restriction (ECHA, 2020) for synthetic polymer microparticles consumer and professional uses of lubricants containing micro-powder PTFE are expected to be restricted. Uses at industrial sites are expected to be derogated ^{a)} . The projection assumes that demand for micro-powders PTFE continues to grow slightly in 2021 and 2022 (2% increase in 2021 and further 1% increase in 2022).
Other PFAS-based additives than PTFE	See text below
PFAS-based solvents used as carrier/deposition fluids	See text below
PFAS-based solvents used as cleaning agents	See text below

PFAS groups	Assumption (2020 – 2070)
before lubrication	

a) The volume of use at non-industrial sites is not known

Based on the information provided in Table E.149, for the baseline scenario of PFAS use and emissions in the lubricants sector a yearly real 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 same trends have been applied to PFAS-based solvents and additives in lieu of better data. The same trends have also been applied for PFAS-based solvents used as cleaning agents before lubrication.

Besides market trend data as discussed above, projections of PFAS use and emissions of lubricants considered feedback from industry stakeholders. 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. The potential effect of a REACH restriction on synthetic polymer microparticles on the future use of micro-powder PTFE has not been accounted for but could have a substantial impact as consumer and professional uses are likely to be banned.

The start year of the projection of tonnage and emission estimates is 2020 as presented in Table E.150.

Table E.150. Projected yearly PFAS use and emissions in the lubricants sector of the EEA between 2020 and 2070 in tonnes (mean values based on market trend data).

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	1 666	2 126	2 713	3 069	3 473	3 650	3 836	4 237	4 681
PFAS emissions	219	279	357	403	457	480	504	557	615

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during formulation and the use phase (thus not the waste stage).

In Annex B.9.15.2 emissions from PFAS-based lubricants were determined by applying standard environmental release categories to the range of tonnages (low and high) provided by stakeholders (Annex A.3.15.2). Emission estimates represent emissions during the service-life of products containing PFAS and their formulation (including manufacture of sealed articles). Table E.150 provides mean values projections of these emission estimates.

The life-cycle stage with the highest emissions is 'in-use' sealed applications (likely from maintenance, faults, leaks, etc.). However, proportionately 'in-use' open applications are far more emissive. In terms of substance groups emissions is dominated by polymeric PFASs (PFPE base oils and micro-powder PTFE) that account for approx. 80%. However, the polymeric PFASs also account for 93% of the tonnage. Proportionately PFAS-based solvents are more emissive as they account for approx. 20% of the emissions, even though, they only account for 7% of the tonnage. Emissions from the use of PFAS-based solvents is dominated by cleaning as the use of cleaning agents before the lubrication process account of the approx. 80% of the total use of PFAS-based solvents. Other lubricant additives than micro-powder PTFE account for less than 1% of the emissions and tonnages.

Based on the assumptions made about market trends for PFAS-based lubricants, emissions can be expected to increase over time. During the assessment period emissions will likely more than double.

Figure E.24 shows expected PFAS use and emissions (all PFASs) for the lubricants sector as a whole, based on available market data and assumptions on growth rates shown in Table E.149. Growth rates adopted for PFAS use were also applied to emission projections.

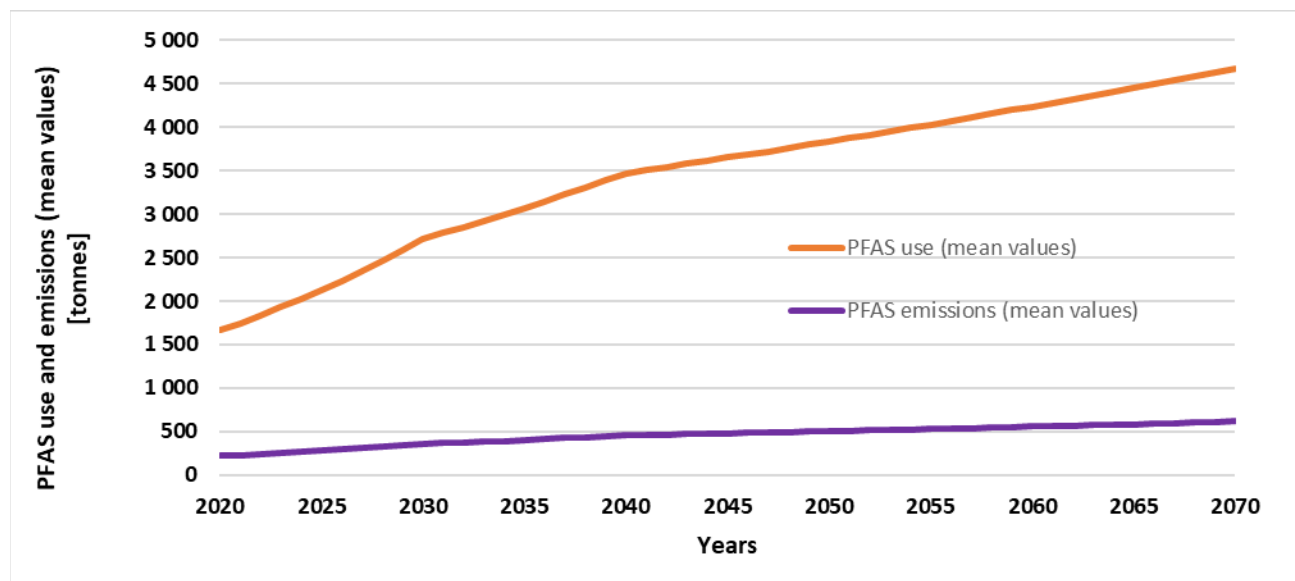


Figure E.24. Expected PFAS use and emissions in EEA under the baseline in the lubricants sector (mean values) [tonnes].

E.2.14.2. Alternatives

E.2.14.2.1. Description of the use and function of the restricted substance(s)

As described in Annex A.3.15.1 PFASs is used in lubricants as base oils in low viscosity lubricants and greases (PFPEs, PCTFE and fluorosilicone oil), and as additives (e.g. micro-powder PTFE, PFPEs and surfactants) in low viscosity lubricants, greases and solid/dry-films lubrication with release-agents being a special type of solid/dry-films lubrication. Besides the uses mentioned above, PFAS-based solvents are also used for special applications as carrier and deposition solvent in lubrication and as cleaning agents for precision cleaning before the lubrication process (not part of the lubricant).

According to stakeholders, PFAS-based lubricants are used in many sectors in situations where they are superior in terms of technical performance under extreme/harsh conditions compared to other lubricants and/or where other types of lubricants would not be technically feasible. A description of technical functions of PFAS-based lubricants is given in Annex A.3.15.1. Key functions that are often mentioned are: Temperature resilience (large temperature service range), chemical inertness and a very low coefficient of friction.

E.2.14.2.2. Availability of alternatives

The amounts/volumes of PFAS-based lubricants account for less than 1% (or even less than 0.1%) of the overall lubricants market, depending on how exactly lubricants are defined. One stakeholder in reply to the 2nd stakeholder consultation estimates that PFPE lubricants account for less than 0.015% of the total lubricant market.

Even though there is a large non-PFAS lubricant market most responses to the CfE state that no or no appropriate alternatives to PFAS-based lubricants are known or available for the

specific applications for which the PFAS-based lubricants are applied. Several stakeholders note that various alternatives have been researched and tested over the past decades, but without success. This message was generally repeated during the targeted stakeholder consultation and the 2nd stakeholder consultation.

E.2.14.2.3. Identification of potential alternative substances and techniques fulfilling the function

Alternatives to PFAS-based base oils

Some common non-PFAS lubricant base oils on the European market are:

- Crude oil: Mineral oil available in many different fractions.
- Synthetic base oils: e.g. poly- α -olefins (PAOs), silicone oils (polysiloxanes) and esters of fatty acids with alcohols (including polyols)
- Natural sources (oils, fats and waxes of vegetable or animal origin) other than crude oil

In general, stakeholders agree that it is very difficult to substitute PFPE as base oil in many applications, exemplified by the following statement from the 2nd stakeholder consultation: *"There is currently no alternative which has the same properties as PFPE such as low vapor pressure, amphiphilic, resistance against aggressive media, resistance of oxygen, not being flammable, being inert, clean in the usage of high temperature applications, very long service life time behavior and excellent low temperature properties up [down] to -80 °C and radiation resistant."*

The temperature service range for the PFPE base oils goes from approx. -80 °C to approx. 350 °C (depending on the type of PFPE). The type of non-PFAS lubricant base oils mentioned above, that come closest to this, are silicon oils with a temperature service range of approx. -70 °C to approx. 200 °C. Silicone lubricants and greases are used for some specific applications for which a temperature above 200 °C is not required. According to replies in the 2nd stakeholder consultation they are compatible with most elastomers (except silicone) but they are more affected by radiation than PFPEs and have at worst lubrication behaviour and cause more wear and tend to spread. Breakdown voltage of silicone is poor compared to PFPE formulated lubricants. Silicone oil is not considered as flammable material but can burn when it reaches a certain temperature, which is not the case of PFPE formulated lubricants. Furthermore, it is commented in the 2nd stakeholder consultation that: *"Silicone alternatives can remain on the finished articles surface and will reduce the technical performance. E.g. silicone on tire surface will reduce grip between tire and road which is relevant for road safety."*

For these reasons silicon oil is not considered a proper alternative to PFPE base oil – at least not for all applications, and especially not under harsh conditions. Long service life can also be a key property for safe functioning and safety of equipment exemplified by circuit breakers and switchgear that must work reliable when required even if not being used for years. According to the 2nd stakeholder consultation Switchgear can have a lifetime of 40+ years.

No information was received on potential alternatives to other PFAS base oils like PCTFE or fluorosilicon oils. However, the technical properties of PCTFE and fluorosilicon base oils is comparable to the technical properties of PFPE base oils (Annex A.3.15.1).

Alternatives to micro-powder PTFE as lubricant additive

As described in Annex A.3.15.1 micro-powder PTFE is used as both a friction modifier and grease thickener. Micro-powder PTFE provides one of the lowest coefficients of friction of any solid lubricant on the market. As a grease thickener micro-powder PTFE provides superior chemical inertness in harsh/extreme operating conditions that enables longer grease life in service. Many PFPE greases use PTFE as the thickener providing a grease where both base oil

and thickener have superior chemical inertness allowing the finished grease to provide long and effective service in harsh chemical environments.

Ebnesajjad S. & Morgan R (Eds.) (2019) mention that in addition to fluoropolymers such as micro-powder PTFE, the other solid additives that may typically be used in lubricants are graphite, molybdenum disulphide (MoS_2), and boron nitride (BN). For Low Viscosity Lubricants and dry-film lubrication Ebnesajjad S. & Morgan R (Eds.) (2019) highlights that a mixture of micro-powder PTFE and boron nitride performs better than micro-powder PTFE and boron nitride on their own and also better than graphite and molybdenum disulphide.

For grease clays e.g. bentonite may be used in combination with PTFE to thicken synthetic base oils such as polyalphaolefin oils, esters and PFPE oils. Silicon oil (polysiloxane) greases are commonly thickened with a mixture of amorphous fumed silica and PTFE. Molybdenum disulphide, graphite, talc and zinc oxide can also be used as grease additives (Ebnesajjad S. & Morgan R (Eds.), 2019).

The solid additives mentioned by Ebnesajjad S. & Morgan R (Eds.) (2019) was also mentioned by stakeholders in the CfE and targeted stakeholder consultation. A few other potential alternatives were identified in literature such as Black Phosphorous (BP) (Wang et al., 2018), Tungsten disulphide (WS_2), (modified) graphene (Liu et al., 2019), and silicone oil thickened with polyurea as a substitute for a PTFE-thickened silicone oil (ELKALUB, 2020).

In the questionnaire for the 2nd stakeholder consultation, stakeholders were asked if the above mentioned non-PFAS alternatives are seen as technically feasible alternatives to micro-powder PTFE in their products or processes. A summary of the stakeholder replies is given below.

- Graphite and molybdenum disulphide are used in combination with PTFE micropowders but cannot be used alone as thickeners for PFPE base oils due to incompatibility. They do not provide the same coefficient of friction that PTFE does. They are more beneficial in carrying load rather than providing low friction. Micro-powder PTFE is more chemically resistant than graphite and molybdenum disulphide and allows for clean conditions. Micro-powder PTFE has an excellent plastic/elastomer compatibility where graphite or molybdenum disulphide fail. Graphite and molybdenum disulphide is not inert or water resistant. Graphite needs water to fully activate its low friction properties and some applications may under no circumstances contain water (e.g. HVACR refrigerant circuits). Modern lubricants are formulated to function at different temperatures – commonly from -40 °C (or even lower) to 260 °C (the highest heat resistance among organic lubricants). PTFE is an important component to achieve that. Molybdenum disulphide is electrically conductive, PTFE is resistive. It is also highlighted that PTFE is suitable for incidental food contact applications whereas graphite and molybdenum disulphide are not, and that PTFE is white whereas molybdenum disulphide and graphite are black. One stakeholder state that this leads to more pollution in the production facilities.
- Boron nitrides are used in combination with PTFE micropowders but cannot be used alone as thickeners for PFPE base oils due to incompatibility. Boron nitride has a completely different lubrication behavior than PTFE. Modern lubricants are formulated to function at different temperatures – commonly from -40 °C (or even lower) to 260 °C (the highest heat resistance among organic lubricants). PTFE is an important component to achieve that. One stakeholder also states that their customers do not allow them to use boron nitride, especially the automotive industry does not allow this (not further explained).
- Other inorganics: Talc is used in combination with PTFE micropowders. Graphene, silica and zinc compounds have a completely different lubrication behavior compared to micro-powder PTFE and that for many applications in the electronic industry it is difficult to use graphene as an alternative to micro-powder PTFE because of its

hardness, which can damage the mating material, the higher dosage, and the potential for electrical effects when released due to its electrical conductivity. Silica is hard and not low in friction. Silica thickened grease can perform poorly in high shear applications. One stakeholder further state that their costumers do not allow them to use silica, especially the automotive industry does not allow this (not further explained).

- Silicone oil thickened with polyurea: The question in the questionnaire for the 2nd stakeholder consultation on the use of polyurea as a substitute for a PTFE-thickened silicone oil is related to a specific application in a progressive distributor on the central filler carousel in a brewery. This was commented on in the 2nd stakeholder consultation where one stakeholder agreed that “*polyurea is a very good option in bearing with a very high-speed application*” but that micro-powder PTFE-thickened silicone oil can do the same job and has additional applications/benefits as well. It was also stated in the 2nd stakeholder consultation that polyurea thickeners don't perform well in harsh chemical environments and can degrade at elevated temperatures meaning that the lubricant will fail or require more frequent lubrication (if possible). Further it is stated that life span of PFPE-based lubricants much longer than polyurea lubricants (up to 21 times).

In the questionnaire for the 2nd stakeholder consultation there was also a question on the use of 'water-based phenolic-melamine gold lacquer' as an alternative. However, it does not seem like this is used as a lubricant and is therefore not further discussed.

Besides answers on the specific alternatives mentioned in the questionnaire for the 2nd stakeholder consultation and summarised above, several stakeholders in general stated that the suggested alternatives don't meet requirements for their applications. In fact, only two stakeholders replied that they considered the alternatives to be technically feasible, one NGO and one downstream user in the food industry (without mentioning specific application). The other nine stakeholders that specifically mentioned food industry in their answers generally did not see the alternatives as technically feasible for their applications.

The replies to the 2nd stakeholder consultation refer to the use of micro-powder PTFE in many different sectors such as food industry, transportation (including aerospace and aircrafts), energy sector, electronics industry, chemical industry etc. (see also Annex A.3.15.1). In most replies stakeholders refer to uses under harsh conditions (very high or low temperatures, very high or low pressure, strong chemical conditions like strong acids/bases or corrosive chemicals, oxidizing or reducing substances, radiation etc.) and safety such as chemical contamination of food, pharma and medical products.

Some uses of micro-powder PTFE do, though, not take place under harsh conditions or for safe functioning and safety of quipment – exemplified by dry-film lubrication of bike chains and lubrication of door hinges and noise reduction in automotive.

Lubrication of bikes chains is not mentioned in the 2nd stakeholder consultation. However, in the targeted stakeholder consultation, this lubricant use was not considered important by stakeholders. Furthermore, Glüge et al. (2022) states for bicycle lubricants that: “*There are lubricants on the market that do not contain PTFE and perform well according to tests and user experiences*”.

For lubrication of door hinges and for noise reduction in automotives no information was received in the 2nd stakeholder consultation on the applicability of graphite, molybdenum disulphide, boron nitride etc. There are other lubricants on the market than PTFE-based lubricants that can be used for door hinges in automotives such as lithium grease (e.g. WD-40® Specialist® High Performance White Lithium Grease) or silicone (e.g. WD-40® Specialist® High Performance Silicone Lubricant). An alternative marketed for (among other things) reduction of friction and noise in automotive components is tungsten disulphide (WS₂) (2020 © Micro Surface Corp) is also available. It can't be excluded that these alternatives

require re-lubrication.

The availability of alternatives to micro-powder PTFE for lubrication of door hinges and for noise reduction in automotives suggests that there are alternatives on the market applied under conditions that is not considered to be harsh or for safe functioning and safety of equipment. However, it is uncertain if alternatives are available for all these types of applications, as only a limited number of these application has been identified (Table A.58 in Annex A.3.15.1).

It should be noted that non-industrial uses of micro-powder PTFE will likely be targeted by the restriction proposal on microplastics, as RAC and SEAC in their opinion on an Annex XV dossier proposing restrictions on intentionally added microplastics (ECHA, 2020) proposes only a derogation on the use of microplastics at industrial sites. It is specifically mentioned in the opinion that: "*SEAC considers that insufficient information was provided to assess the need to derogate lubricants*". If the EU commission follows this opinion, it will be the driver for substituting the use of micro-powder PTFE in lubricants in non-industrial uses.

Alternatives to PFAS-based solvents and additives (other than micro-powder PTFE)

As described in Annex A.3.15.1 PFAS-based lubricant additives other than micro-powder PTFE can be both polymeric PFASs and non-polymeric PFASs. Functionalised PFPEs is used e.g. as corrosion inhibitors for oils and grease based on PFPE base oils (used under harsh conditions) and as lubricants for magnetic media, where high thermal stability is required. Only four of the substances identified as being in use or used at some point in lubricant applications in Annex A.3.15.1 was non-polymeric PFASs. There is limited information on their exact uses, but they all seem to be intended for use at high temperatures.

PFAS-additives are the only additives that is compatible with PFPE base oils. In the targeted stakeholder consultation, stakeholders commented that: *Fluorinated additives act as strong adsorbing agents for PFPE/PTFE and therefore reduce leakage of PFPE/PTFE into the environment. As long as PFPE-based lubes have to be used, the function of the fluorinated additives -they are polymers- cannot be substituted.*" In the 2nd stakeholder it was repeated that PFAS-additives cannot be substituted. Given the available information the Dossier Submitters assume that this statement means that they cannot be substituted under harsh conditions. No further information on additives was identified.

In relation to the use of PFAS-based solvents/functional fluids (referred to as fluorinated solvents in Annex E.2.8) as carrier and deposition solvent in lubrication, it was stated in the targeted stakeholder consultation that: *"Fluorinated solvents cannot be substituted as long as PFPE/PTFE is to be dissolved for minimum quantity lubrication"*. This message was repeated in the 2nd stakeholder consultation where one stakeholder added that the solvent that comes closest to the PFAS-based solvents in terms of technical feasibility is the chlorinated and brominated solvent: trichloroethylene, tetrachloroethylene, dichloromethane, and N-propyl bromide. These substances all have a harmonised classification under CLP as CMR and can therefore not be seen as safe and feasible alternatives. The same goes for benzene, D4 and hexane mentioned by another stakeholder in a reply to the 2nd stakeholder consultation. The same stakeholder also mentioned trans-1,2-dichloroethylene, isopropyl alcohol and heptane as carrier solvents. trans-1,2-dichloroethylene seems only to be used in combination with PFASs (hydrofluoroethers) (3M, 2021). According to Ebnesajjad S. & Morgan R (Eds.) (2019) solid/dry-film lubricants can contain e.g. water, low-MW hydrocarbons, or a polar organic compound such as isopropanol or acetone as carrier solvent for easy evaporation. These solvents cannot dissolve PFPEs.

In the present assessment no alternatives to PFAS-based solvents as carrier and deposition solvents have been identified that can be used in combination with PFPE base oils.

E.2.14.2.4. Risk reduction, technical and economic feasibility of alternatives

Technical feasibility of alternatives

See previous section.

Economic feasibility of alternatives

PFAS based lubricants, in general

In response to the 2nd stakeholder consultation one stakeholder noted how PFAS-based grease only is selected when there are no alternatives, due to the high cost. The costs have also been commented upon by a lubricant producer during the targeted stakeholder consultation, who underlined the price difference between respectively PFAS-based and non-PFAS-based lubricants with the comment: "*Fluorinated lubricants may cost the end-user 300-600 \$/kg. Non-fluorinated lubricants have a purchase price of perhaps 15-40 \$/kg and a little higher if one moves into a basic silicone grease.*"

PFPE base oils

It has not been possible to perform any quantitative estimates on comparative unit costs between PFPE base oils and alternatives.

Stakeholders argue how the use of PFAS-based lubricants is of higher price than when applying traditional lubricants, which leads to a natural substitution when possible; this has however been challenged by Rudnick (2020). Rudnick (2020) finds the many benefits of PFPE based oils and greases makes these lubricants the most cost-efficient solution, despite the initial price being higher. As the lubricants based on PFPE base oils have a longer lifetime and increased load-carrying capability, the equipment where it is applied is likely to have a longer lifetime whereby costs are reduced. Additionally, these lubricants have a lower need for re-lubrication, which decrease the labour costs. By regenerating the PFPE base oils, manufactures are moreover able to reuse oils at low costs. Hereby, the total cost of lubrication is not considered, when arguing alternatives are cheaper, why the oils and greases based on PFPE base oils can be used for general-purpose lubrication. Grechin et al. (2018) has also commented on the total costs and how less re-lubrication, when using PFAS-based lubricants, can lead to lowered operation/maintenance costs. This is however only relevant when there are technically available alternatives which just need more re-lubrication.

Micro-powder PTFE as lubricant additive

In respect to micro-powder PTFE alternatives one stakeholder stated in the 2nd stakeholder consultation how non-PFAS materials are either more expensive or at least not cheaper than PFAS solutions. This was supported by two other stakeholders, who commented on how the alternatives boron nitride and graphene are of higher cost than PTFE, and additionally show reduced performance. More specifically the stakeholder noted how the costs are 2 to 3 times higher when applying the alternatives instead of micro-powder PTFE, while requiring the same dosage rates. It was moreover noted how the alternatives will require to be tailored to the relevant applications.

According to data presented by Ebnesajjad S. & Morgan R (Eds.) (2019) the alternative graphite is of lower cost than micro-powder PTFE, while molybdenum disulphide and boron nitride are of higher costs.

PFAS-based solvents and additives (other than micro-powder PTFE)

Stakeholders **have commented that there are no technical nor economic alternatives.** According to one stakeholder, the PFAS-based solvents can cost up to 10 times more than non-fluorine containing materials. Therefore, the PFAS-based solvents are only applied when

their properties cannot be met by other materials. To replace the costs related to research, development, testing, qualifications, and changes of processes are to be expected. These costs are, according to the stakeholder, likely to be passed on to downstream users.

Stakeholder input on transition periods

As described in Annex A.3.15.1 PFAS-based lubricants are used in many different sectors. Almost all the described uses are under harsh conditions, which means that uses in many cases are related to safety. For all these different sectors there are different legislation and/or standards. In reply to the 2nd stakeholder consultation, the following was mentioned: Food industry approval (including lubricant that allows for incidental contact with food), drinking water approval, gas contact approval, approval for oxygen contact, Medical Device Regulation, in Vitro Diagnostics Regulation, Low Voltage Directive, Machinery Directive, Pressure Equipment Directive etc. According to stakeholders' approval can take up to 5 years depending on application.

According to stakeholders the critical point is to develop alternatives. This will take at least 10 years if at all possible PFPE base oils.

Concluding remarks

PFAS-based lubricants are superior in terms of technical performance under harsh conditions (very high or low temperatures, very high or low pressure, strong chemical conditions like strong acids/bases or corrosive chemicals, oxidizing or reducing substances, radiation etc.) compared to other lubricants and/or where other types of lubricants would not be technically feasible. Further, they are also used for safe functioning and safety in e.g. circuit breakers and switchgear (long lifetime) and according to stakeholders also in food industry (avoid chemical contamination due to inertness). No alternatives to the use of PFAS base oils and micro-powder PTFE under harsh conditions or for safe functioning and safety of equipment have been identified. As PFAS-additives (other than micro-powder PTFE) and PFAS-based solvents are the only additives and solvents that are compatible with PFAS-base oils, they must follow the PFAS base oils in terms of a ban or derogation. The Dossier Submitters, therefore, conclude based on information from CfE, literature review and stakeholder consultations, that the evidence is sufficiently strong that technically feasible and economically feasible alternatives are unavailable for the quantities required for use in lubricants under harsh conditions or for safe functioning and safety of equipment and that the substitution potential is low.

For PFAS-based lubricants used under other conditions there is an indication that alternatives are available. This is exemplified for the use of micro-powder PTFE for lubrication of dry-film lubrication of bike chains and lubrication of door hinges and noise reduction in automotive. However, it is unclear to the Dossier Submitters, if alternatives are available for all uses PFAS-based lubricants not applied under harsh conditions or for safe functioning and safety of equipment.

Cleaning agents for precision cleaning before the lubrication process, is covered in the assessment of industrial cleaners in Annex E.2.8 (Application of fluorinated gases).

E.2.14.2.5. Human health and environmental hazards

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log K_{ow}) and bioconcentration factor (BCF) were assessed. Additionally, it was assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHA's dissemination site.

In relation to lubricants, the list of alternatives contained 20 unique CAS numbers. Fourteen (14) of the substances with unique CAS were classified according to CLP (harmonised

classification or self-classification). Of these seven substances, as also mentioned in Annex E.2.14.2 has a harmonised classification as CMR. One of the substances with unique CAS number (Octamethylcyclotetrasiloxane (D4)) do, according to the registration dossier, fulfil the PBT or vPvB criteria. For the other substances with unique CAS number, the PBT or vPvB criteria were not fulfilled or were not applicable. Silicon oil may contain D4, D5, and/or D6 as residues. It is noted in ECHA (2019) that under certain conditions (high temperatures, presence of certain types of fillers), silicone polymers can break down resulting in low concentration of D4, D5 and D6 within the polymer matrix. D4, D5 and D6 have been identified by ECHA's Member State Committee as SVHC substances with PBT/vPvB properties (ECHA, 2019).

The list contained additional substance with a common name for which no CAS numbers were available. For this substance, no information on classification or PBT and vPvB assessments were available. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.14.3. Environmental impact

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.14.1, assuming baseline and, consequently, on-going use of PFAS-based lubricants and emissions. The analysis of environmental impacts focuses on two restriction options:

- **RO1**, adopting a ban of all PFASs used in the lubricants sector;
- **RO2**, adopting a ban on PFASs in combination with use-specific derogations. Regarding the duration of the derogations two variants are distinguished, i.e. a 5-year derogation and a 12-year derogation, both preceded by a transition period of 18 months.

Environmental impacts of RO1 are analysed quantitatively. Likewise for the use-specific derogations emission are available, though not in the same way for all PFAS groups affected by the derogation. There is, however, information available about maximum additional emissions assuming a full derogation of the relevant PFAS groups. Note that this reference scenario does not represent a restriction option but is used for comparative purposes only. Table E.151 below summarizes the characteristics of the restriction options, and the maximum additional emissions scenario.

Table E.151. Characteristics of restriction options and of maximum additional emissions scenarios.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---
RO2	Ban with use-specific derogations	Proposed derogation: Lubricants where the use takes place under harsh conditions or use is for safe functioning and safety of equipment– 12 years	18 months	12 years
Maximum additional emission scenarios	Ban with full derogation of entire PFAS groups	PFAAs incl. PFAA precursors; polymeric PFAS, PFPEs, fluorinated gases	18 months	12 years

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, restriction

options are expected to be implemented in 2027. All emission estimates represent mean values. Table E.152 shows mean emissions and the expected mean emission reduction for a time path of 30 and 45 years (starting in 2025) for RO1 as well as for the maximum additional emission scenarios.

Table E.152. Total mean emissions and emission reduction of RO1 and maximum additional emission scenarios (lubricants sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	20 698	---	---
RO1	884	19815	96
Maximum additional emission scenario '12-year derogation of all fluoropolymers'	2 349	18 349	89
Maximum additional emission scenario '12-year derogation of all PFPEs'	1 833	18 865	91
Maximum additional emission scenario '12-year derogation of all PFAAs incl. PFAA precursors'	890	19 809	96
Maximum additional emission scenario '12-year derogation of all fluorinated gases'	1 808	18 890	91
Maximum additional emission scenario '12-year derogation of all fluoropolymers, PFPEs, PFAAs incl. precursors, and fluorinated gases'	6 088	14 610	70
2025-2070			
Baseline	33 990	---	---
RO1	884	33 107	97
Maximum additional emission scenario '12-year derogation of all fluoropolymers'	2 349	31 641	97
Maximum additional emission scenario '12-year derogation of all PFPEs'	1 833	32 157	94
Maximum additional emission scenario '12-year derogation of all PFAAs incl. PFAA precursors'	890	33 101	97
Maximum additional emission scenario '12-year derogation of all fluorinated gases'	1 808	32 182	95
Maximum additional emission scenario '12-year derogation of all fluoropolymers, PFAAs incl. precursors, and fluorinated gases'	6 088	27 902	82

* Maximum additional emission scenarios denote worst-case emission scenarios (assuming a full derogation of a particular PFAS group) against which emissions of proposed use-specific derogations are evaluated qualitatively. They do not represent restriction options. Source: Own calculations based on emission calculations (Annex B.9.15.2) and estimated market trend data collated by the Dossier Submitters.

As illustrated in Table E.152, a full ban (RO1) on PFAS-based lubricants leads to a mean

emission reduction of about 96% compared to the baseline scenario, depending on the length of the timeline. A generic derogation of fluoropolymers and PFPEs leads to higher emissions and reduces the effectiveness of the restriction. Environmental impacts of RO2 are discussed below for the proposed derogation.

- (i) Proposed derogation: Lubricants where the use takes place under harsh conditions or use is for safe functioning and safety of equipment

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 about 96% of fluoropolymer emissions. There is, therefore, sufficiently strong evidence that the proposed derogation will cause substantial additional emissions. Assuming that the derogation causes all emissions from PFPEs, PFAAs and their precursors, and fluorinated gases, and 90% of fluoropolymer emissions to continue for 12 years, additional mean emissions can be expected to be about 5 249 t, which is close to the maximum additional emission scenario (= 6 088 t). As a result of the derogation, the effectiveness of the restriction is expected to decrease to 70%.

Figure E.25 shows the time path of mean emissions from the use of PFAS-based lubricants under the baseline, RO1 and maximum additional emission scenarios.

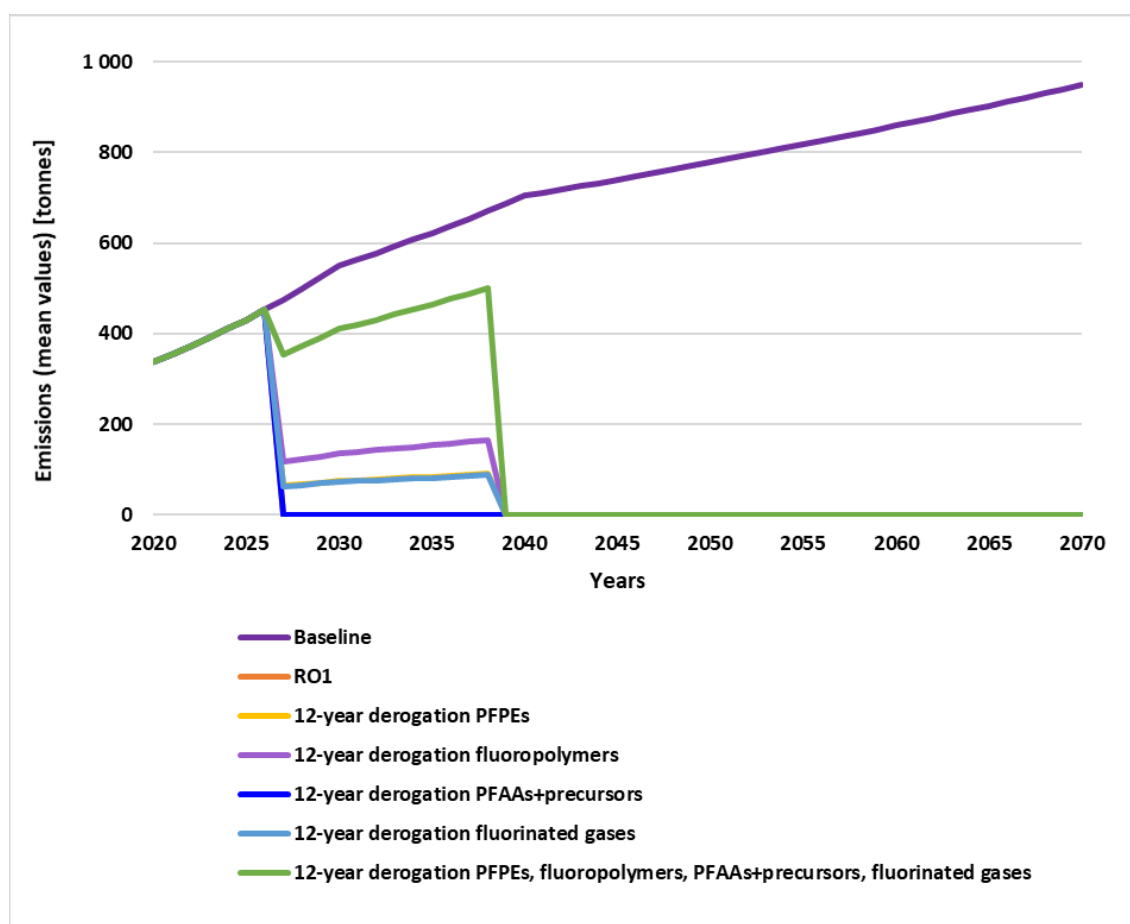


Figure E.25. Time path of mean emissions from the use of PFAS-based lubricants under the baseline, RO1 and maximum additional emission scenarios [tonnes].

Source: Own calculations based on emission calculations (Annex B.9.15.2) and estimated market trend data collated by the Dossier Submitters.

E.2.14.4. Economic and other impacts

Lubricants are used in many products and applications, within a broad range of sectors and industries and throughout various supply chains. Less than 1% (some say <0.1%) of all lubricants on the EU market are PFAS-based. No safe alternatives to the use of PFAS-based lubricants under harsh conditions or for safe functioning and safety of equipment has been identified. Therefore, according to industry, substitution of the PFAS-based lubricants has not been considered up until now. Industry expects that a ban of PFAS-based lubricants will have large impacts on substitution costs, technical and transitional cost related to development and implementation of alternatives, and costs related to functionality loss. These impacts will not just be inflicted on the lubricant industry, but also the downstream users of lubricants – and hence the products and sectors where the PFAS-based lubricants are applied.

Despite the broad use of lubricants, it has not been possible to identify any information in literature associated to potential costs related to the substitution of PFASs within this industry. To assess some of the effects of a restriction, information has instead been collected through CfE, targeted stakeholder consultation and 2nd stakeholder consultation.

In the CfE and stakeholder consultations it was recognised that the industry has not performed any in-depth assessment of the consequences and impacts following a restriction on PFAS-based lubricants. According to industry such an assessment will require substantial effort and time, following the complexity of the many affected downstream sectors and uses. The many complex and individual productions and uses of PFAS-based lubricants, means that it will not just be challenging to assess economic impacts, but that it also will be difficult to perform substitution and transition to alternatives.

E.2.14.4.1. Substituting PFAS-based lubricants

PFAS-based lubricants have many properties, especially under harsh conditions, and developing and implementing new types of lubricants with the same high level of performance is generally challenging as there are few or no relevant alternatives available -this is especially the case for PFAS base oils, though there are some exceptions. For (some) applications of micro-powder PTFE under non-harsh conditions and where safe functioning and safety of equipment is not an issue, there are alternatives available. This is for example the case for dry-film lubrication of bike chains, lubrication of door hinges, and noise reduction in automotive. As alternatives for these applications may require re-lubrication, it can have an impact on downstream users. Following the absence of drop-in alternatives or alternatives with similar properties under harsh conditions or for safe function and safety of equipment, substituting PFASs in lubricants will take a long time, which is estimated to take at least 10 years by stakeholders. The Dossier Submitters note that the industry responses seem not to have accounted for an anticipated ban on micro-powder PTFE used at non-industrial sites following the expected restriction on synthetic polymer microparticles (microplastics). During the development of this restriction opinion SEAC received a derogation request for lubricant applications, however SEAC considered insufficient information was provided to assess the need to derogate lubricants (ECHA, 2020). Based on the expected ban on synthetic polymer microparticles, the Dossier Submitters consider any costs related to transitioning away from micro-powder PTFE in lubricants, for the consumer and professional markets, not to be relevant for this restriction proposal on PFASs, as the costs are likely to be absorbed by the restriction on synthetic polymer microparticles.

E.2.14.4.2. Costs related to a restriction of PFAS-based lubricants

While there currently is no known safe drop-in alternative available under harsh conditions or for safe functioning and safety of equipment, the industry expressed how a possible, future transition to alternatives is likely to be costly, take time and not necessarily be safer, additionally, approval for use might (for some sectors) also be a lengthy and costly process.

Despite the lack of data, stakeholders agree on how the costs of a ban will be very high, and the impacts likely to be passed on to downstream sectors using the PFAS-based lubricants. It is expected that these users will have to develop new technologies or discontinue their operations following a restriction.

Based on the CfE and targeted stakeholder consultations it was possible to define the following expected economic costs of substitution:

- R&D and reformulation costs
 - Search for and development and testing of alternatives
 - Reformulation and industrialisation of alternatives in lubricants
 - Regulatory approval or certification costs
- Substitution costs
 - Raw material costs (i.e. price difference with PFASs and differences in volumes needed)
- Costs incurred by downstream users
 - Changes in equipment/machinery/installations
 - Training of personnel
 - Occupational safety measures (?)

E.2.14.4.3. Substitution costs

Among the anticipated substitution costs were the costs of higher quantities of alternatives compared to the current amounts of applied PFAS-based lubricants. Despite not having much information on the price (differences), higher volumes of alternative substances might indicate higher costs in general. Some stakeholders have estimated these costs could range between €50 000 to €5 million, but without any reasoning for the estimates. One stakeholder supported this with the example on how 15-25 times higher quantities of lubricant are needed when using a premium quality ester-based lubricant as a substitution for the PFPE-based ones. It was also suggested how there in some environments might be a need for more often reapplication of the lubricants, when using alternatives for PFAS-based lubricants.

With respect to alternative technologies (without further specification) possible costs were estimated as follows: €50 000 to €200 000 per industrial application, €200 000- €500 000 per automotive application, €500 000 to €1 000 000 per aerospace application.

The total substitution costs for an average project duration of 3-5 years per product were estimated to range between €500 000-€1 000 000 per product. At least 3 raw materials would be affected for this particular stakeholder, so the costs for them would be in the order of €1.5-3 million. The estimated substitution costs are presented in the Table E.153 below.

Table E.153. Substitution costs as estimated by stakeholders.

Substitution costs type		Estimated costs
Costs of higher substance quantities		€50 000 to €5 million
Alternative technologies	Per industrial application	€50 000 to €200 000
	Per automotive application	€200 000 to €500 000
	Per aerospace application	€500 000 to €1 000 000
Total substitution cost, for an average project (3-5 years) per product		€500 000 to €1 000 000

With respect to the development of new alternatives, stakeholders from various sectors

suggested to need at least a 10-year period to develop and qualify new alternatives.

E.2.14.4.4. Other costs

According to some stakeholder input, reformulation costs (i.e., costs covering the effort to change the chemical formulation of products when PFASs is replaced with an alternative in that product) could range between some €50 000 and €3 million per lubricant formulation and/or per application. It was, however, also emphasized that it is not possible to put a specific estimate on these costs, as there are no relevant alternatives available.

A possible reformulation is likely to impact the design of downstream uses and productions, which creates ground for a requirement of a long transition period, which is likely to be costly in terms of time as well as R&D, laboratory and field tests, screening, implementation, etc.

E.2.14.4.5. Functionality loss

PFAS-based lubricants are used in many downstream products, installations, and applications within a broad range of sectors/industries such as the food industry, transportation (including aerospace and aircrafts), energy sector, electronics industry, chemical industry etc. Some of the uses require high levels of security, safety and certainty, which the PFAS-based lubricants deliver, with their many properties such as long service life, non-flammability, stability under low and high temperature as well as pressure, resistance to radiation, and chemical resistance etc. As no safe alternatives have been identified to the use of PFAS-based lubricants under harsh conditions or for safe functioning and safety of equipment, alternatives used under these conditions are likely to induce functionality losses. As these losses would fall within many categories, they are difficult to estimate and might, according to stakeholders, have unforeseeable effects.

Table E.154 below summarizes an overview of the economic impacts of a ban on PFASs in the lubricants sector. From the supplied data it appears that the impacts of a ban can be expected to be substantial and affect many more sectors and industries than the lubricants sector alone.

Table E.154. Economic impacts related to a ban of PFASs in lubricants.

Substitution costs	Transitional costs	Loss of functionality
There are currently no “drop in” alternatives available for PFAS-based lubricants used under harsh conditions or for safe functioning and safety of equipment. The industry stakeholders estimated the costs of a ban of PFAS-based lubricants under harsh conditions or where safe functioning and safety of equipment is an issue, to reach at least €50 000 per industrial application, and between a million to several billion euros for each of their individual companies, as a restriction would require complete industry restructuring and alternative development.	Developing, substituting and applying alternative lubricants to be used under harsh conditions or for safe functioning and safety of equipment may require several years of transition time and induce substantial costs for both the production industry as well as downstream users. As there are many complex supply chain structures and downstream users of PFAS-based lubricants it is important to pay attention to elements like safety measures, quality assurance, reliability, and hazard, to assure the functionality of the products where lubricants are applied.	PFAS-based lubricants have a broad range of properties. These includes, but are not limited to long service life, non-flammability, stability under low and high temperature, stability under low and high pressure, resistance to radiation, and chemical resistance. For applications where (some of) these properties are required, no safe alternatives have been identified and substitution to the currently available alternatives will likely induce some functionality losses, which are important to consider when summarizing the costs.
As no specific or justified costs calculations are available, it has not been possible to perform a cost calculation or comparison.	It has not been possible to make specific estimates on the transitional costs and possible lower levels of performance, which the affected unknown number of end-users and industries might	For uses of PFAS-based lubricants under non-harsh conditions and where safe functioning and safety of is not an issue, alternatives might for some uses have a shorter lifetime, which will require more
For uses of PFAS-based lubricants		

ANNEX XV RESTRICTION REPORT – Per- and polyfluoroalkyl substances (PFASs)

Substitution costs	Transitional costs	Loss of functionality
under non-harsh conditions and where safe functioning and safety is not an issue, alternatives have been identified for some uses. It is unclear to the Dossier Submitters if alternatives are available for all these uses. Due to missing information, it has not been possible to perform a cost calculation or comparison of these alternatives	face, due to insufficient information. For uses of PFAS-based lubricants under non-harsh conditions and where safe functioning and safety of is not an issue, drop-in alternatives have been identified for some uses. It has not been possible to estimate the related cost.	frequent re-lubrication.

As PFAS-based lubricants are applied to many products within many sectors, where various properties are required, it is complex to define and distinguish feasible alternatives. For many uses functioning lubricants are important in terms of performance and safety, why costs related to e.g. research and development, quality checks, reliability and hazard tests are important to be aware of, in addition to the substitution costs covering alternatives development. Potential functionality loss is also important to pay attention to, as lubricants with decreased functions might have extended effects to an unknown number of products.

Because of the complexity of the use of PFAS-based lubricants, it has not been possible to identify generally technically feasible alternatives to be used under harsh conditions or for safe functioning and safety of equipment. Consequently, a broad restriction on the use of PFAS-based lubricants is likely to affect various businesses in terms of production challenges as well potential ceasing. Due to the wide-ranging use of lubricants it is difficult to assess the number of affected users, and how these are to be influenced. The identified costs information is therefore insufficient in several respects, but it is expected that downstream sectors and users would suffer from the economic impacts of a restriction.

E.2.14.4.6. Potential effects on employment

The Dossier Submitters have no information on how a ban on PFAS use in lubricants would affect unemployment in the lubricants sector. Effects on downstream users of lubricants is expected to be insignificant.

E.2.14.5. Summary of cost and benefit assessment

Table E.155 summarises the assessment of the costs and benefits for PFAS-containing lubricants. More detailed information can be found in the accompanying text following the table.

Table E.155. PFASs in lubricants – Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban		Sufficiently strong evidence that technically and economically feasible alternatives are unavailable for the uses of PFAS-based lubricants under harsh conditions or for safe functioning and safety of equipment There is inconclusive evidence on the existence of technically and economically feasible alternatives for PFAS-based lubricants which are not applied under harsh conditions or for safe functioning and safety of equipment. For some uses they are available, but probably not for all. Low substitution potential at EiF for lubricants applied under harsh conditions or for safety functioning [sufficiently strong evidence]. Unclear substitution potential at EiF for lubricants not applied under harsh conditions or for safe functioning or safety of equipment [inconclusive evidence].	Sufficiently strong information that RO1 leads to a reduction of emissions of about 93% (30-year period). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	A full ban on PFAS-based lubricants is likely to have high socioeconomic costs, due to the non-existence of alternatives. Costs related to functionality loss, e.g. performance level and lifetime, are expected to affect an unknown number of industries and end-users, as economic impacts are likely to be passed on to downstream users. There is however not sufficient data to make a cost estimate. Economic impacts are likely to be passed on to downstream users. Product reformulation costs are estimated within a range of tens of thousands and several million Euros, but it has not been possible to make more specific estimates. Reformulation is, however, unlikely within the given timeframe. No evidence on the effects on employment losses, but these are expected to be insignificant.	The basis of the cost impacts is based on information provided by stakeholders.
Ban with use-specific derogations	5 years	Technically feasible alternatives used under harsh conditions or for safe functioning and safety of equipment are likely not available within 5 years; the substitution potential is low.		Following the presumed unavailability of alternatives, the cost impacts will be similar to the ones mentioned under "full ban" above.	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
	12 years	The substitution potential is unknown and depends on the development within the sector. However, with a transition period of 18 months and a 12-year derogation the extended time will enable room for further research and development to identify alternatives, for relevant uses under harsh conditions and/or for safe functioning and safety of equipment.	There is sufficiently strong evidence that the proposed derogation will cause substantial additional emissions. Assuming that the derogation causes all emissions from PFPEs, PFAAs and their precursors, and fluorinated gases, and 90% of fluoropolymer emissions to continue for 12 years, additional mean emissions can be expected to be about 5 249 t, which is close to the maximum additional emission scenario (= 6 088 t) . As a result of the derogation, the effectiveness of the restriction is expected to decrease to 70%.	If technically and economically feasible alternatives are identified within the 12-year period, functionality losses identified under RO1 are likely avoided, while substitution and reformulations costs will remain, but be spread out over several years.	
Conclusion	A full ban of PFAS-based lubricants with a transition period of 12 years for uses under harsh conditions or for safe functioning and safety of equipment is proposed, preceded by a transition period of 18 months.				

According to industry stakeholders a ban of PFASs in lubricants would have significant effects on the economy. In the information submitted by stakeholders, it is noted how there are no drop-in alternatives under harsh conditions or for safe functioning and safety of equipment, and therefore product reformulation is needed for an extensive number of uses. The product reformulations will not only result in impacts directly related to the development and implementation of the new products, but also impacts related to elements such as quality assurance and safety measures. It is also noted how there are additional potential costs related to product functionality losses resulting in elements such as shorter lifetime, potential functional downtime, increased frequency and maintenance uses.

These impacts and challenges would mainly be passed on to downstream sectors where impacts could be 100 – 1 000 times more costly than for the lubricant sector itself, if access to PFAS-based lubricants or parts with these lubricants are no longer available. Many downstream sectors would be at risk of significantly reducing efficiency, productivity, competitiveness, and perhaps even have to discontinue their operations. The effects would be seen among many industries including automotive, aviation, medical, chemical, renewable energy sectors etc. For more information on these sectors and affected see section A.3.15.1.

The Dossier Submitters consider, based on evidence gathered from CfE, targeted and 2nd stakeholder consultation, that the evidence is sufficiently strong that a ban on PFAS in lubricants is likely to have high socioeconomic costs. The main uncertainty relates to the insufficient data. To some extent there are alternatives to PFAS-based lubricants for some applications, when the lubricants are not applied under conditions that are harsh or for safe functioning and safety of equipment. Stakeholders have indicated that when it is possible PFAS-free lubricants are applied already, and that PFAS-based lubricants are only used when there are no relevant alternatives. In respects to PFPE base oils and greases this statement is, however, challenged by Rudnick (2020), who find the many benefits of PFPE based oils and greases makes these lubricants the most cost-efficient solution, despite the initial price being higher. As the lubricants based on PFPE base oils have a longer lifetime and increased load-carrying capability, the equipment where it is applied is likely to have a longer lifetime whereby costs are reduced. Additionally, these lubricants have a lower need for re-lubrication, which decrease the labour costs. By regenerating the PFPE base oils, manufacturers are moreover able to reuse oils at low costs. Hereby, the total cost of lubrication is not considered, when arguing alternatives are cheaper, why the oils and greases based on PFPE base oils can be used for general-purpose lubrication. Grechin et al. (2018) has also commented on the total costs and how less re-lubrication, when using PFAS-based lubricants, can lead to lowered operation/maintenance costs. This is however only relevant when there are technically available alternatives which just need more re-lubrication.

Stakeholders have stated that a full ban without delay on the use of PFAS in lubricants is likely to have substantial consequences for the lubricants sector, and downstream users of PFAS-based lubricants relying on the specific functionalities of PFASs. The Dossier submitters find that there currently is limited information on the necessary time required for substitution of the PFAS-based lubricants; several stakeholders have, however, indicated that several years are required.

Due to the extensive consequences a full ban with an 18-month transition period would impose, a 12-year derogation, preceded by a transition period of 18 months, is instead proposed. Despite alternatives existing for some uses of lubricants, there is evidence that these alternatives are unable to live up to the required functionalities of the PFAS-based lubricants under harsh conditions or for safe functioning and safety of equipment, and therefore, the proposed derogation should only apply under these conditions. The Dossier Submitters consider that a long transition period is required to identify, assess and implement alternatives in the many applications and use sectors.

E.2.15. Petroleum and mining

E.2.15.1. Baseline

Precise growth rates for PFAS use in petroleum and mining are not known. According to a recent report (NEA, 2021a), 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) (NEA, 2021a). The start year of the projection of tonnage and emission estimates is 2020 as presented in Table E.156.

Table E.156. Projected yearly PFAS use and emissions in the petroleum and mining sector of the EEA between 2020 and 2070 in tonnes (mean values based market data).

	2020	2025	2030	2035	2040	2045	2050	2060	2070
PFAS use	5 507	5 788	6 083	6 393	6 719	7 062	7 422	8 199	9 057
PFAS emissions	2 028	2 132	2 240	2 355	2 475	2 601	2 734	3 020	3 335

Source: Own calculations by the Dossier Submitters based on market data provided.

The assessment of environmental impacts under the baseline and the restriction scenarios is conducted at sector level and covers tonnage and use estimates during manufacture and the use phase (thus not the waste stage).

For the assessment of emissions in the baseline scenario a basic source-flow model has been developed to make use of the data gathered and collated from the market analysis and substance identification. It should be noted that, while a number of specific applications and products using PFAS or fluoropolymer have been identified in the petroleum and mining sector, these applications can cover a relatively large number of individual PFAS, with the quality of data available varying significantly across all substances identified. Therefore, the approach taken has not tried to develop estimates on a substance-by-substance basis, but rather taken a grouping approach. Where availability of data varies significantly on a substance-by-substance basis a key benefit of using a grouping approach is that impacts of varying specific substance data are lessened. The trade-off of using such an approach is that it means the estimates provided will have a higher uncertainty attached to them overall. However, this approach can still provide useful data to estimate the orders of magnitude for emissions when comparing PFAS groups and different sectors. The approach can be used for further refinement when better data become available.

Emission estimates for each of the three main PFAS groupings described above (tracers, anti-foaming agents, fluoropolymer) were derived using both ECHA environmental release factors (ERCs) as documented in the ECHA Guidance (ECHA, 2016) and, where available, product-specific information on PFAS use and discharge. ERCs were applied to annual volumes of use of PFAS in each product category. For a detailed overview of scenarios and assumptions we refer to the report prepared by the NEA (2021a). Figure E.26 shows expected low and high PFAS emissions between 2020 and 2070 in tonnes.

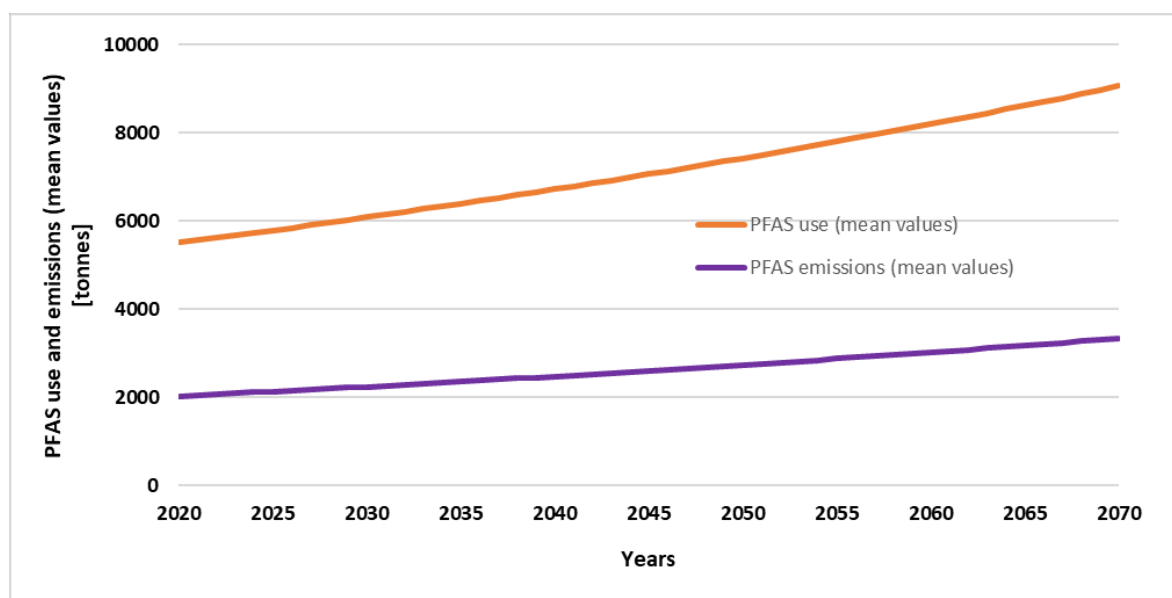


Figure E.26. Expected PFAS use and emissions in EEA under the baseline in the petroleum and mining sector (mean values) [tonnes].

Source: Own calculations based on market data collated by the Dossier Submitters (NEA, 2021a).

Based on the assumptions made about market trends for PFAS use, emissions can be expected to increase over time. Though emissions increase less than in other sectors (e.g. construction, energy) due to the assumed low market growth, the fraction of emissions to the environment arising from PFAS use is much higher. Fluoropolymers (used in pipelines, seals, gaskets valves and o-rings) account for the by far largest share of total emissions in this sector.

E.2.15.2. Alternatives

E.2.15.2.1. Description of the use and function of the restricted substance(s)

Non-polymeric PFAS

There are two key current applications for non-polymeric PFAS in the oil and gas sector that have been identified in this assessment:

- Fluorinated siloxanes used as anti-foaming agents
- Fluorinated alkanes used as tracers in oil fields

The key properties that make these PFAS substances desirable in these applications are summarised in Table E.157 below.

Table E.157. Summary of uses and properties of non-polymeric PFAS in the oil and gas industry.

Use	Type of PFAS used	Key properties
Tracers	Perfluorinated alkanes and others	Very low limit of detectability, very low background levels ^[1]
Anti-foaming agents	Fluorinated siloxanes	High efficiency, versatile and practical for both aqueous and nonaqueous systems, compatibility for high performance applications ^[2]

[1] Based on industry input; [2] see Shaban (1995).

Fluoropolymers

The uses of fluoropolymers (fluoroplastics and fluoroelastomers) in the petroleum and mining industry and the specific properties provided by these materials that are particularly desirable for these applications is discussed in detail in Section A.3.16. A brief summary is provided in Table E.158 below.

Table E.158. Summary of uses and properties of fluoropolymer in the petroleum and mining industry.

Application	Examples	Properties
Lining of piping, flowmeters and fittings, fluid-handling components, process vessels, tanks, storage and transport containers	• Polytetrafluoroethylene (PTFE) • Perfluoralkoxy polymer (PFA) • Fluorinated ethylene propylene (FEP)	High temperature resistance High mechanical strength Chemical resistance Corrosion resistance Inertness Non-adhesive/low friction resistance Low permeation Flexibility/ductility Light weight Non-flammable
Seals, liners, valves, O-rings, gaskets, packer elements.	• Fluoroelastomer (FKM)	High temperature resistance Rapid gas decompression resistance Resistance to compression fluids
Cable and wiring insulation	• Perfluoralkoxy polymer (PFA) • polyvinylidene fluoride (PVDF) • Fluorinated ethylene propylene (FEP) • Ethylene tetrafluoro-ethylene (ETFE)	High temperature resistance Flexibility/ductility

E.2.15.2.2. Availability of alternatives

All alternatives considered below have been identified because they are products that are currently marketed and sold in Europe, and consultation with industry and national authorities suggest they are in use in significant volumes. Very limited specific quantitative data on the relative levels of production, sales or use of alternatives have been provided in this assessment, however.

E.2.15.2.3. Identification of potential alternative substances and techniques fulfilling the function

Non-polymeric PFAS

Tracers

For 'injected gas' tracers such as the perfluorinated alkane tracers identified in this assessment, a number of alternative options have been identified (Bjørnstad, 1991). These include:

- Isotopic radioactive/radiolabelled tracers, e.g. inorganic gases (xenon, krypton) and other ($d^{13}C$, $d^{18}O$) labelled tracers¹¹⁶.
- Polyhalogenated hydrocarbons (e.g. freon-11, and -12).
- Fluorinated benzoic acids¹¹⁷.

Both halogenated and radioactive tracers could possibly be used in the oil and gas industry in Europe (IAEA, 2003). Radioisotopes have been used to study the in-situ placement and flow of various subsurface processes in the oil and gas sector for many decades (Abernathy et al., 1994). The tracers emit gamma radiation capable of penetrating the casing and being detected by wireline conveyed instruments, and offer cost-effective means of determining the location and placement of many types of treatments and procedures frequently performed on wells. The most common types of gamma emitters used in oil and gas tracer are, for example, ^{46}Sc , ^{140}La , ^{56}Mn , ^{24}Na , ^{124}Sb , ^{192}Ir , ^{99m}Tc , ^{131}I , ^{110m}Ag , ^{41}Ar and ^{133}Xe ¹¹⁸. In addition to other halogenated substances, industry has also mentioned noble gas isotopic tracer, xenon, radioactive tracers, and radiolabelled compounds ($d^{13}C$, $d^{18}O$) as alternatives.

It is noted that a number of fluorinated benzoic acids (FBAs) identified as being used as tracers in this sector do not meet the criteria of PFAS in this restriction proposal. FBAs are becoming increasingly favoured as stable, non-radioactive tracers, commonly being used to investigate flow dynamics in geothermal, hydrothermal and oil well applications¹¹⁹.

However, input provided by one supplier suggests FBA tracers are not considered as alternatives to fluoroalkane-based tracers, as their chemical properties are different and their specific use and application may be quite different. For example, FBAs are known to partition within the aqueous phase and are considered as water-based tracers, while the fluoroalkane tracers are highly hydrophobic and considered as gas-tracers.

Industry input has suggested loss of functionality for some applications when using alternatives, and loss of information on reservoir outflow if no tracers are used. Based on the input of one supplier in the CfE, it is expected that industry would tend towards using radio-

¹¹⁶ Identified as being in current use on the basis of input from one supplier of tracers.

¹¹⁷ Identified as being in current use on the basis of data received from national authorities, confirming these substances are actively being used and discharged in offshore oil and gas installations in Europe.

¹¹⁸ Note that 'm' signifies 'metastable', see https://www-pub.iaea.org/MTCD/publications/PDF/TCS-40_web.pdf, date of access: 2023-01-13.

¹¹⁹ See https://www.perkinelmer.com/lab-solutions/resources/docs/APP_Analysis_of_Fluorobenzoic_Acids_for_Water_Tracers_013880_01.pdf, date of access: 2023-01-13.

labelled tracers for the applications where PFAS-based tracers are currently used, in the event of a restriction on these substances.

Anti-foaming agents

One specific alternative to fluorinated silicone/siloxane products for use as anti-foaming agents has been suggested to be non-fluorinated silicone/siloxane-based products.

It is reported that poly(dimethylsiloxane) (PDMS) oils are the most common chemical foam control agents, and that fluorosilicone fluids are used in some relatively 'severe' cases to provide foam control at small dose levels (Chen et al., 2019).

It is known that a number of manufacturers are marketing various non-fluorinated silicone-based anti-foaming agents for use in the oil and gas sector¹²⁰ and it has been indicated that products containing PDMS are being used in the oil and gas industry in Europe. The level of sales and use of non-PFAS based anti-foaming agents is far greater than that of PFAS-based products.

Input from one supplier indicates that fluorinated siloxane products is a relatively niche use in this sector and may be favoured in a small number of installations because relatively small concentrations are required. It was indicated by the same supplier, that the industry considered that, if required, alternatives would be available to provide the same function.

Further industry input indicates that other alternatives include ethyl siloxanes, polypropylene glycol, naphthalene/1,2,4-trimethylbenzene based products, dipropylene glycol monomethyl ether and 2,6-dimethylheptan-4-one, and that alternatives are often less efficient and need to be used in higher quantities/concentrations, which has implications for cost and storage requirements.

Fluoropolymers

A wide variety of different fluoropolymer materials (including fluoroplastics and fluoroelastomers) have been identified as being used in the oil and gas sector, and the number of individual products/components manufactured from these materials for ongoing use in the oil and gas sector totals is in the thousands.

It has not been possible to conduct an analysis of potential alternatives for all individual uses or components produced from fluoropolymers in this assessment, and relatively limited information on specific alternative materials has been provided during this assessment (as part of the CfE and from further consultation with manufactures, suppliers and downstream user associations).

It is important to note that, most of the information on alternatives collected for this assessment has been collected from fluoropolymer manufacturers and suppliers. Limited input was received from either the downstream producers of specific products used in the petroleum and mining industry, or operators in the petroleum and mining sector using these products. Hence, the below sections should be read with caution, as limited information has been provided from downstream users.

During the consultation for this assessment, manufactures and suppliers have emphasised that, in general, it is very challenging for suppliers to replicate the combination of required properties of materials that is required by downstream users for application in the oil and gas sector using non-fluoropolymer materials. It has been noted by several suppliers, that use of fluoropolymer is generally used only when the high-performance functionality, as described

¹²⁰ <https://www.wacker.com/cms/en-us/products/brands/silfoam/silfoam.html>, date of access: 2023-01-13.

above, is required. The oil and gas sector was highlighted by the manufacturers and suppliers consulted, as an area where this high-performance functionality consistently is required, so in general this sector displays a tendency towards opting to use fluoropolymer over other alternatives, despite the overall unit costs of material often being much higher.

It is noted that, in some cases, manufacturers consulted indicated that they consider that the most viable alternative for one form of fluoropolymer in oil and gas application, is to use another type of fluoropolymer. For example, one supplier noted that the main alternative to PFA is PTFE. Since this assessment is considering a potential restriction on all types of fluoropolymers and is taking a general approach of considering all fluoropolymer use combined, this aspect is considered in the following discussion.

In general terms, the potential alternatives for fluoropolymer materials in the oil and gas sector include the following:

Steel and other metal alloys

A number of suppliers indicated that, if fluoropolymers (e.g. PTFE) in constructing pipes or the lining of pipes in the oil and gas sector were no longer available or restricted, it is expected that the oil and gas sector would most likely revert to using corrosion-resistance steel pipes as they would be the only alternative that could demonstrate a similar performance. Other corrosion-resistant alloys that do not require the additional lining of fluoropolymer have been suggested, including¹²¹:

- Copper Base alloys (with Ni, Fe, Mn)
- Nickel-based alloys (with Cu, Mo and Cr)

However, it is noted that steel is considered less favourable as the pipelines or other components are heavier, less flexible, and more carbon intensive to produce.

Non-metal materials

Other potential options considered by industry as possible alternatives to fluoropolymers in this sector include ceramic-based materials and epoxy-based systems, either using glass fibres or carbon fibres. No specific information on the types of components that could be constructed for these materials in the oil and gas sector, or a relative comparison with existing fluoropolymer material has been provided in this assessment.

Fluorine-free polymers

A number of different non-fluorinated polymers are available for use in this sector, and supplier have highlighted specific examples where they could be utilised. However, a number of manufacturers and suppliers have emphasised that these alternatives may not be able to fulfil all technical criteria required to match the performance of fluoropolymers in this sector (see further discussion in section E.2.15.4).

Examples include:

- Crosslinked polyethylene (XL PE) as a possible alternative to ETFE
- Polyamides such as ethylene propylene diene monomer (EPDM)
- Hydrogenated Nitrile Rubber (HNBR) as an alternative to fluoroelastomers

¹²¹

https://nickelinstitute.org/media/1732/nickel_containingalloy_piping_for_offshore_oil_and_gas_production_10033_.pdf, date of access: 2023-01-13.

- Polyether ether ketone (PEEK)

Nylon

Another non-fluorinated substance cited by industry in the CfE is nylon, which is reportedly used in a number of engineering applications to replace other materials such as aluminium and steel, with desirable properties such as high mechanical strength and wear resistance. However, it is not clear to what extent this material is used in the petroleum or mining sector.

E.2.15.2.4. Human health and environmental hazards

For the chemical alternatives relevant for this use sector, information on classification, the octanol/water partition coefficient (Log Kow) and bioconcentration factor (BCF) was assessed. Additionally, it was assessed whether the alternatives fulfil PBT or vPvB criteria and/or whether there are additional concerns. The assessment of the PBT/vPvB criteria is taken from the registration dossier that is published on ECHA's dissemination site.

In relation to petroleum and mining, the list of alternatives contained 33 unique CAS numbers. Twenty-three (23) of the substances with unique CAS were classified according CLP (harmonised classification or self-classification). Seven (7) of the substances with unique CAS number did, according to their registration dossier, not fulfil the PBT or vPvB criteria. For the other substances with unique CAS number, the PBT or vPvB criteria were not applicable or no data were found. For one of the substances (PDMS-based alternatives (poly(dimethylsiloxanes)), it was indicated that they may contain residues of the cyclic siloxanes D4, D5 and D6. These are considered to be PBT/vPvB substances and D4 is considered to be an endocrine disruptor.

The list contained an additional 41 substances with unique substance names for which no CAS numbers were available. For these substances, no information on classification or PBT and vPvB assessments were available. For 2 substances (silicone polymers, Nylon), it was indicated that they may contain residues of D4, D5 and D6 cyclic siloxanes. Appendix E.2. contains a table presenting this information along with further data on alternatives for the various uses assessed in this dossier.

E.2.15.2.5. Risk reduction, technical and economic feasibility of alternatives

In this section, a summary of available information on the technical, economic, and health & environmental risks of identified alternatives to the specific PFAS-containing products is presented, based on information gathered during this assessment.

Non-polymeric PFAS

Tracers

As discussed above, the principal alternatives identified for the use of PFAS-based tracers in the oil and gas industry are radioisotope-based products. While some isotopes are known to be widely used in the oil and gas industry, it is not clear, based on the input received from the supplier of tracer which specific radiolabelled products or substances are currently available for use in this application in Europe specifically as an alternative to the perfluorinated alkane products.

Technical feasibility:

It is indicated that radio-labelled tracers are a feasible alternative and have been widely used in the oil and gas industry for many years. Input from one supplier in the CfE in 2020 indicated that these are considered the likely alternative in the presence of a restriction on use of PFAS.

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Quantitative information on the comparative level of technical performance (e.g. the detection limit, chemical and thermal stability) between different tracers was not available in this assessment. It is indicated that one of the desired properties of fluoroalkane tracers is the very low levels of detection (e.g. parts per quadrillion). It is noted that, while there is some indicative values of detection limits for different types of tracers in Bjørnstad (1991), providing an accurate comparison with PFAS-based tracers is challenging as different units are used.

It is not clear to what extent radiolabelled tracers are able to match this technical performance. Difference in detectability would potentially have knock-on effects on the volume/concentration of alternative product needed.

Health and environmental risks:

An important consideration will be the potential safety aspects relating to the use of radioactive substances for this application. Use of radioactive tracers as an alternative to fluoroalkane tracer, presents a potential safety risk to workers handling these materials, and possibly the wider environment depending on the volumes used. A specific advantage highlighted by the supplier of the fluoroalkane tracer product is the non-toxic, non-radioactive properties. It has not been possible to quantify the significance of the risk posed by radio-labelled tracers, as data is lacking on the specific products used and the volumes and concentrations involved.

Economic feasibility:

No quantitative comparison has been possible. The overall costs will be dependent on required dose rate. Stakeholder information in the CfE indicates that PFAS-based tracers are used in low quantities, approximately 1 t/y, due to extremely low (parts per quadrillion) detection levels, so overall cost may ultimately be lower than alternative. It is indicated that fluoroalkane-based tracers are considered very expensive (>€600/kg) so alternatives may offer a less expensive option. Information is lacking to be able to carry out a full assessment.

It should also be noted that the use of alternative tracers could have implications on overall efficiency of extraction/production for operators, which affects economic productivity of an installation. Again, it is not possible to provide a detailed assessment of this aspect due to the overall lack of data.

There has been no information submitted in the call for evidence or in the 2nd stakeholder consultation that indicate that a restriction would lead to considerable economic impacts.

Anti-foaming agents

The principal alternatives for the use as anti-foaming agents are based on poly(dimethylsiloxane) (PDMS). Relatively limited information has been provided to perform a comprehensive comparison for an in-depth alternatives assessment.

Technical feasibility:

Stakeholder input in the CfE indicates that PDMS-based anti-foaming agent products are widely available in Europe and can perform with a comparable level of functionality in most cases, although the required dose rate is likely to be much higher.

The Dossier Submitters note that the annual quantities of PDMS-based anti-foaming agents are far higher than those of the PFAS-based agents. This is further support to the statement above that PDMS-based agents are technically feasible in most cases.

There may be specific types of installation and characteristics of crude oils where PDMS-based anti-foaming agents may be less effective than PFAS-based siloxanes. It has not been possible

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to assess how many, or what type of installations this applies to, or derive an approximation of the proportion of installations or the volume of petroleum reserves this applies to. Input from one supplier in the CfE indicated that, in the event of a restriction on PFAS-based products, it is expected that alternatives could be obtained that can perform the required function.

Health and environmental risks:

No specific risks have been identified from the use of PDMS-based alternatives compared to fluorinated siloxane products.

PDMS-based agents are approved for use in the oil and gas sector in OSPAR countries, so it is expected that registered products will be assessed for potential health and environmental risks.

It is noted in ECHA (2019) that under certain conditions (high temperatures, presence of certain types of fillers), silicone polymers can break down resulting in low concentration of D4, D5 and D6 within the polymer matrix. D4, D5 and D6 have been identified by ECHA's Member State Committee as SVHC substances with PBT/vPvB properties (ECHA, 2019).

Economic feasibility:

Stakeholder input indicates that PDMS-based alternatives are likely to be marginally less expensive than the PFAS-based products, however no quantitative comparison has been possible.

Overall quantities used will be higher as higher dose rates are required for PDMS, meaning overall costs could be higher than PFAS-based products. However, a quantitative estimate of difference in dose rates or volumes used has not been possible.

As mentioned above, the quantities of PFAS anti-foams used is relatively minor, far lower than that of PDMS-based anti-foams.

There has been no information submitted in the call for evidence or in the 2nd stakeholder consultation that indicates that a restriction would lead to considerable economic impacts.

Fluoropolymers

Technical feasibility:

It is noted that, in general, the fluoropolymer-containing components and products supplied to the oil and gas sector are made to a specific order for downstream users and operators, so the specific functionality (and by design the necessary chemical ingredients) required will be unique to individual products. Given the many hundreds or thousands of individual products likely to be provided to the oil and gas sector, this makes the assessment of technical feasibility for potential alternatives very challenging.

As discussed in earlier sections, it is clear from the information received in this assessment (in the CfE and further consultation with manufacturers and suppliers) that the petroleum and mining sector (particularly the oil and gas industry) require a very high and very specific level of performance from materials in the components/products used, for example to ensure efficiency of operations by preventing failure of components and the leakage of chemicals and/or oil. For fluoropolymers used in oil and gas industry, durability, high temperature resistance (>270 °C) and chemical resistance and high mechanical strength in harsh environments, are highlighted as being an important aspect of their technical function.

Several possible fluorine-free alternatives have been identified for fluoropolymers in some

applications (see section E.2.15.2.3). However, manufacturers and suppliers have noted concerns over different technical aspects that will impact their ability to be used for applications in the oil and gas industry. This is summarised in Table E.159 below.

Table E.159 Overview of technical considerations for alternatives to fluoropolymer in the oil and gas industry.

Material	Fluoropolymer to be replaced	Specific application(s)	Summary of technical considerations
Stainless steel and other metal alloys	PTFE and others	Pipes, other unspecified components	Can provide the required temperature, chemical and corrosion resistance performance but is heavier, less flexible and can have higher life-cycle CO ₂ emissions
PEEK	PTFE	Various	Provides comparable temperature resistance and better mechanical and tensile strength. Lower chemical resistance (e.g. to H ₂ S and other acids) PEEK also cannot be readily coloured for identification (e.g. cables).
XL PE (crosslinked polyethylene)	PTFE	Cables	Lower chemical resistance, it cannot manage temperature range needed as the maximum temperature it can handle is 150 °C for single cables.
HNBR (Hydrogenated Nitrile Rubber)	FKM	Seals, gaskets, other components	HNBR can be used in steam and oil and gas applications up to about 150 °C but may not be suitable above that temperature
EPDM (ethylene propylene diene monomer)	FKM	Seals, gaskets, other components	EPDM can only work up to 150 °C - and needs far more gasket changes and production time down

Several comparisons between the performance and costs of PEEK, compared to PTFE, have been carried out¹²². While it is considered that PEEK has excellent mechanical and chemical resistance at high temperature, and is resistant to thermal degradation as well as attack by both organic and aqueous environments, there are concerns regarding potential susceptibility to halogens, strong acids (e.g. sulphuric acid) as well as some halogenated compounds and aliphatic hydrocarbons at high temperatures.

PEEK is generally considered more 'machinable' than PTFE and can be processed by conventional methods such as injection moulding, extrusion, and compression moulding. PEEK is a much higher unit price polymer but provides value by offering the possibility of manufacturing parts that are lightweight and durable with the ability to survive longer in harsh environments.

¹²²<https://fluorocarbon.co.uk/news-and-events/post/55/ptfe-versus-peek>, date of access: 2023-01-13.

PEEK offers the possibility of manufacturing parts with several beneficial characteristics¹²³. For these reasons, PEEK is identified in a number of specific products on the market, with specific use in the oil and gas sector, such as:

- Insulated cable and wiring materials
- Heat shrinkable material for encapsulation and protection for sensitive components
- Materials for seals and backup rings, connectors, compressor components, pumps (surface and submersible), plugs and packers, composites, tubes and pipes, insulating components.

Health and environmental risks:

Several manufacturers and suppliers have emphasised that a key functional requirement of the materials used in the oil and gas installations where fluoropolymer is current favoured, is to prevent the failure of components that can lead to leakage (of either petroleum reserves or chemicals). For example, the lack of either the required resistance to temperature or chemicals has been highlighted by a number of manufacturers as being an aspect that could prevent alternatives being favoured for uses in this sector.

The use of alternative materials with potential lower levels of functional performance would have potential implications for a greater potential for leakage, which in turn has implications, both for exposure of workers to chemical, or leakage of oil or other components to the environment. There could also be a higher risk of exposure of staff to hazardous substances due to more frequent maintenance and more shutdowns.

Economic feasibility:

Quantitative estimates on comparative unit costs between fluoropolymers and fluorine-free alternatives is generally lacking in the public domain. This level of information, although requested, has not been provided by suppliers or downstream users in the CfE or further consultation with multiple companies.

For some alternatives, an indicative comparison is available. PEEK is for example indicated to cost 5- 10 times more than PTFE.

For most applications where products containing these materials are used in the oil and gas industry, manufacturers and suppliers have highlighted that fluoropolymers are typically a more expensive option (per unit) compared with most fluorine-free alternatives.

It should be emphasised that the economic implications of switching to alternatives for fluoropolymer in this sector are not limited to the differences in unit cost. Several manufacturers and suppliers have noted that, while the unit cost of most fluoropolymers is likely to be higher than other materials, downstream users still favour its use in the petroleum and mining sector as it ensures the required functionality, and overall cost saving can be made over the full working life of the product (e.g. due to avoided downtime and maintenance associated with more frequent failure and replacement of components) so consideration of alternatives need to be viewed with the potential knock-on implications for the efficiency of operations in the oil and gas sector.

Stakeholders have also claimed that use of fluorine-free components could reduce future clean-up and waste-handling costs of fluorinated polymers.

The general feedback from manufacturers and suppliers (based on CfE responses and further consultation) is that the widespread use of fluoropolymer-containing components in the oil and gas sector reflects the need for the functionality provided by fluoropolymer compared to

¹²³ <https://omnexus.specialchem.com/selection-guide/polyetheretherketone-peek-thermoplastic>, date of access: 2023-01-13.

alternatives. Where the required performance can be achieved with non-PFAS based materials, this is expected to be already being used in practice.

E.2.15.2.6. Stakeholder input on transition periods

Non-polymeric PFAS

For non-polymeric PFAS uses in tracers and anti-foaming agents, it is indicated based on input from suppliers that alternatives are currently available on the market and can be used in the relatively short-term to achieve broadly the same functionality. In the case of anti-foaming agents, one supplier noted that it may take up to four years for users to transition towards using alternatives.

Fluoropolymers

In the case of fluoropolymers, manufacturers and suppliers have indicated that it could take a relatively long time (several years to several decades) to transition towards using alternatives that can achieve the same level of performance. It has been emphasised that downstream users demand an assured level of high performance and function from the material used in applications for the petroleum and mining sector, and any product based on fluorine-free materials must be thoroughly quality assured. Given the relatively large (up to hundreds or thousands) number of individual products supplied in this sector, all with different specific formulations, this would be a complex undertaking and sufficient timescales would need to be allowed to ensure adequate performance in this sector.

E.2.15.2.7. Concluding remarks

Non-polymeric PFAS

The Dossier Submitters conclude based on information from CfE, literature review and stakeholder consultations, that the evidence is sufficiently strong that technically and economically feasible alternatives are available for the quantities required for use in oil and gas tracers and anti-foaming agents and that the substitution potential is high.

The Dossier Submitters note that one stakeholder claims that a transition period of up to 4 years might be required. The assessment of the Dossier Submitters is that this claim will need further justification (in the Annex XV report consultation) to be considered.

Fluoropolymers

The Dossier Submitters conclude based on information from CfE and literature review and stakeholder consultations, that the evidence is sufficiently strong that technically and economically feasible alternatives are not generally available for fluoropolymer applications in the petroleum and mining sectors and that the substitution potential is uncertain.

E.2.15.3. Environmental impacts

Environmental impacts are assessed in comparison to the baseline scenario discussed in section E.2.15.3, assuming baseline and, consequently, on-going PFAS use and emissions. The analysis of environmental impacts focuses on two restriction options:

- **RO1**, adopting a ban of all PFAS used in the petroleum and mining sector
- **RO2**, adopting a ban on PFAS in combination with a use-specific derogation for fluoropolymers. Regarding the duration of the derogations two variants are distinguished, i.e. a 5-year derogation and a 12-year derogation.

Environmental impacts of RO1 are analysed quantitatively. The proposed use-specific derogation covers all fluoropolymers used in the sector. Since emission data are available for this derogation, environmental impacts of RO2 could also be quantified. Table E.160 below summarizes the characteristics of the restriction options, and the maximum additional emission scenarios.

Table E.160. Characteristics of restriction options and of maximum additional emissions scenarios.

Restriction option abbreviation	Short description	Derogations	Transition period after entry into force	Duration of derogation
RO1	Full ban	---	18 months	---
RO2	Ban with use-specific derogations	Derogation of fluoropolymer applications	18 months	5 years
				12 years

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 and RO2 are expected to be implemented in 2027. Environmental impacts of RO1 and RO2 are expressed in relation to the baseline scenario discussed in section E.2.15.3. All emission estimates represent mean values. Table E.161 shows mean emissions and the expected mean emission reduction for time paths of 30 and 45 years (starting in 2025).

Table E.161. Total mean emissions and emission reduction under the baseline, RO1 and RO2 (petroleum and mining sector, in tonnes).

Restriction option	Mean total emissions [t]	Mean total emission reduction [t]	Mean total emission reduction [%]
2025-2055			
Baseline	77 018	---	---
RO1	4 284	72 733	94
RO2 (5-year derogation)	14 726	62 291	80
RO2 (12-year derogation) ^b	30 246	46 772	60
2025-2070			
Baseline	123 726	---	---
RO1	4 284	119 442	97
RO2 (5-year derogation)	14 726	109 000	88
RO2 (12-year derogation) ^b	30 246	93 480	75

Source: Own calculations based on data collated by the Dossier Submitters.

As illustrated in Table E.161, a full ban on PFAS use in this sector leads to a mean emission reduction of at least 94% compared to the baseline scenario. There is **strong evidence (i.e. based on referenced quantitative data)** that a derogation of all fluoropolymers leads to substantially higher emissions compared to a full ban (RO1). A 5-year derogation causes expected emissions which are more than double as much compared to RO1 (14 726 t compared to 4 284 t under RO1). Expected emissions under a 12-year derogation are more than 4 times higher compared to RO1 (30 246 t compared to 4 284 t under RO1). The amount of emissions avoided of a 12-year derogation is 60% compared to 94% under RO1.

Figure E.27 shows the time path of mean emissions of the baseline, RO1 and RO2.

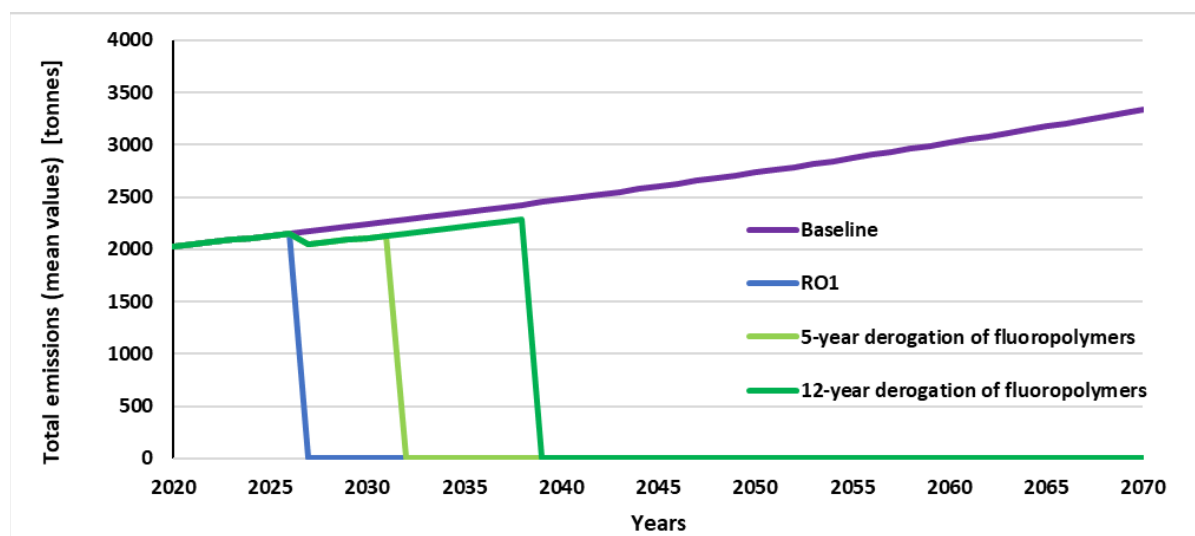


Figure E.27. Time path of mean emissions under the baseline, RO1 and RO2 (petroleum and mining sector, in tonnes).

Source: Own calculations based on data collated by the Dossier Submitters.

E.2.15.4. Economic and other impacts

The impacts of a ban on PFAS use in the petroleum and mining sector varies considerably depending on the types of PFAS covered. Therefore, the assessment here is separated into non-polymeric PFAS (in tracers and anti-foaming agents) and fluoropolymers, respectively. The impacts of a ban on non-polymeric PFAS are expected to be relatively limited, while a ban on fluoropolymers would be likely to have substantial impacts on the sector.

E.2.15.4.1. Market overview

An overview of the oil and gas, and mining sectors, based on Eurostat data is provided in Table E.162 and Table E.163 respectively.

Table E.162. Number of enterprises, employment, turnover and value added in the oil and gas sector, 2019.

	Number of enterprises	Number of persons employed	Turnover (€ million)	Value added (€ million)
EU27	207	24 991 ¹²⁴	29 951	7 917

Source: Eurostat, Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) (sbs_na_ind_r2), extracted 2022-09-08.

¹²⁴ Data from 2018. No data available for later years.

Table E.163. Number of enterprises, employment, turnover and value added in the mining and quarrying sector, 2019.

	Number of enterprises	Number of persons employed	Turnover (€ million)	Value added (€ million)
EU27	16 932	392 246	86 394	33 055

Source: Eurostat, Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E) (sbs_na_ind_r2), extracted 2022-09-08.

The margins in the petroleum and mining sector are high (value added as share of total turnover is 26% and 38%, respectively, in the tables above), which implies that there is room to internalize potential substitution costs instead of passing them on to consumers. The EEA producers are also likely to be price-takers on global commodity markets which makes it difficult to pass on substitution costs to consumers. The costs of substitution are therefore likely to be borne in full by the producer in the form of reduced producer surplus/profits.

Value added as share of total turnover is relatively (26% and 38%, respectively) high in both sectors, indicating that the sectors have high margins and that any costs arising in the sectors due to a restriction would primarily result in lower margins in the sectors, rather than in higher prices for consumers.

An overview of each of the three categories of use is provided in Table E.164, with an indicative description of the likely relative number of workers and users.

Table E.164. Overview of information available on workers and users involved.

	Number of workers	Number of users
Tracers	Very low One producer/supplier identified	Low Expected to be used only at a limited number of installations
Anti-foaming agents	Low Relatively few producers/suppliers expected ^[1]	Low Expected to be used at a limited number of installations
Fluoropolymers	High Large number of manufacturers and suppliers of FP and products in the EEA	High Most petroleum and mining installations expected to use fluoropolymer

[1] Two suppliers identified in the CfE, no indication given of overall market share or total number of suppliers or locations.

It is expected that only a small proportion of the installations in the oil and gas industry and very few if any mining installations are actively handling non-polymeric PFAS-based substances. The number of users of non-polymeric PFAS in the sector is therefore expected to be relatively small.

The use of fluoropolymer at oil and gas, and mining facilities is expected to be much more widespread across the sector. In both cases, quantitative estimates on the numbers of workers producing or using PFAS or fluoropolymer in the petroleum and mining sector are not possible.

E.2.15.4.2. Non-polymeric PFAS

For oil and gas tracers it is indicated based on input from suppliers in the CfE that alternatives are currently available on the market and can be used in the relatively short-term to achieve broadly the same functionality. The PFAS-based tracers are generally used in niche applications, and the identified alternatives are much more commonly used. A similar conclusion can be drawn for anti-foaming agents, but one supplier has noted that it may take up to four years for users to transition towards using alternatives. The eventual impacts on anti-foaming agent applications of an implementation period shorter than that still need to be clarified.

The number of companies supplying PFAS tracers and anti-foaming agents are assumed to be very few (three companies identified). These companies might be affected by a loss of revenue, unless they can compensate the revenue losses by selling substitutes. No information on the number of employees affected have been identified. The revenue generated by these products seem to be quite limited:

- The quantity of PFAS-based tracers used in the EEA is indicated to be only 1 000 kg/y. The cost per kg is claimed to be >€600/kg. This indicates an annual market value of around €0.6 million.
- The quantities of use for PFAS-based anti-foaming agents is far lower than that of PDMS-based agents.

The economic implications for downstream users are summarized in Table E.165 below. Overall, the economic implications for downstream users are expected to be minimal. Substitution costs and transitional costs are expected to be relatively small. No reformulation costs, one-off capital costs or administrative costs related to the transition have been identified.

Table E.165. Overview of economic impacts of a ban of non-polymeric PFAS in petroleum and mining applications.

Product category	Substitution costs	Transitional costs	Loss of functionality
Tracers	No comparison between PFAS-based tracer and radio-labelled alternatives has been possible in this assessment. It is indicated that PFAS-based tracers are considered relatively expensive so alternatives may offer a less expensive option.	Likely to be minimal, as alternatives are available and currently on the market. Expected to be relevant in a relatively small number of installations.	Alternative tracer products (e.g. radio-labelled tracers) can deliver the required functionality. Unclear if alternatives will match the low limits of detection delivered by PFAS-based tracers (implication on dose rate). It is not expected that use of alternative tracers will have a significant impact on the overall production levels of oil and gas in Europe.
Anti-foaming agents	No unit cost data has been made available in this assessment, so costs comparison has	Likely to be minimal, as alternatives are available and currently on the market.	Fluorinated anti-foams are expected to offer a superior functionality relative to the

Product category	Substitution costs	Transitional costs	Loss of functionality
	not been possible. Indicated that higher dose rate of non-fluorinated product would be required to fulfil the same function and therefore a much higher overall volume of use, and hence overall higher costs can be expected.	Expected to be relevant in a relatively small number of installations.	alternatives. Non-PFAS based products are more widely used than PFAS-based foams, with the latter used only for a relatively small number of 'niche' locations. Overall impact of losing this functionality would be relatively minor and would not result in a significant loss of production or revenue.

Loss of functionality could prove to be a more important implication, but the consultations with stakeholders indicate that only a small share of oil and gas installations would be affected and that overall production levels of oil and gas in Europe would not be significantly impacted by a ban.

Based on evidence gathered from the CfE, the 2nd stakeholder consultation and literature, the Dossier Submitters conclude that there is sufficiently strong evidence that a ban on PFAS in oil and gas tracers and anti-foaming agents is likely to have low socioeconomic costs. The main uncertainty relates to short-term transitional impacts for users of PFAS-based anti-foaming agents.

E.2.15.4.3. Fluoropolymers

It is clear from the information received in this assessment (in the CfE and further consultation with manufacturers and suppliers) that the petroleum and mining sector (particularly the oil and gas industry) require a very high and very specific level of performance from materials in the components/products used, for example to ensure efficiency of operations by preventing failure of components and the leakage of chemicals and/or oil. In general, the fluoropolymer-containing components and products supplied to the oil and gas sector are made to a specific order for downstream users and operators, so the specific functionality required will be unique to individual products. Given the many hundreds or thousands of individual products likely to be provided to the oil and gas sector, this makes the assessment of technical feasibility for potential alternatives very challenging. This implies that it could be a relatively long (several years to several decades) and complicated transition towards using alternatives that can achieve the same level of performance.

An overview of the economic impacts of a ban on fluoropolymers in the sector is provided in Table E.166. Overall, the impacts of a ban can be expected to be substantial.

Table E.166. Overview of economic impacts of a ban of fluoropolymers in petroleum and mining applications.

Product category	Substitution costs	Transitional costs	Loss of functionality
Fluoropolymers	Transition to using alternatives to fluoropolymer in	Substitutions of new materials for fluoropolymers could	Alternatives need to match the high-performance function delivered by fluoropolymer

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Product category	Substitution costs	Transitional costs	Loss of functionality
	the oil and gas sector cannot be viewed as a simple 'drop in' replacement of one material for another. For product reformulation, costs can range from tens of thousands of Euros to millions of Euros for any single formulation, so the overall costs could be expected to extend (in total) up to several millions of Euros per company.	take substantial time (years if not decades) and costs. The relative complexity in the supply chains is an important factor. Quality assurance, both for the material/formulation supplied by the manufacturer, and of the actual products containing those material supplied to downstream users in the petroleum and mining industry (e.g. need for quality checks to assure adequate performance, efficiency and reliability, as well as a review of potential hazards, toxicology, environmental impacts).	(mechanical strength and stability, high resistance to high temperatures and chemical corrosion, found in the harsh environments associated with deep drilling depths). The potential differences in overall costs between using the fluoropolymers and fluorine-free alternative options are therefore likely to cover the following aspects: • Differences in operational lifetime of components • Overall frequency and costs of maintenance • The production efficiency and amount of operational downtime (e.g. to carry out maintenance) • Difference in clean-up costs (e.g. due to leakage or leaching) • Difference in waste disposal costs

For a limited number of applications alternatives are available. For example, PEEK is a feasible alternative to PTFE in some applications even if it comes at a considerable additional cost (the material cost of PEEK is stated to be 5-10 times that of PTFE). All substitution would also require transitional costs in the form of reformulation costs and extensive quality checks to assure adequate performance, efficiency, and reliability. Quantitative information on substitution costs and transitional costs is generally lacking.

Due to the complex nature of the market, where fluoropolymer containing articles are often made to a specific order for downstream users and operators, the Dossier Submitters have not been able to identify (and clearly define) the fluoropolymer applications where technically feasible alternatives are available, and where such alternatives are not available. Therefore, the Dossier Submitters expect that a general ban on fluoropolymers in the sector could lead to business closures or operation disruptions, even though the scale of closures and disruptions has not been clarified.

Most petroleum and mining installations are expected to use fluoropolymers, so the number of users and affected employees (see Table E.162 and Table E.163 in section E.2.15.4.1) are potentially high. It has not been possible to derive an estimate for the total number of workers involved in operations where fluoropolymers are used in these sectors, due to a lack of data and the relatively large number of steps and complexity in the supply chain.

Based on evidence gathered from the CfE and the 2nd stakeholder consultation, the Dossier submitters conclude that there is sufficiently strong evidence that a ban on fluoropolymer

applications in the petroleum and mining sectors is likely to have high socioeconomic costs.

The implications of a (time-limited) derogation on economic impacts depends on the successfulness in identifying and developing alternatives. A derogation would allow for more time and, presumably, a higher probability for success in this process. If technically and economically feasible alternatives are not identified the economic impacts would be largely unchanged. If technically and economically feasible alternatives are identified:

- The costs related to loss of functionality would be avoided.
- The costs related to product reformulation and quality assurance would (at least partly) remain but would be postponed or spread out over a longer period.

E.2.15.5. Summary of cost and benefit assessment

Table E.167 summarises the outcomes of the assessment of costs and benefits for the petroleum and mining sectors. More detailed information can be found in the accompanying text following the table.

Table E.167. Petroleum and mining - Summary table on assessment of costs and benefits, based on a general transition period of 18 months.

Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
Full ban	Not applicable	Non-polymeric PFAS Sufficiently strong evidence that technically and economically feasible alternatives are available. No evidence pointing to a shortage in supply of alternatives is available to the Dossier Submitters. As a result, the evidence is sufficiently strong that the substitution potential is high. Fluoropolymers Strong evidence that technically and economically feasible alternatives are not generally available. The substitution potential is low.	Emissions of PFAS to the environment (relative to baseline) estimated to be reduced by 70 559 t over the period 2025-2055. Over the period 2025-2070 the estimated reduction in emissions is 117 267 t. Emissions reported in this table only account for the use phase. PFAS that are not emitted in this phase will at some point be transferred to waste management in quantities described in Section 1.3.1 (Main text). As the environmental impact assessment does not cover the waste phase, emissions under the baseline as well as emissions avoided as a result of the restriction are likely underestimated.	The costs of substitution are likely to be borne in full (in the form of reduced producer surplus/profits) by the firms in the sector. Non-polymeric PFAS The economic implications for downstream users are expected to be minimal. Substitution costs and transitional costs are expected to be relatively small. No reformulation costs, one-off capital costs or administrative costs related to the transition have been identified. As a result, there is sufficiently strong evidence that a ban on PFAS in oil and gas tracers and anti-foaming agents is likely to have low socioeconomic costs. The main uncertainty relates to short-term transitional impacts for users of PFAS-based anti-foaming agents. Fluoropolymers Product reformulation costs can range from tens of thousands of Euros to millions of Euros for any single formulation. Product reformulation will also imply costs relating to quality assurance.	

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
				Loss of functionality of products in this sector could have substantial economic implications, including shorter operational lifetime of components, increased frequency and costs of maintenance, and increased operational downtimes.	
Ban with use-specific derogations: Derogation for fluoropolymers.	5 years	Sufficiently strong evidence that technically and economically feasible alternatives will not be generally available, and that the substitution potential will be low.	Emissions of PFAS to the environment (relative to baseline) estimated to be reduced by 60 117 t over the period 2025-2055. Over the period 2025-2070 the estimated reduction in emissions is 106 825 t. The emissions are estimated to be 9 632 t higher than if there would be no derogation. As the environmental impact assessment does not cover the waste phase, additional emissions as a result of the derogation are likely underestimated.	Due to the expected unavailability of feasible alternatives, the costs are expected to be similar to situation with no derogation.	n/a
	12 years	Unknown substitution potential, depending on R&D progress, but continued R&D increases the chance that alternatives for the relevant applications will be identified.	Emissions of PFAS to the environment (relative to baseline) estimated to be reduced by 44 598 t over the period 2025-2055. Over the period 2025-2070 the estimated reduction in emissions is 91 306 t. The emissions are estimated to be 25 961 t higher than if there would be no derogation.	If technically and economically feasible alternatives are identified: The costs related to loss of functionality would be avoided. The costs related to product reformulation and quality assurance would (at least partly) remain but would be postponed or spread out over a longer period of time.	n/a

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Restriction option	Duration of derogation	Alternatives	Environmental impact	Cost impact	Other aspects
			Relative to the 5-year derogation scenario, the emissions are estimated to increase by 16 329 t. As the environmental impact assessment does not cover the waste phase, additional emissions as a result of the derogation are likely underestimated.		
Conclusion	A full ban of non-polymeric PFASs in petroleum and mining with a transition period of 18 months is proposed. A full ban of fluoropolymers in petroleum and mining with a transition period of 18 months and a 12 year derogation is proposed.				

E.2.15.5.1. Non-polymeric PFAS

A ban on the use of non-polymeric PFAS in the petroleum and mining sector are indicated to have minor consequences and can be considered proportional.

For anti-foaming agents, where one stakeholder has claimed that a period of up to four years is needed to transition from PFAS-based agents, a ban could lead to a temporary pause in the niche applications where PFAS-based agents are used. The assessment of the Dossier Submitters is that this claim will need further justification (in the Annex XV report consultation) to be considered.

E.2.15.5.2. Fluoropolymers

The Dossier Submitters note that, in general, the fluoropolymer-containing components and products supplied to the oil and gas sector are made to a specific order for downstream users and operators, so the specific functionality required will be unique to individual products. Furthermore, it is clear from the information received in this assessment that the petroleum and mining sector (particularly the oil and gas industry) require a very high and very specific level of performance from materials in the components/products used. Given the many hundreds (or thousands) of individual products likely to be provided to the sector, this makes the assessment of technical feasibility for potential alternatives, and the substitution potential, very challenging. Even though several possible fluorine-free alternatives have been identified for fluoropolymers in some applications, manufacturers and suppliers have noted concerns over different technical aspects that will impact their ability to be used for applications in the oil and gas industry.

The Dossier Submitters note that the information received on cost implications of restricting the use of fluoropolymers in the petroleum and mining sectors are primarily qualitative, but that several aspects indicate that the costs could be substantial. Stakeholders claim that transition to using alternatives cannot be viewed as a simple 'drop in' replacement of one material for another, which implies that more extensive product reformulations are required. Stakeholder input indicates that product reformulation costs can range from tens of thousands of Euros to millions of Euros for any single formulation. Product reformulation will also imply costs relating to quality assurance, both for the material/formulation supplied by the manufacturer, and of the actual products containing those material supplied to downstream users. The Dossier Submitters also note that loss of functionality of products in this sector could have substantial economic and other implications, including shorter operational lifetime of components, increased frequency and costs of maintenance, and increased operational downtimes.

The Dossier Submitters have limited information on the timelines required for substitution. Manufacturers and suppliers have indicated that it could take a relatively long (several years to several decades) to transition towards using alternatives that can achieve the same level of performance as products containing fluoropolymers.

All in all, the above strongly indicates that a full ban, within an 18-month transition period, on the use of fluoropolymers in the petroleum and mining sector is likely to lead to high socio-economic costs. Therefore, a time-limited derogation is proposed.

A 12-year derogation in addition to the 18 months transition period is proposed. Although the provided information indicates that alternatives seem to be technically and economically feasible in some applications where fluoropolymers are currently used, there is sufficiently strong evidence that alternatives cannot provide the required functionality in many applications in the petroleum and mining industries. Due to the complex nature of the industry, the harsh conditions the industry is operating under, the need for extensive testing before use and the wide range of fluoropolymer applications, the Dossier Submitters note that a long transition period is needed to identify and assess alternatives in all the various applications in the sector.

E.3. Other impacts

E.3.1. Human health impacts

E.3.1.1. Health impacts of exposure to PFAS

The hazard properties of PFAS for human health have been extensively described in section B.5. However, a detailed toxicological assessment for each of the thousands of PFAS is not possible. The available scientific literature on PFAS that has investigated the hazards associated with PFAS exposure through animal and epidemiological studies suggests that numerous PFAS can exert multiple adverse effects in biological systems (for details see sections B.5.2 and B.5.4). Specifically, experimental animal studies demonstrate toxicological effects of PFAA on the liver, kidney, thyroid, immune system, and reproduction. In addition to their ability to accumulate in the environment, some PFAS also have the ability to bioaccumulate in the human body (see section B.5.1.5). 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 section B.4.1. for details) and hence, also indirectly add to the concern. Hence, also fluorinated gases and polymeric PFAS will contribute to the overall exposure to and risks of PFAAs.

Epidemiological studies show an association between increased serum levels of various PFCA and PFSA (mostly PFOA and PFOS) and reduction in vaccine antibodies, increased propensity of infections, reduced birth weight, increased serum cholesterol and increased serum alanine transferase (ALT) (section 1.1.4) with immune effects considered as the most sensitive endpoint in humans (see sections B.5.2.5 and B.5.2.1). Increased serum cholesterol is a risk factor for cardiovascular disease and is associated with diabetes. Increased serum alanine transferase could indicate non-alcoholic fatty disease, the most common liver disorder in adolescents. The fact that exposure occurs almost always to mixtures rather than single substances complicates the risk assessment. Data available for less well-studied PFAA arrowheads and some PFAA precursors suggests that these PFAS have similar hazard properties to the well-studied substances (PFOA and PFOS) mentioned above (see Annex B.5). A striking feature of PFAS toxicity is the diversity of biological pathways that are affected, especially given that most of the toxicological data currently available for PFAS are for a few individual PFAA (legacy PFAS, e.g. PFOS, PFOA, PFDA, PFNA).

In almost all the biomonitoring studies ubiquitous presence of already restricted PFAS in the EU (legacy PFAS, e.g. PFOS, PFOA, PFDA, PFNA) were reported at detectable levels (see section B.9.23). In general, the detected PFAS are dominated by long-chain perfluoroalkyl sulfonates (PFSA with more than 6 fluorinated carbons) and out of the thousands of existing PFAS, only a very small fraction is addressed in targeted routine monitoring campaigns. Therefore, human exposure to PFAS may be underestimated. Studies of the European population demonstrate that a considerable fraction of the extractable organofluorine detected in human samples is not explained by the individual PFAS that are routinely analysed in target analysis (see section B.9.23.1).

Available studies show that children are exposed to PFAS prenatally via placental transfer and postnatally via breast milk, as demonstrated by the presence of PFAS in umbilical cord blood, placenta, breast milk and in the blood of nursing children (see section B.9.21.).

E.3.1.2. Health impact of the proposed restriction options

The impact of continued use of, and increased human exposure to, PFAS 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 E.168) 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 E.168. Current health impacts in the general population due to exposure to the most analysed PFAS (see B.5.3.5.).

Health impact category	Type of health effects
Immune outcomes	Reduced vaccine responses in children
	Increased propensity of lower respiratory tract infections
	Reduced 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
	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

PFAS 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 PFAS, 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). Any additional exposure to other PFAS, 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 PFAS needs to be minimised.

It is likely that under continued use, other (not well-studied) PFAS will be detected in human breast milk or umbilical cord blood. Continued use of PFAS might thus present a concern for (unborn) infants.

The Nordic council of ministers published the report "The cost of inaction – a socioeconomic analysis of environmental and health impacts linked to exposure to PFAS" (Goldenman et al., 2019). The conclusions are based on different scenarios but conclude that the annual health costs of exposure to PFAS in Europe could be between €52 and €84 billion. This exemplifies that the health costs could be significant in the baseline scenario and that there are substantial health benefits from the proposed restriction options. A recent analysis of the disease burden and associated costs of PFAS exposure in the United States shows health costs are in the same order of magnitude as estimated for Europe, when adjusted for population size and exchange rates (Obsekov et al., 2022).

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Due to the persistence, PFAS will stay in the environment for a very long time once they are emitted. As emission prevention techniques are missing or too expensive, PFAS emissions 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 PFAS 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 PFAS. The magnitude of the impact of continued use of PFAS on human health cannot be quantified but current combined exposure to some regulated PFAS already exceeds existing limit values. Therefore, due to structural similarities and a similar hazard profile, (co-)exposure to other, non-regulated PFAS should be minimized. This implies that the restriction option that reduces the increase of the environmental pollution burden of PFAS 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 PFAS exposure.

E.4. Practicability and monitorability

E.4.1. Practicability of restriction options

E.4.1.1. Implementability

Both RO1 (full ban with 18 months transition period) and RO2 (full ban with 18 months transition period and use-specific derogations) are concluded to be implementable. As described in Annex E for the specific use sectors, alternatives for PFASs are already being used by a number of stakeholders. For other uses, late stage product and process oriented research will make alternatives available on the short term. Stakeholders in several sectors are currently moving away from the use of PFASs in their processes and products for various reasons, e.g. customer and investor requests, legislative and regulatory actions.

Indications are that for a large number of applications alternatives for PFASs are sufficiently available, and/or customer demand for PFAS-containing products are decreasing. For specific uses for which the alternatives are not available or are not expected to become available in the short term, RO2 may be more readily implementable from an industry perspective. Use-specific, time-limited derogations in this restriction option give users and manufacturers the opportunity to develop functional alternatives for these specific uses or processes.

The Dossier Submitters emphasize that only for uses for which stakeholders supplied sufficiently strong information demonstrating alternatives are not (readily) 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 in this restriction, no derogations were proposed for uses and sectors for which no, inconclusive or weak evidence for the current absence of alternatives was submitted. Implementability of the RO1 for these uses and sectors was considered to be sufficient.

E.4.1.2. Enforceability

Enforceability of both RO1 and RO2 is considered to be sufficient. 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. of the main report). Activities relating to RO1 and RO2 of this proposal can be integrated in current enforcement activities in the Member States. The enforceability is partly dependent on the availability of sufficiently efficient and effective analytical methods for monitoring, which are in rapid development. This is further described in the following paragraphs. The enforceability can also benefit from the reporting requirements for manufacturers, importers and formulators of PFAS containing products that are covered by a 13.5 year or non-timelimited derogation. Information on PFASs and type and amount of products containing PFASs can help in targeting uses and sectors for specific enforcement activities and actions, also based on these reporting requirements. These can for example be targeted on uses and/or sectors that are expected to make use of these derogations, but that do not follow-up on the reporting requirements. The broad chemical scope proposed in this dossier is beneficial to enforcement, since all PFASs are covered by the scope of the restriction, excluding only a few substances which can fully degrade under normal environmental conditions. This is beneficial in avoiding discussions on applicability of the restriction and legal uncertainties when PFASs are being found during enforcement activities, also when it comes to import of PFAS containing products.

E.4.1.3. Manageability

The restriction may be broad, the manageability however is sufficiently practical. As this restriction targets manufacture and placing on the market besides use of PFASs, downstream users of PFASs that are less knowledgeable with regard to regulations and restrictions in particular, have knowledgeable partners (manufacturers). This is similar for import. When the restriction enters into force, manufacturers and importers can no longer provide the less knowledgeable downstream users with PFASs as such or with PFAS containing products, unless derogations apply. In this approach, their downstream users will be made aware of the restriction conditions by their suppliers.

The reporting requirement is mainly applicable for larger, generally more knowledgeable stakeholders (manufacturers, importers and formulators) and require only annual reporting for 13.5 year time-limited derogations and for the non-timelimited derogations. Assigning this responsibility to a limited number of generally larger stakeholders helps in limiting the administrative burden for their downstream users. This also means that for authorities the number of received reports will be better manageable and processable than with a broad reporting requirement for all downstream users.

E.4.1.4. Analytical methods

The availability of analytical methods for PFAS was assessed and information collected and compiled in a Nordic Council report developed by Ramboll/VITO as a part of the work with this restriction proposal: "Analytical methods for PFAS in products and the environment" (NCM, 2022). A comprehensive review of analytical methods for PFAS is also found in the paper by Al Amin et al. (2020): "Recent advances in the analysis of per- and polyfluoroalkyl substances (PFAS)—A review", see also Appendix E.4.

E.4.1.4.1. General introduction to analytical methods for PFAS

A short introduction to the different types of analytical methods relevant for PFAS is found below. For additional details we refer to the Nordic Council report on PFAS analytical methods. In general, PFAS analytical methods may be distinguished in three types with respective sub types:

1. Targeted Substance Analysis, in which a certain subset of PFAS substances is analytically determined. The individual substances are quantified relative to analytical reference standards (today ca. 40 different substances available) in a gas/liquid chromatographic system coupled to an MS instrument. A key limitation of this method is the availability of reference standards. Several EU-wide and international standard methods are available that rely on targeted analysis.
2. Sum parameter: Total fluorine methods or oxidisable precursor measurements, that measure fluorine in all (organic) substances or PFASs after oxidative breakdown of precursors. So far, there is no standardised total fluorine analysis available. However, the US EPA is currently developing a standard for Total Oxidisable Precursors (TOP) assay and total organic fluorine (TOF) in environmental matrices that are planned to be published soon. Total fluorine may be measured directly on a sample or after some pre-treatment that is chosen in line with the purpose of the analysis and the matrix. Quantification of fluorine may be by a range of different methods which are described in the Nordic Council report, including the frequently used Combustion Ion Chromatography (CIC) and Particle-Induced Gamma-ray Emission spectroscopy (PIGE). Explanation of some relevant concepts for total fluorine measurements is found below:
 - a. The Total Fluorine (TF) in a sample is equal to the sum of inorganic fluorine (IF, e.g. fluoride ions) and organic fluorine (OF, fluorine covalently bound to carbon), see Figure Y below. The organic fluorine may be extracted from a sample using a

solvent. However, there is a risk that a part of the OF is not extractable (e.g. polymeric PFAS). Methods relying on extractions are termed Extractable Organic Fluorine (EOF), while if an adsorption step is used to collect organic fluorine in a solution, the method is called Adsorbable Organic Fluorine (AOF). Alternatively, IF may be attempted removed from the sample, e.g. through washing with water. The EOF part of a sample may be divided into quantifiable organic fluorine (for which analytical reference standards exist) and unquantifiable organic fluorine. Further, the unquantifiable organic fluorine may be divided into identified and unidentified organic fluorine, depending on whether it is possible to find the structural identity of the substances through non-target or suspect screening.

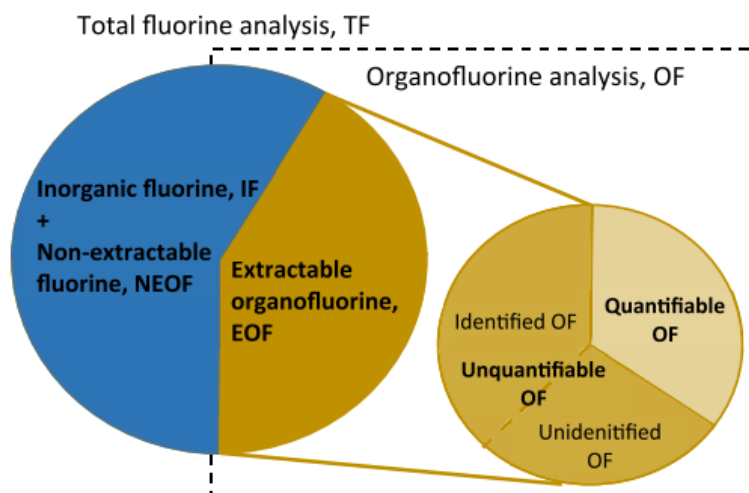


Figure Y. Mass balance analysis of fluorine. From Koch et al. (2020).

- b. Total Organic Fluorine (TOF) gives a quantitative assessment of any organic fluorine substances in samples. TOF reports a cumulative single parameter, which is given as organic fluorine in mg F/L in liquid or as mg F/kg in solid samples, respectively. The fluorine content of the sample can be determined by e.g. combustion ion chromatography (CIC), optionally after removal of inorganic fluorine. The organic fluorine as determined in the test may serve as a proxy for the overall concentration of PFASs (including end products as well as precursors). However, the method also includes potential organic fluorine substances that are not PFAS (e.g. hexafluorobenzene).
- c. Extractable Organic Fluorine (EOF): There are several extraction methods available extracting organic fluorine from a sample to determine the levels of EOF. Conceivably, different extraction procedures isolate different types and amounts of organic fluorine, and therefore solvent and method should be selected with care. Distinguishing between non-extractable fluorine (NEOF) and EOF may be needed. Fluorine content of the extracts can be determined by e.g. CIC.
- d. Adsorbable Organic Fluorine (AOF) allows for the determination of trace levels of organofluorine substances in water samples. The sample will need to pass through a mixed-mode anion exchange solid phase extraction (SPE), which will adsorb the PFAS compounds in the water. The PFAS are eluted from the solid phase with a solvent, and the overall content of fluorine can be determined by e.g. CIC. AOF is useful in the evaluation of PFASs but is more labour intensive and takes more time than EOF due to the extra steps.
- e. Total Oxidizable Precursor Assay (TOP assay or TOPA) converts PFAS precursor compounds under strong oxidative conditions into perfluoroalkyl carboxylic acids (PFCAs), which are subsequently quantified by standard targeted substance analysis. This method has generally a lower detection limit compared to the total fluorine methods. However, there is a risk that PFASs with degradation products that are not covered by targeted analysis (due to lack of reference standards) are overlooked, and there are also PFAS that may resist the oxidative treatment in

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TOPA. Any analysis may report both pre-TOPA and post-TOPA data, i.e. concentrations of targeted PFAS before and after oxidation. It is important to note that the TOP assay does not identify and/or quantify the amount of PFAS precursors, just the PFCA oxidation products.

- Non-target methods: Non-Target Screening (NTS) uses a high-resolution mass spectrometer, such as a Orbitrap or time-of-flight mass spectrometer for an accurate mass measurement of trace level compounds. From the accurate mass and fragmentation pattern in the MS instrument, information about the molecular structure may be deduced. More recently, hybrid instruments such as linear ion trap-orbitrap (LTQ-Orbitrap) and quadrupole-TOF (Q-TOF) have been used increasingly more, as they allow for accurate-mass acquisition of both full-spectrum as well as product-ion spectrum data. Advantages of NTS are the broad screening of unknown samples and help detecting previously unknown compounds. Identified substances can be quantified using the same approaches as in targeted analysis (provided that the respective standards are commercially available) and similar detection limits can be reached. However, the methods are relatively labour intensive and require much time, and a high degree of analytical expertise is needed. In Suspect Screening Analysis (SSA) the accurate mass, isotope pattern and fragmentation pattern of molecular features obtained from high resolution MS are compared to databases with known PFASs (e.g. the USEPA CompTox Chemistry Dashboard and NORMAN Suspect List Exchange).

Total fluorine measurements are typically reported as mg F per kg or L sample material, while it is oftentimes desired to have the measured values in mg PFAS per kg or L sample. The conversion from mg F to mg PFAS is dependent upon the specific PFAS substance(s) in the sample and the percentage of F atoms in their molecular structures. Some examples of substances and the percentage of F atoms in their respective molecular structures are given in Table E.169 below.

Table E.169. Selected PFAS substances and the percentage fluorine content in their molecular structures.

Substance	Chemical formula	% Fluorine
TFA	<chem>C2HF3O2</chem>	50.0
PFHxA	<chem>C6HF11O2</chem>	66.5
PFOS	<chem>C8HF17O3S</chem>	64.6
	<chem>C15H21F13N2O2S</chem>	45.7
Perfluorodekane	<chem>C10F22</chem>	77.7

Using the above percentages of F in the molecular structures for e.g. TFA and PFOS, we can calculate the concentration of TFA and PFOS in a sample that e.g. 50 mg F/kg would correspond to (%F in PFAS substance x Mass PFAS in sample = measured F in sample):

In the case of TFA: 50 mg F/kg -- >100 mg TFA/kg

In the case of PFOS: 50 mg F/kg -- >77.4 mg PFOS/kg

In general, the limit of detection (LOD) and quantification (LOQ) of the total fluorine methods is currently considerably higher as compared to the targeted PFAS analyses. In addition, LODs/LOQs at different levels have been reported for different products/matrices. For example, Schaidler et al. (2017) operate with an LOD for PIGE in FCM paper of approximately 10 ppm.

Bartlett and Davis (2018) looked at the risk of cross-contamination from PFASs that may occur during sampling as PFASs are commonly used in sampling materials and personal protective equipment. For reliable analytical results they recommended a conservative approach when developing and executing a PFAS sampling program including substituting known PFAS-containing products with PFAS-free alternatives, evaluating products and materials that are suspected of containing PFAS, and coordinating with the analytical laboratory to further reduce cross contamination and ensure data quality. Rodowa et al. (2020) investigated the potential for contamination of PFAS field samples by sampling materials and analyzed 66 relevant materials for PFASs as a possible source of contamination. However, they recommended that future efforts should focus only on materials that come in direct contact with field samples and have a plausible pathway for impacting the concentrations of PFASs to levels of concern. The NORMAN Network PFAS Analytical Exchange (Environment Agency, 2022) also looked into what measures laboratories have implemented to minimize contamination during PFAS analysis. Hence, good routines and procedures (e.g. in line with Good Laboratory Practice, GLP) should be developed and used for work with PFAS analysis in laboratories, keeping in mind that PFAS-containing materials may be used in laboratory equipment.

E.4.1.4.2. Analysis of polymeric PFAS

In general, polymeric PFAS (defined in Figure 1, Section 1.1.1) cannot be quantified in the same way as low-molecular weight PFAS as reference standards are not available and the methods are unsuitable. However, the various total fluorine methods will include fluorine from polymeric PFASs (in addition to fluorine from non-polymeric PFASs). The side-chains of side-chain fluorinated polymers may be cleaved off from the polymeric backbone in TOP assay treatment and be included in the quantification of targeted PFAS when the identity of the side-chain cleavage products are covered by the analytical reference standards.

The Nordic Council report on PFAS analytical methods summarizes the methods available for the measurement of polymeric PFASs (NCM, 2022). Options exist for the determination of the type of polymer used, the molecular weight and the layer thickness of polymer. However, the methods are generally not suited for absolute quantification.

E.4.1.4.3. Accredited, standard and validated methods

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 extensive and cover accuracy, precision, linearity and application range, limit of detection (LOD), limit of quantification (LOQ), selectivity/specificity, recovery and robustness/ruggedness. Extensive validation leads in most cases 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.

E.4.1.4.4. Cost considerations

There is a large variety in analytical approaches to analyse PFASs in various matrices. Therefore, it is very difficult to set a specific price for a typical analysis. A number of different parameters with an analytical project will influence the price per sample, such as: number of samples, matrix, technique(s) used, number of PFASs to detect and report, targeted vs. untargeted methods, and post analysis work like modelling or data visualization. However, a rough cost estimate is 100 € per sample for a standardized targeted LC-MS/MS analysis in a commercial lab. These prices increase with increasing level of complexity. For more complex

questions like non-target screening, commercial labs are most often not sufficiently equipped and universities, research institutes or high-end commercial labs need to be approached. In such cases prices can increase significantly. Total fluorine methods are significantly cheaper and faster compared to substance-specific MS measurements. However, CIC instruments, which are most often used in these measurements, are not widely distributed.

E.4.1.4.5. Analytical methods for PFASs in specific products and matrices

The Nordic Council report "Analytical methods for PFAS in products and the environment" developed together with this restriction dossier, presents information on analytical methods for PFASs collected in a comprehensive literature search (NCM, 2022). The information is sorted into the following products and matrices:

- Packaging material, FCM & food & feed processing equipment
- Fluorinated gases and refrigerants including blowing agents
- Ski wax
- Medical devices and pharmaceuticals
- Consumer products
- Flame retardants & resins
- Fire-fighting foams
- Cosmetics
- Textiles
- Waste treatment of PFAS articles & industrial waste
- Lubricants
- Oil, gas and mining
- Construction products
- Metal plating
- Production of PFAS, including polymers
- Transportation, automotive, aircraft, space and ships
- Electric and electronic equipment including semiconductors
- Human and environmental samples for monitoring

For some PFAS applications and their respective matrices a standard analytical method for targeted PFAS is available. The standard CEN/TS 15968 has been adapted for use in food contact materials, ski wax, consumer articles and textiles, and may possibly be adapted to fit other matrices as well. For other PFAS uses, no standard methods are currently available, but PFASs in these uses can be determined with variations of mass spectrometry as shown by many reports and scientific publications, although some adaption might be necessary. For a few of the PFAS application groups, neither standard methods nor relevant scientific publications been found, like for e.g. "transportation" or "oil, gas, and mining". However, this is primarily due to that these subgroups are defined at a sector level rather than at a product level. The analysis of PFAS in the matrices is not principally different from the measurements of other matrices.

There is a large variety of analytical standards available for the monitoring of PFAS in environmental samples, e.g. water, sludge and soil: ISO 21675:2019, ISO 25101:2009, DIN 38407-42:2011-03, EPA METHOD 533 (12/2019), EPA Draft Method 1633, EPA METHOD 537.1 (12/2018), US EPA OTM45, EPA method 8327:2019, ASTM 7979-19:2019 (11/2019), ASTM D7968-17a, DIN 38414-14. It should however be highlighted that the substances addressed in the individual standards differ significantly. Harmonisation of the substances addressed would be beneficial for a harmonised approach to monitoring of PFAS.

Reference is made to the Nordic Council report for specific details for the different matrices. The information on analytical methods is also compiled in a Documentation Sheet in excel which is included in Appendix E.4. The Documentation Sheet contains information on the relevant publications identified which is easily accessible by for example sorting via text search. Information on standard methods is included. Every matrix discussed in the report has a separate sub-sheet. Publications or standards which could be assigned to more than

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one category are available in each respective sub-sheet.

The Documentation Sheet contains:

- Bibliographic information on the reference (author, title, journal, year, DOI)
- Substances addressed (if available with CAS)
- Sample amount used
- Pre-treatment of sample
- Extraction method
- Brief generic method classification
- Clean-up method
- Quantification method
- Working range of the method
- Possible matrices
- Reported levels – in the case indicated
- Information on validation of the method
- Limitations (e.g. reported matrix effects)
- LOD and LOQ
- Further comments on the matrix

A summary overview of the availability of analytical methods for the different matrices as assessed in the Nordic Council report may be found in Table E.170 and Table E.171.

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Table E.170. Available analytical methods for PFAS in selected matrices as assessed in the Nordic Council report (part I) (NCM, 2022)

Method Matrix	FCM	Ski Wax	Consumer products	Cosmetics	TULAC	Metal plating
Main PFASs used	Side-chain fluorinated polymers, fluoropolymers, FT phosphate monoester, Perfluoropolyether-based phosphates, PFCAs (PFOA), PFSAs PFOS, other perfluorinated surfactants	Perfluoroalkanes, semifluorinated n-alkanes, fluoropolymers, and others. PFCAs, PFSAs and FTOHs may be present as impurities	Various depending on article	PFCAs, FTSS, PAPs, fluoropolymers (e.g. PTFE) and others	Side-chain fluorinated polymers, fluoropolymers, PFCAs, PFOAs, various others	FTs, PASFs, PACFs, PFPEs or other fluoropolymers
Other bans/prohibitions (worldwide)	PFASs prohibited in DK as measured by TOF (20 ppm) ¹²⁵ PFASs prohibited in California as measured by TOF (100 ppm) ¹²⁶	International Ski Federation (FIS): ban on fluorine in ski wax will apply to all competition ¹²⁷	California ¹²⁸ Product safety: juvenile products: chemicals: perfluoroalkyl and polyfluoroalkyl substances Blue Angel bans	US Senate: No PFASs in cosmetics act ¹³⁰	Several eco labels ban use of PFAS (Blue Angel ¹³¹ , Oeko-Tex ¹³²) Californian regulation of PFAS as a class in carpets and rugs under the Safer Consumer Products	None

¹²⁵ <https://www.foedevarestyrelsen.dk/english/SiteCollectionDocuments/Kemi%20og%20foedevarekvalitet/UK-Fact-sheet-fluorinated-substances.pdf>, date of access: 2022-11-28.

¹²⁶ https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB1200, date of access: 2022-11-28.

¹²⁷ <https://www.fis-ski.com/en/ski-jumping/ski-jumping-news-multimedia/news/2020-21/ski-wax-only-without-fluorine>, date of access: 2022-11-28.

¹²⁸ https://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=202120220AB652, date of access: 2022-11-28.

¹³⁰ https://www.collins.senate.gov/imo/media/doc/No%20PFAS%20in%20Cosmetics%20Act_0.pdf, date of access: 2022-11-28.

¹³¹ General ban on PFAS, no limit and analytical testing needs to be stated. <https://produktinfo.blauer-engel.de/uploads/criteriafile/en/DE-UZ%20154-201707-en-Criteria-V1.9.pdf>, date of access: 2022-11-28.

¹³² Individual substances as stated in this document, no limits and analytical testings stated. https://www.oeko-tex.com/importedmedia/downloadfiles/STANDARD_100_by_OEKO-TEX_R_-_Limit_Values_and_Individual_Substances_According_to_Appendices_4_5_en.pdf, date of access: 2022-11-28.

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Method Matrix	FCM	Ski Wax	Consumer products	Cosmetics	TULAC	Metal plating
			use of certain PFASs in toys ¹²⁹		(SCP) framework ¹³³	
Available Standards	CEN/TS 15968 (adopted) DIN EN ISO 10304-1 & DIN 51723	CEN/TS 15968 (adopted)	CEN/TS 15968 (adopted)	None	CEN/TS 15968 (adopted) ISO standard 23702-1 DRAFT DIN standard 17681 ¹³⁴ DIN standard 38407-42 ¹³⁵	None
Targeted	LC-MS/MS, LC-HRMS	LC-HRMS, LC-MS/MS	GC-MS, LC-MS/MS,	GC-MS, LC-MS/MS, GC/ECNI/MS	GC-MS, LC-MS/MS, GC/ECNI/MS	LC-MS/MS- or GC-MS/MS
Sum parameter (total fluorine)	TOF (PIGE; 2–15 ppm), TF, EOF (CIC, PIGE, instrumental neutron activation analysis (INAA)), TOP	EOF TOF not possible	EOF, TOF, TOP	TOF, TF, EOF	TF, TOF, TOP, EOF	NA
Non-targeted / Suspect screening	Yes	NA	Yes	NA	NA	NA

¹²⁹ 20 ppm for PFCA/Ss and 1000 ppm for FTOHs. Substances listed in Annex D. Measured with CEN/TS 15968. <https://produktinfo.blauer-engel.de/uploads/criteriafile/en/DE-UZ%20207-201701-en%20Criteria-V4.pdf>, date of access: 2022-11-28.

¹³³ <https://dtsc.ca.gov/scp/carpets-and-rugs-with-perfluoroalkyl-and-polyfluoroalkyl-substances-pfass/>, date of access: 2022-11-28.

¹³⁴ Textiles and textile products. Organic fluorine Part 2. Determination of non- and volatile compounds by extraction method using gas chromatography <https://www.beuth.de/en/draft-standard/din-en-17681-1/337939568>, date of access: 2022-11-28.

¹³⁵ <https://www.beuth.de/en/standard/din-38407-42/137282966>, date of access: 2022-11-28.

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Method Matrix	<i>FCM</i>	<i>Ski Wax</i>	<i>Consumer products</i>	<i>Cosmetics</i>	<i>TULAC</i>	<i>Metal plating</i>
Others (including non-standard methods)	X-ray photoelectron spectroscopy (XPS), Contact angle measurement analysis to determine limits of performance (LOP)	SkiFT (X-ray fluorescence = XRF)	X-ray photoelectron spectroscopy (XPS)	NA	Pyrolysis GC-MS	NA

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Table E.171. Available analytical methods for PFAS in selected matrices as assessed in the Nordic Council report¹³⁶ (part II).

Method Matrix	Fluorinated gases	Medical devices & Pharmaceuticals	Flame retardants	Lubricants	Construction	PFAS-Production	Transportation, Automotive, Aircraft, Space and Ships	Oil, Gas, and mining	E&E
Used PFAS	HFCs, PFCs, perfluoroketones, HFEs, HFOs	Fluorocarbons (only C & F), fluoropolymer, 1-bromoperfluorooctane	PFCAs, PTFE	Mainly micro-powder PTFE, PFPE, PFAS-based additives and solvents	Fluoropolymers. Ffluorinated gases and others	Fluoropolymers, PFCAs, PFECA	Fluoropolymers, Fluoroorganic additives (PTFE), Fluorinated gases	Fluoropolymers, Side-chain fluorinated polymers, Fluorinated gases	PFECA, Fluoropolymers, 1H-pentafluoroethane
Other bans/prohibitions (worldwide)	F-Gas regulation ¹³⁷ , Blue Angel ¹³⁸ bans use of halogenated substances in blowing	None	Blue Angel bans use of halogenated flame retardants ¹³⁹	None (PFAS/fluor/halogens not included in EU Ecolabel,	Blue Angel label prohibits use of halogenated flame retardants and	None	None	None	Blue Angel bans the use of halogenated polymers and additives. Excluded

¹³⁶ <https://www.norden.org/en/publication/analytical-methods-pfas-products-and-environment>, date of access: 2022-11-28.

¹³⁷ https://ec.europa.eu/clima/eu-action/fluorinated-greenhouse-gases/eu-legislation-control-f-gases_en, date of access: 2022-11-28.

¹³⁸ Indirectly as the Blue Angel-label requires that no halogenated blowing agent is used in insulating material above 1000 ppm <https://produktinfo.blauer-engel.de/uploads/criteriafile/en/DE-UZ%20132-201510-en%20Criteria-2020-01-07.pdf>, date of access: 2022-11-28.

¹³⁹ Indirectly as the Blue Angel-label requires that no halogenated flame retardant is used (above 1000 ppm) in many construction products, for example in insulating material. This method is applicable for solid, pasty and liquid samples with more than 25 ppm. <https://produktinfo.blauer-engel.de/uploads/criteriafile/en/DE-UZ%20132-201510-en%20Criteria-2020-01-07.pdf>, date of access: 2022-11-28.

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Method Matrix	Fluorinated gases	Medical devices & Pharmaceuticals	Flame retardants	Lubricants	Construction	PFAS-Production	Transportation, Automotive, Aircraft, Space and Ships	Oil, Gas, and mining	E&E
	agents			Blue Angel, Nordic Swan)	blowing agents (see fluorinated gases and flame retardants)				are additives >0.5%w/w and fluoropolymers ¹⁴⁰
Available Standards	DIN EN 14582 ¹⁴¹	None	DIN EN 14582 ¹⁴¹	None	None	None	None	None	None
Targeted	GC-MS	NA	NA	Time-of-Flight Secondary Ion Mass Spectrometry (TOF-SIMS), Laser Desorption Ionization Time of Flight	multigas analyzer, LC-MS/MS, LC-HRMS	LC-MSMS, LC-HRMS, LC-conductivity	LC-MS/MS, GC-MS	GC-ECD, GC-MS	GC-MS, LC-MS/MS,
Sum parameter	NA	NA	Total fluorine as	NA	NA	NA	NA	NA	NA

¹⁴⁰ For example in printers and multifunction devices. No chemical testing is needed. <https://produktinfo.blauer-engel.de/uploads/criteriafile/de/DE-UZ%20205-201701-de%20Kriterien-2020-07-17.pdf>, date of access: 2022-11-28.

¹⁴¹ Characterization of waste - Halogen and sulfur content - Oxygen combustion in closed systems and determination methods <https://www.beuth.de/en/standard/din-en-14582/249016181>, date of access: 2022-11-28.

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Method Matrix	<i>Fluorinated gases</i>	<i>Medical devices & Pharmaceuticals</i>	<i>Flame retardants</i>	<i>Lubricants</i>	<i>Construction</i>	<i>PFAS-Production</i>	<i>Transportation, Automotive, Aircraft, Space and Ships</i>	<i>Oil, Gas, and mining</i>	<i>E&E</i>
(total fluorine)			described in DIN EN 1458215						
Non-targeted/ Suspect screening	NA	NA	NA	NA	LC-HRMS	NA	NA	NA	NA
Other (including non-standard methods)	Perfluoroketones using UV Absorption Spectrum, Infrared Absorption Spectra (IR)	None	None	¹⁹ F NMR, Gel permeation chromatography (GPC)	NA	NA	NA	NA	NA

E.4.1.4.6. Other relevant work and ongoing activities

In 2020 a workshop was organized by the European Commission on the monitoring of PFASs. A workshop report¹⁴² from the event was compiled which contains a collection of analytical methods for PFAS used in monitoring, including analysis of PFASs in:

- abiotic environmental matrices
- air samples
- consumer products
- human matrices

Details of the different analytical methods were compiled in a table format similar to the Documentation Sheet developed for this dossier.

In the NORMAN Network¹⁴³ different projects on PFAS monitoring and analysis have recently been carried out or are in progress, including:

- PFAS Analytical Exchange¹⁴⁴ – A questionnaire was distributed to laboratories in 2021 to investigate topics such as which PFAS the laboratories are currently focusing on, current limits of detection for individual PFAS in different matrices, the analytical techniques currently being adopted, and the future direction which laboratories are planning. The questionnaire also included questions on measures implemented to minimize contamination during PFAS analysis. A report was published summarising the findings.
- Per- and polyfluoroalkyl substances (PFAS) TOP Assay Method Comparison – A survey with the purpose of establishing what methods are currently employed by different laboratories and gather information on their suitability, practicality and limitations, e.g. which media are being analysed, steps taken to improve recovery, accompanying analysis and instrument setup.

The European research programme Partnership for the Assessment of Risks from Chemicals (PARC)¹⁴⁵ may include work on the validation of methods for total fluorine analysis. Specific initiatives to develop analytical methods to support enforcement have already been initiated within the programme's task 4.2 Environmental Monitoring and 4.3 Innovative Tools and Methods, as well as activity 6.4.3 (under WP6: Innovation in regulatory risk assessment).

During 2023, a project to evaluate and describe the regulatory needs for reliable enforcement of restricted PFASs in different matrices will be carried out under the Nordic Council of Ministers subgroup NORAP (Nordic Risk Assessment Project). The project will include a description of what method development and/or standardization/validation of analyses of individual PFASs, precursor substances ("related substances") and total organic fluorine/total fluorine (including screening methods) that is needed in order to enforce current and coming PFAS-restrictions. The project aims to inform decision makers, the scientific community, and relevant projects such as PARC on what concrete measures that are needed and to provide valuable input to ongoing PFAS restriction processes.

The United States Environmental Protection Agency (US EPA) are developing validated analytical methods for PFAS in drinking water, groundwater, surface water, wastewater, and solids including soils, sediments, biota, and biosolids, which may eventually become

¹⁴² <https://library.wur.nl/WebQuery/hydrotheek/2301946>, date of access: 2022-11-28.

¹⁴³ <https://www.norman-network.net/>, date of access: 2022-11-28.

¹⁴⁴ <https://www.norman-network.net/sites/default/files/files/OA-QC%20Issues/2021%20NORMAN%20network%20PFAS%20Analytical%20Exchange%20Final%20Report%2014022022.pdf>, date of access: 2022-11-28.

¹⁴⁵ <https://www.anses.fr/en/content/european-partnership-assessment-risks-chemicals-parc>, date of access: 2022-11-28.

standard methods or research methods. An overview of their current methods and activities in this area may be found on their webpages, including a list of finalized US EPA standard methods¹⁴⁶. Standard methods for Total Organic Fluorine (TOF) and Total Oxidizable Precursor Assay (TOPA) are under development and will be published soon according to the webpage.

ASTM International (American Society for Testing and Materials) has published a Standard Guide for PFAS Analytical Methods Selection (ASTM E3302-21)¹⁴⁷. The guide provides an overview of analytical methods, techniques, and procedures that may be used in determination of PFAS in environmental media. It may be used by various parties involved in response actions for PFAS-impacted environmental media, including regulatory agencies, project sponsors, environmental consultants and contractors, site remediation professionals, analytical testing laboratories, data reviewers, data users, academic institutions, research institutes, and other stakeholders. The organization is also in the process of developing a PFAS standard for consumer products.

In the POPFREE¹⁴⁸ project a suite of different analytical techniques are being tested on different consumer products (e.g. textiles, frying pans, cookware, skiwax, etc) and compared for performance (detection limits, specificity, robustness, etc). Of particular interest are rapid screening techniques such as HH-LIBS and ATR-FTIR, which would facilitate rapid, on-site screening of products for the presence of fluorine. They are also exploring methods that offer more structural information with minimal sample preparation, such as pyrolysis-GC. Finally, a survey of total fluorine on a wide range of products is being carried out using CIC.

In the PERFORCE3¹⁴⁹ project some of the more “emerging” analytical approaches (mostly CIC, TOP, HRMS) are applied to answer various questions related to occurrence, fate, and behaviour of PFAS. A tiered approach to gather information on the character of fluorine in samples is investigated. For example, TF measurements (if positive) may be followed by EOF analysis. A negative EOF measurement may then indicate the presence of polymeric PFAS. In another step, TOP assay may reveal if the polymer is degradable (likely side-chain fluorinated polymer) or non-degradable (likely fluoropolymer). The tiered approach may be used both for analysis of PFAS in products and to identify the identity of fluorine in environmental samples.

Under the Drinking Water Directive, the Commission is obliged to establish technical guidelines by 12 January 2024 regarding methods of analysis for monitoring of PFASs under the parameters ‘PFAS Total’ and ‘Sum of PFAS’, including detection limits, parametric values and frequency of sampling.

In the ZeroPM project, analytical procedures are being developed to track the fate of TFA and other short chain PFAS during wastewater treatment (e.g. anaerobic digestion and hydrothermal carbonisation) and drinking water treatment. Methods are targeting wastewater effluents, sludge and emissions to the air to gauge the performance of advanced treatment procedure to remove these substances from water and wastewater. Passive sampling methods and total fluorine analyses are being developed and applied to these matrices to provide time average concentrations and an idea of the total amount of organic fluorine in a specific sample or matrix. In addition, the substantially improved protocol for the TOP assay which allows for the inclusion of TFA and perfluoropropionic acid will be applied. The TOP assay will be optimized and evaluated for its suitability to be used as the parametric value ‘PFAS Total’ in the revised EU drinking water directive (DWD).

¹⁴⁶ <https://www.epa.gov/water-research/pfas-analytical-methods-development-and-sampling-research>, date of access: 2022-11-28.

¹⁴⁷ www.astm.org/e3302-21.html date of access: 2022-11-27.

¹⁴⁸ <https://www.ri.se/en/popfree>, date of access: 2022-11-28.

¹⁴⁹ <https://perforce3-itn.eu/>, date of access: 2023-01-13.

E.5. Proportionality

For details on the proportionality of the proposed restriction, see section 2.4.4 of the main report.

Appendices to Annex E

Appendix E.2.



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Appendix E.4.



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Analytical methods.)

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EUROPEAN
COMMISSION

Brussels, XXX
D090609/01
[...] (2023) XXX draft

ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) .../...
of XXX

**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 octamethylcyclotetrasiloxane (D4),
decamethylcyclopentasiloxane (D5) and
dodecamethylcyclohexasiloxane (D6)**

ANNEX

Entry 70 of Annex XVII to Regulation (EC) No 1907/2006 is replaced by the following:

‘70. Octamethylcyclotetrasiloxane (D4) CAS No 556-67-2 EC No 209-136-7 Decamethylcyclopentasiloxane (D5) CAS No 541-02-6 EC No 208-764-9 Dodecamethylcyclohexasiloxane (D6) CAS No 540-97-6 EC No 208-762-8	1. Shall not be placed on the market (a) as a substance on its own, (b) as a constituent of other substances, or (c) in mixtures in a concentration equal or greater than 0,1 % by weight of the respective substance after [<i>OP, please insert the date: 2 years after the entry into force of this amending Regulation</i>]. 2. Shall not be used as a solvent for the dry cleaning of textiles, leather and fur after [<i>OP, please insert the date: 2 years after the entry into force of this amending Regulation</i>]. 3. By way of derogation: (a) for D4 and D5 in wash-off cosmetic products, paragraph 1, point (c), shall apply after 31 January 2020. For the purposes of this point, ‘wash-off cosmetic products’ means cosmetic products as defined in Article 2(1), point (a), of Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*) that, under normal conditions of use, are washed off with water after application; (b) for leave-on cosmetic products, as defined in point (1)(b) of the Preamble of Annexes II to VI to Regulation (EC) No 1223/2009, paragraph 1 shall apply after [<i>OP, please insert the date: 3 years after the entry into force of this amending Regulation</i>]; (c) for devices as defined in Article 1 (4) of Regulation (EU) 2017/745 of the European Parliament and of the

	Council (**), paragraph 1 shall apply after <i>[OP, please insert the date: 5 years after the entry into force of this amending Regulation]</i>; (d) for medicinal products, as defined in Article 1, point 2, of Directive 2001/83/EC, and for veterinary medicinal products, as defined in Article 4(1) of Regulation (EU) 2019/6(***), paragraph 1 shall apply after <i>[OP, please insert the date: 7 years after the entry into force of this amending Regulation]</i>; (e) for D5 as a solvent in the dry cleaning of textiles, leather and fur, paragraphs 1 and 2 shall apply after <i>[OP, please insert the date: 10 years after the entry into force of this amending Regulation]</i>. 4. By way of derogation, paragraph 1 shall not apply to the: (a) placing on the market of D4, D5 and D6 for the following industrial uses: – as a monomer in the production of silicone polymer; – as an intermediate in the production of other silicone substances; – as a monomer in polymerisation; – in the formulation or (re)packing of mixtures; – in the production of articles; – in non-metal surface treatment; – as laboratory reagent in research and development activities carried out under controlled conditions; (b) placing on the market of D5 and D6 for use as devices, as defined in Article 1(4) of Regulation (EU) 2017/745, for the treatment and care of scars and wounds, the prevention of wounds and the care of stoma;

	(c) placing on the market of D5 for professional use in the cleaning or restoration of art and antiques. 5. By way of derogation, paragraph 1, point (b), shall not apply to the placing on the market of D4, D5 and D6 as a constituent of a polymer where the polymer is for use in the formulation of a mixture derogated under paragraph 6. 6. By way of derogation, paragraph 1, point (c), shall not apply to the placing on the market of mixtures that contain D4, D5 or D6 as residues from silicone polymers, under the following conditions: (a) D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in adhesion, sealing, gluing and casting; (b) D4 in a concentration equal to or less than 0,5 % by weight, or D5 or D6 in a concentration equal to or less than 0,3 % by weight of either substance in the mixture for use as protective coatings (including marine coatings); (c) D4, D5 or D6 in a concentration equal to or less than 0,2 % by weight of the respective substance in the mixture, for use as devices as defined in Article 1 (4) of Regulation (EU) 2017/745; (d) D5 in a concentration equal to or less than 0,3% by weight in the mixture or D6 in a concentration equal to or less than 1 % by weight in the mixture, for use as devices as defined in Article 1(4) of Regulation (EU) 2017/745, for dental impression; (e) D4 in a concentration equal to or less than 0,2 % by weight in the mixture, or D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture for use as silicone insoles for horses, or as horseshoes; (f) D4, D5 or D6 in a concentration

	equal to or less than 0,5 % by weight of the respective substance in the mixture, for use as adhesion promoters; (g) D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in 3D-printing; (h) D5 in a concentration equal to or less than 1 % by weight in the mixture or D6 in a concentration equal to or less than 3 % by weight in the mixture, for rapid prototyping and mould making, or high performance uses stabilised by quartz filler; (i) D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture, for use in pad printing, or manufacturing of printing pads; (j) D6 in a concentration equal to or less than 1 % by weight of the mixture, for professional use in the cleaning or restoration of art and antiques. 7. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for use, or to the use, of D5 as a solvent in strictly controlled closed dry cleaning systems for textile, leather and fur, where the cleaning solvent is recycled or incinerated. (*) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (OJ L 342, 22.12.2009, p. 59). (**) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). (***) Regulation 2019/6 of the European Parliament and of the Council of 11 December 2018 on cosmetic veterinary medicinal products and repealing Directive 2001/82/EC (OJ, L 004, 7.1.2019, p. 43).

Til: Daniel Atli Larsen (EM-DEP) (████@em.dk)
Cc: Koncerncenter (████@em.dk)
Fra: Koncerncenter (████@em.dk)
Titel: Anmodning om udtalelse i forbindelse med behandling af aktindsigtsanmodning
Sendt: 07-06-2023 11:17
Bilag: Samlet materiale.pdf; Ekstraherede oplysninger.docx;

Kære Daniel.

Jeg har modtaget denne henvendelse i hovedpostkassen, er den til dig? ☺

OBS:
*Du skal huske, når du modtager en henvendelse fra den officielle hovedpostkasse, er du **selv** ansvarlig for at oprette sagen, inkl. evt. vedhæftninger og korrespondance i F2.*

Husk altid at svare tilbage til hovedpostkassen, █████@em.dk og aldrig til enkelte personer.

Mvh. Gitte



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Mobil 91 39 94 33



EAN 5798000026001

Fra: Victor Christopher Olsen <████@mim.dk>

Sendt: 7. juni 2023 10:07

Emne: Anmodning om udtalelse i forbindelse med behandling af aktindsigtsanmodning

Til rette vedkommende

Ved e-mail af 25. april 2023 har Ingeniøren anmodet Miljøministeriet om aktindsigt på følgende måde:

"Ingeniøren anmoder i henhold til miljøoplysningsloven om aktindsigt i den nationale handleplan for PFAS for dokumenter/akter oprettet efter 16. december (da jeg sidst bedte om dette). Ring endelig på 28 13 93 58, hvis jeg skal præcisere/indsnævre min anmodning."

Da aktindsigtsanmodningen bl.a. vedrører dokumenter, som Jeres ministerium har været involveret i, skal Miljøministeriet hermed anmode om en udtalelse om, hvorvidt offentlige interesser er til hinder for meddelelse af hel eller delvis aktindsigt i de pågældende dokumenter. Det Miljøministeriet påtænker at udlevere i forbindelse med aktindsigten, er bl.a. en række ekstraherede oplysninger, som er vedhæftet denne e-mail i et særskilt dokument. De dokumenter, der er ekstraheret fra, er også vedhæftet, hvis I har behov for at se kontekst. Derudover påtænker Miljøministeriet at udlevere en række e-mails og oplysninger i en række e-mails. Der henvises til følgende sider i det samlede materiale: s. 5-6, 29-30, 36, 58-59, 61-62, 64-65, 88-89, 91-92, 99-100, 102-103, 105-107, 109-111, 113-114, 141, 143-144, 147-148, 150-151, 180-182, 190-193, 195, 197, 199, 201, 228. Det materiale der *ikke* er markeret i det samlede materiale, er det, der påtænkes udleveret.

Miljøministeriet anmoder venligst om et svar **senest onsdag den 14. juni 2023 kl. 12.00. I bedes vende tilbage til**

undertegnede på e-mail ████@mim.dk.

Venlig hilsen

Victor Christopher Olsen

Fuldmægtig | Jura

+45 21 64 01 39 | ████@mim.dk

Miljøministeriet

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Miljøministeriet
Departementet

Frederik Marcher Hansen
Sendt pr. e-mail til: [redacted]@ing.dk

Jura
J.nr. 2023-4483
Ref. VICCO
Den 24. maj 2023

Ekstraherede oplysninger
Sags. nr. 2023-625.
Akt id 398600

[Miljøministeriet]
[Indenrigs- og Sundhedsministeriet]
[Klima-, Energi- og Forsyningsministeriet]
[Ministeriet for Fødevarer, Landbrug og Fiskeri]
[Erhvervsministeriet]
[Finansministeriet]

De seneste år er vi blevet klogere på udbredelsen af PFAS-forurening. Jo flere steder, vi leder, jo mere finder vi. Der er fundet PFAS i grundvandet, i græs ved Vesterhavet og i isbjørne i Arktis. Stofferne har været brugt i årtier, og problemstillingen er ikke ny.

[Miljøministeriet]
[Indenrigs- og Sundhedsministeriet]
[Klima-, Energi- og Forsyningsministeriet]
[Ministeriet for Fødevarer, Landbrug og Fiskeri]
[Erhvervsministeriet]
[Finansministeriet]

Bilag 3 - Initiativer i national handlingsplan for PFAS i perioden 2024-2026

28. marts 2023

På baggrund af sagen i Korsør i 2021 blev PFAS-indsatsen intensiveret markant. Der er ikke afsat yderligere midler af hertil i MIM. Finansieringen af en styrket indsats mod PFAS, som har involveret en markant styrket overvågning og kontrol har kunnet lade sig gøre midlertidigt pga. omprioriteringen i MIM samt på baggrund af midler i politiske aftaler om bl.a. kemikalieindsats og vandplaner, som ikke er varige midler. Udgifterne til en styrket overvågning og kontrol er varige, og kan ikke alle afholdes inden for ministeriernes egen ramme.

Følgende udgifter kan ikke dækkes inden for MIMs egen ramme ved en fortsættelse af 2022-indsatsen:

Begrænsning af anvendelse af PFAS: 0,35 mio. kr.

I aftale om Kemiindsats 2022-25 er der afsat midler til EU-anvendelsesbegrænsning og nationalt forbud i brandslukningsskum. Herfra er 0,35 mio. kr. i

2022 gået til PFAS-anvendelsesbegrænsning.

Aarhus Universitet oplyser ifm. videnssyntese om biokul i dansk landbrug, at der ikke er tilstrækkelig viden og data til at beskrive,

under hvilke forhold nedbrydning af PFAS sker.

- Håndtering af PFAS i drikkevandet (70 mio. kr. i 2025 og 80 mio. kr. i 2026)
Der afsættes en tilskudspulje på til vandforsyninger, der er udfordret ift. PFAS i drikkevandet, herunder til etablering af afværgeboringer, nye drikkevandsboringer, nødforsyningsledninger samt rensning.

Baggrunden for

initiativer er, at der i de seneste år er set flere forekomster af PFAS i bl.a. drikkevand. Med ændring af drikkevands-bekendtgørelsen af 26. november 2021 blev der fastsat et nyt lavt drikkevandskvalitetskrav for summen af 4 PFAS-stoffer (PFOA, PFOS, PFNA & PFHxS) på 2 ng/L. Vandselskaberne er ansvarlige for, at drikkevandet overholder de fastsatte kvalitetskrav, f.eks. ved rensning eller nye boringer og rørledninger.

Der er pr. 31. januar 2023 fundet PFAS i den seneste drikkevandskontrol hos 99 almene vandforsyninger, hvor én drikkevandskontrol ikke overholder kvalitetskravet (Kyndeløse Strand Vandværk). Erfaringstal fra Fanø Vandværker viser, at det koster ca. 2 kr. pr. kubikmeter at rense for PFAS.

Med ændring af drikkevands-bekendtgørelsen af 26. november 2021 blev der fastsat et nyt lavt drikkevandskvalitetskrav for summen af 4 PFAS-stoffer (PFOA, PFOS, PFNA & PFHxS) på 2 ng/L. Vandselskaberne er ansvarlige for, at drikkevandet overholder de fastsatte kvalitetskrav, f.eks. ved rensning eller nye boringer og rørledninger.

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[Miljøministeriet]

[Indenrigs- og Sundhedsministeriet]

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[Erhvervsministeriet]

[Finansministeriet]

Bilag 4 - Regionernes indsats ift. PFAS

Regionerne har ansvaret for indsatsen omkring jordforurening, herunder kortlægning af forurenede grunde samt oprensning af den kortlagte jordforurening. Ved den offentlige indsats fjernes den risiko, som en jordforurening vurderes at udgøre, for de offentlige indsatsområder – grundvand, menneskers sundhed, overfladevand og natur.

Regionerne modtager årligt i ca. 537 mio. kr. (pl 2023 niveau) til jordforureningsopgaven. Regeringen aftalte med RV, SF, EL og ALT i forbindelse med finansloven for 2021, at der i perioden 2021-2025 skulle afsættes i alt 630 mio. kr. til regionernes arbejde med oprensning af generationsforureningerne for 2021 til 2025. Regionerne fik 20 mio. kr. ekstra årligt fra 2023 til en øget indsats for oprensning af forurenede jord. Danske Regioner havde oprindeligt rejst et DUT-krav på 100 mio. kr. årligt pga. skærpede kvalitetskrav i jord og grundvand til at revurdere allerede kortlagte grunde, hvor der kan forekomme forurening med PFAS.

Regionerne havde pr. maj 2022 systematisk undersøgt ca. 1.200 af disse lokaliteter for PFAS. Af disse er cirka 900 grunde påvist forurenede med stoffet.

Regionerne antager, at omkring 2.500 boliggrunde er omfattet af regionernes kortlægning af potentielle PFAS-forureninger. Danske Regioner har senest i januar 2023 meldt ud, at det kan koste op til 4,5 mia. kr. for regionerne at komme i bund med PFAS-problematikken.

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[Finansministeriet]

National handlingsplan for PFAS

Problem

Der skal tages stilling til indhold og finansiering af handlingsplan for PFAS, [som er lovet i regeringsgrundlaget](#).

Baggrund

PFAS er en gruppe af ca. 10.000 syntetisk fremstillede fluorstoffer, der har været brugt siden begyndelsen af 1950'erne i hele verden. Stofferne er svært nedbrydelige og er vand- og fedtskyende og kan akkumuleres i kroppen hos dyr og mennesker. PFAS bruges i bl.a. i brandslukningsskum, overfladebehandling og imprægnering. Nogle af stofferne er i dag forbudt. Nye målinger har vist PFAS i søvand, drænvand, havskum, dyrevildt og økologiske æg. Herudover har Danske Regioner i 2023 opgjort, at 16.000 grunde er under mistanke for at være forurenede med PFAS, og at der på 104 steder i Danmark er målt over 100 gange så meget PFAS i grundvandet som grænseværdien, [der i 2021 blev sænket med en faktor 50](#). Helbredseffekter af PFAS skaber bekymring, da en høj eksponering bl.a. tyder på at medføre forhøjet kolesterolt, nedsat fødselsvægt, påvirkning af immunforsvaret samt øget risiko for nyrekræft. Helbredsrisikoen for den enkelte vurderes ikke alvorlig sammenlignet med andre risikofaktorer og miljøpåvirkninger, men befolkningens udbredte eksponering giver anledning til bekymring, da der endnu ikke er sikker viden om langtidseffekter, og der er bekymring for, at fremtidig forskning vil pege på flere helbredseffekter. Der indsamles fortsat viden om de sundhedsmæssige langtidsvirkninger og effekter.

Ifølge regeringsgrundlaget skal der fremlægges en national handlingsplan for at afværge, inddæmme og oprense PFAS-forureninger, og at regeringen vil arbejde for et forbud mod PFAS-stoffer på EU-plan og tage initiativer til at begrænse brugen i Danmark samt se på kravene til rensning af spildevand. Nuværende væsentligste initiativer er opsummeret i [boks 1](#).

Boks 1: Igangsatte initiativer vedr. PFAS

- National kortlægning af tidligere brandøvelsespladser (MIM, FMN, Regioner, Kommuner)
- Opsporing af punktkilder (MIM, FMN, Danske Regioner, Kommuner)
- Styrket overvågning af PFAS i drikkevand, badevand, vandløb, søer, fødevarer mv. (MIM, FVM, ISM)
- Sundhedsvurdering af badning i vand med PFAS-indhold (MIM, ISM)
- Skærpelse af kvalitetskravene for PFAS i drikkevand og jord (MIM)
- Vejledende grænseværdier for PFOS i industrispildevand (MIM)
- Ny strategi for miljøfarlige stoffer i vand- og havmiljøet (MIM)
- EU-forslag om at forbyde gruppen af PFAS-stoffer til al brug, som ikke er nødvendig (MIM)
- Grænseværdier for PFAS i visse animalske fødevarer (FVM)
- Forberedelse af grænseværdier for PFAS i spildevandsslam til jordbrugsformål (MIM)
- Nationalt forbud mod PFAS i brandslukningsskum på brandøvelsespladser (MIM)
- Ekspertgruppe for helbredseffekter ved eksponering for PFAS-stofferne (ISM)
- Forskningsprojekt omkring brandfolks udsættelse for PFAS-stofferne (ISM)

· Forskningsprojekt omkring kolesterolsænkende medicin (ISM)

Både stat, regioner og kommuner er involveret i arbejdet med PFAS. Regionerne har gennemført et omfattende arbejde med kortlægning af forurenede grunde, *jf. bilag 45*. Forsvarsministeriets Ejendomsstyrelse meldte i foråret 2022 ud, at 36 af de lokaliteter, hvor der er mistanke om PFAS-forurening, er blevet undersøgt for forekomsten af PFAS.

Undersøgelser af PFAS-forurening på Naturstyrelsens (NST) arealer viser, at 60 ud af 67 lokaliteter har forhøjede koncentrationer.

Rigsrevisionen igangsatte i 2022 en undersøgelse af myndighedernes håndtering af PFAS

Fødevarestyrelsens løbende kontrol af økologiske æg har endvidere medført, at der er fundet PFAS over EU's grænseværdier i et parti æg. Som følge heraf er partiet tilbagekaldt. Kilden til PFAS er fiskemel, som er tilsat foderet i små mængder for at sikre, økologiske høns får den nødvendige proteinforsyning.

Implementering

Miljøministeriet har det overordnede ansvar for den nationale handlingsplan for PFAS. For at sikre implementering af initiativerne i handlingsplanen nedsættes en taskforce bestående af Miljøministeriet, Indenrigs- og Sundhedsministeriet, Ministeriet for Fødevarer, Landbrug og Fiskeri, Danske Regioner, Kommunernes Landsforening, repræsentanter for de danske vandværker og spildevandssektoren samt repræsentanter fra universiteter samt de arbejds- og miljømedicinske klinikker

Akt id. 398599

[Miljøministeriet]

[Indenrigs- og Sundhedsministeriet]

[Klima-, Energi- og Forsyningsministeriet]

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[Erhvervsministeriet]

[Finansministeriet]

Bilag 5 - Grænseværdier for PFAS i spildevandsslam

PFAS i spildevandsslam

Spildevandsslam bruges i dag som gødning i landbruget, da det bl.a. indeholder næringsstoffet fosfor, der er en begrænset, nødvendig og uerstattelig ressource. PFAS fra spildevandsslam udbragt på landbrugsjord kan belaste overfladevand, grundvand og jord. Herfra kan det optages i planter og på den måde spredes til foder og fødevarer. Ca. 90.000 ton spildevandsslam opgjort i tørstof blev i 2020 udbragt på landbrugsarealer, og landbrugere får betaling fra forsyningsselskaber herfor. PFAS i spildevandsslam stammer fra anvendelse af stofferne i industri eller fra diffuse kilder i husholdninger.

I affald til jord-bekendtgørelsen er fastsat grænseværdier for miljøskadelige stoffer, fx tungmetaller, som spildevandsslam skal overholde, hvis det skal anvendes som gødning på landbrugsarealer. Bekendtgørelsen indeholder for nuværende ikke grænseværdier for PFAS.

I dag er der udmeldt vejledende grænseværdier på baggrund af jordkvalitetskriterier. De er på henholdsvis 0,01

mg/kg tørstof for PFAS4, som er fire PFAS stoffer og 0,4 mg/kg tørstof for PFAS22, der dækker 22 stoffer. Ca. 24 pct.% af slammet har vist sig ikke at leve op til den vejledende grænseværdi for PFAS4.

Aarhus Universitet (AU) afleverede i marts 2023 en faglig rapport til Miljøstyrelsen med grundlag for fastsættelse af grænseværdier. Rapporten belyser på hvilket niveau, der kan fastsættes grænseværdier i affald til jordbekendtgørelsen, for at begrænse spredning af PFAS til henholdsvis jord, fødevarer og foder, overfladevand samt grundvand.

Kommunikation

MIM varetager kommunikation om grænseværdierne. FVM, ISM og BM varetager spørgsmål inden for eget ressort, men der koordineres mellem ministerierne, så der er enighed om den overordnede linje.

Implementering og lovgivning

De obligatoriske grænseværdier for PFAS i spildevandsslam implementeres i affald til jord-bekendtgørelsen mhp. at beskytte grundvand, overfladevand, jordmiljøet samt fødevarer og foder.

Akt id 398793

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[Erhvervsministeriet]

[Finansministeriet]

[Forsvarsministeriet]

National handlingsplan for PFAS

Baggrund

PFAS er en stor gruppe af syntetisk fremstillede fluorstoffer, der har været brugt siden begyndelsen af 1950'erne. Stofferne er svært nedbrydelige og er vand- og fedtskyende og mange akkumuleres i kroppen hos dyr og mennesker og findes over alt i verden. PFAS har været brugt i bl.a. fødevareremballage, brandslukningsskum, overfladebehandling og imprægnering af fx tekstiler. Nogle er i dag forbudt. Nogle PFAS-stoffer er bl.a. mistænkt for at være kræftfremkaldende og har skadelige effekter på organer og immunsystemet. De senere år er der målt PFAS forekomster mange steder i miljøet. I enkelte tilfælde har også mennesker været eksponeret for høje doser af stofferne. I en meget omtalt sag fra Korsør har en række borgere indtaget PFOS, som er ét specifikt PFAS stof, ved at spise kød fra kvæg, som har græsset i et område, der tidligere har været brugt til brandslukningsøvelser og derfor var forurenet med PFOS. Andre steder er der konstateret forurening af bl.a. søvand, drænvand, havskum, dyrevildt og økologiske æg. Det fremgår af regeringsgrundlaget "Ansvar for Danmark", at *"Desuden skal sikres konkret opfølgning bag den allerede besluttede nationale handlingsplan for at afværge, inddæmme og oprense PFAS-forureninger."*

[...] Regeringen vil arbejde for et forbud mod PFAS-stoffer på EU-plan og tage initiativer til

begrænsning af brugen i Danmark, ligesom regeringen vil sikre mindre brug af farlige kemikalier,

herunder i forbrugsvarer.

[...] Regeringen vil se på kravene til rensning af spildevandet, så spredning af miljøskadelige stoffer

– herunder PFOS/PFAS – minimeres [...]"

Det bemærkes, at der ikke for nuværende foreligger en national handlingsplan for PFAS, idet den daværende miljøminister i august 2022 meldte ud, at S-regeringen ville have en national strategi for PFAS-forurening, men ikke nåede at fremlægge en plan forud for valgudskrivelsen.

Både stat, regioner og kommuner er involveret i arbejdet med PFAS, jf. boks 1.

Boks 1: Igangsatte initiativer vedr. PFAS

- National kortlægning af tidligere brandøvelsespladser (MIM, FMN, Regioner; Kommuner)
- Opsporing af punktkilder (MIM, FMN, Danske Regioner, Kommuner)
- Styrket overvågning af PFAS i drikkevand, badevand, vandløb, søer, fødevarer mv. (MIM, FVM, SUM)
- Sundhedsvurdering af badning i vand med PFAS-indhold (MIM)
- Skærpelse af kvalitetskravene for PFAS i drikkevand og jord (MIM)
- Ny strategi for miljøfarlige stoffer i vand- og havmiljøet (MIM)
- EU- forslag om at forbyde gruppen af PFAS-stoffer til al brug, som ikke er nødvendig (MIM)
- Grænseværdier for PFAS i visse animalske fødevarer (FVM)
- Forberedelse af grænseværdi for PFAS i spildevandsslam til jordbrugsformål (MIM)
- Nationalt forbud mod PFAS i brandslukningsskum på brandøvelsespladser (MIM)

Regionerne har ansvaret for indsatsen omkring jordforurening, herunder kortlægning af forurenede grunde. I dag modtager regionerne ca. 430 mio. kr. årligt til jordforureningsopgaven og fik 20 mio. kr. ekstra årligt fra 2023 til opgaven, herunder til PFAS.

Naturstyrelsen forvalter i hele landet arealer på mere end 20.000 ha med forpagtnings- eller græsningsaftaler inden for en afstand af 5 kilometer fra kysten.

Forsvarsministeriets Ejendomsstyrelse udmeldte i forbindelse med opdatering af overblikket over brandøvelsespladser i foråret 2022, at 36 af de 52 lokaliteter, hvor der er mistanke om PFAS-forurening er blevet undersøgt for forekomsten af PFAS.

Kommunikation

Miljøministeriet varetager kommunikationen i tæt koordination med Sundhedsministeriet og Ministeriet for Fødevarer, Landbrug og Fiskeri.

Implementering

Miljøministeriet har det overordnede ansvar for den nationale handlingsplan for PFAS. For at sikre implementering af initiativerne i handlingsplanen nedsættes en taskforce bestående af Miljøministeriet, Sundhedsministeriet, Ministeriet for Fødevarer, Landbrug og Fiskeri, Danske Regioner, Kommunernes Landsforening, repræsentanter for de danske vandværker og spildevandssektoren samt repræsentanter

fra universiteter samt de arbejds- og miljømedicinske klinikker, *jf. bilag 1.*

Udkast til handlingsplan for PFAS

1. Indledning

I 2021 blev der fundet høje koncentrationer af PFOS, som er et stof i gruppen af PFAS-stoffer, i spildevand fra Korsør Renseanlæg. Forureningen med PFOS stammede fra den lokale brandskole. På baggrund af PFAS-sagen i Korsør er der, på tværs af stat, regioner og kommuner, sat koordineret fokus på forureningen fra PFAS. Som et af de første skridt blev der lavet et overblik for at lokalisere brandøvelsespladser og steder, hvor der kunne være en sundhedsrisiko som i Korsør. På baggrund af det overblik, er der efterfølgende igangsat flere initiativer og gennemført en øget overvågning af PFAS. Med den kortlægning af PFAS forurening der hidtil er gennemført, er der ikke længere tvivl om, at forureningen med PFAS er omfattende i Danmark, hvilket også er tilfældet globalt. Behovet for en handlingsplan er også tydeliggjort af, at Det Europæiske Fødevareagenturs nye risikovurderinger af stofferne. Vurderingerne har vist, at stofferne er mere sundhedsskadelige end hidtil antaget.

3. PFAS og myndighedssamarbejde

PFAS består af en stor gruppe af syntetisk fremstillede stoffer. Gruppen omfatter bl.a. PFOS (perfluoroktansulfonsyre), PFOA (perfluoroktansyre) og en lang række øvrige fluorerede forbindelser. Gruppen af fluorstoffer har været brugt siden begyndelsen af 1950'erne. Stofferne er generelt stabile og er vand- og fedtskyende. PFAS har været brugt og bruges stadig i mange sammenhænge lige fra fødevareemballage og brandslukningsskum til imprægnering af tekstil og i maling samt i elektronik, smøremidler, transportmidler, produktionsmaskiner og [grøn] energiproduktion, hvor mange

2

anvendelser er industrielle. Stofferne kan måles i lave koncentrationer i blodet på befolkningen overalt i verden og findes på verdensplan i miljø og i fødevarer. Den fælles bekymring for alle PFAS-stoffer er, at de enten selv er svært nedbrydelige eller nedbrydes til andre svært nedbrydelige stoffer. De fleste PFAS-stoffer kan derudover enten ophobes i fødekæden eller er mobile i vand, og begge egenskaber medfører eksponering af både mennesker og miljø. En række PFAS-stoffer har skadelige effekter. De er bl.a. mistænkt for at være kræftfremkaldende og har skadelige effekter på organer og immunsystemet.

Mange forskellige myndigheder er involveret i forhold til overvågning og håndtering af PFASforurening.

Kommuner og regioner har ansvar for at lokalisere steder, der er under mistanke for forurening med PFAS samt for at opspore forureningskilden og indhente relevant rådgivning fra andre myndigheder. Miljøstyrelsen overvåger PFAS og andre miljøfarlige stoffer i miljøet. Fødevarestyrelsen overvåger, kontrollerer og håndterer kemiske forureninger i fødevarer og foder. Derudover rådgiver Fødevarestyrelsen forbrugere omkring fluorstoffer i fødevarer, eksempelvis et kogræsserlaug. Styrelsen for Patientsikkerhed er myndighed på området og rådgiver statslige, regionale og kommunale myndigheder i miljømæssige forhold når der er fundet PFAS i miljøet. Sundhedsstyrelsen afdækker de helbredsmæssige effekter af at være eksponeret for PFAS og udarbejder vejledning om, hvilke eventuelle undersøgelser det anbefales at tilbyde borgere, der har været eksponeret for PFAS.

Drikkevand

Med ændring af drikkevandsbekendtgørelsen blev der i 2021 fastsat et nyt lavt nationalt drikkevandskvalitetskrav for summen af 4 PFAS (PFOA, PFOS, PFNA & PFHxS) på 2 ng/L. Kvalitetskravet for de 4 PFAS er det laveste kvalitetskrav for PFAS i EU, der er fastsat på grundlag af

Den Europæiske Fødevarerikkerhedsautoritets (EFSA) seneste vurdering. For at sikre en ensartet og hurtigere gennemførelse af prøvetagning for PFAS i drikkevand blev der med ændring af drikkevandsbekendtgørelsen i 2022, fastsat en frist for gennemførelse af test for de fire PFAS stoffer med en skærpet kravværdi.

Der vil med implementeringen af EU's reviderede drikkevandsdirektiv blive tilføjet 10 nye PFAS til listen over PFAS som vandværkerne skal kontrollere drikkevandet for. Dermed vil vandværkerne skulle kontrollere drikkevandet for i alt 22 PFAS stoffer.

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Danmarks Tekniske Universitet (DTU) har for Miljøstyrelsen gennemført en undersøgelse af US EPA's (den amerikanske miljøstyrelse) foreløbige ikke-bindende anbefaling om indhold af PFAS i drikkevand på maksimalt 0,02 ng/L for PFOS og 0,004 ng/L for PFOA. DTUs undersøgelse konkluderer, at det danske drikkevandskrav på 2 ng/L er på et rimeligt niveau ud fra nuværende datagrundlag. Det undersøges, om der er behov for at tilføje et kvalitetskrav for GenX i drikkevandsbekendtgørelsen.

Grundvand

Der er siden 2017 blevet overvåget for 12 PFAS i grundvand. I 2021 blev der desuden gennemført en massescreening af grundvand for pesticider og disses nedbrydningsprodukter, hvor der også blev screenet for 22 PFAS-stoffer. Miljøstyrelsen undersøgte grundvand fra 278 borer fordelet over hele landet. Formålet med undersøgelsen var at afdække, hvor udbredt PFAS er i vores grundvand i lyset af den nye grænseværdi. I fire procent af borerne (i alt 11 borer) var den nye PFAS-grænseværdi overskredet. I 20 procent af borerne (55 borer) blev der fundet PFAS under grænseværdien. I 76 procent af borerne (212 borer) blev der ikke fundet PFAS.

EU Kommissionen er kommet med forslag til ændringsdirektiv til vandrammedirektivet, direktiv om miljøkvalitetskrav og grundvandsdirektivet. For grundvand er der forslag om, at optage 24 PFAS på bilag I til grundvandsdirektivet med tilhørende EU kvalitetskrav. Direktivforslaget skal forhandles i 2023-2024.

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Badevand og havskum

Fund af PFAS i havskum og badevand ved Lemvig har ført til, at der i 2022 er gennemført omfattende analyser af PFAS i badevand af Miljøstyrelsen og kommunerne. Miljøstyrelsen har derudover undersøgt indholdet af PFAS i havets overfladelag.

Miljøstyrelsens undersøgelse af forekomsten af PFAS i havvand omfattede 50 udvalgte lokaliteter langs kysterne og havde til formål at afdække, om forekomsten af PFAS er en lokal udfordring ved Lemvig, eller om der er tale om en mere udbredt forurening i kystvandet. Resultaterne af Miljøstyrelsens analyse for PFAS i badevand på 50 badevandslokaliteter viste ingen overskridelser af den vejledende grænseværdi for badevand i prøverne af havvand, men høje koncentrationer af PFAS i prøverne af vandets øverste overfladelag fra to indsøer ved Henne Strand i Varde Kommune.

Styrelsen for Patientsikkerhed har i samarbejde med Miljøstyrelsen vurderet, at badevand, der indeholder under 20 gange drikkevandskvalitetskravet for 4 PFAS (PFOA, PFOS, PFNA og PFHxS), umiddelbart ikke vil udgøre en sundhedsrisiko for badende under danske forhold. Det svarer til en vejledende grænseværdi på 40 ng/L. Miljøstyrelsen opfordrede i 2022 kommunerne til at inkludere undersøgelse for 4 PFAS i deres prøver af badevandskvaliteten. Miljøministeren sendte den 1. juli

2022 et brev til alle landets borgmestre med endnu en opfordring til at udtage -badevandsprøver til analyse for PFAS. I kommunernes undersøgelser er der på en enkelt lokalitet fundet indhold af 4 PFAS på over 40 ng/L i Jammerbugt kommune. I en senere prøve udtaget på samme lokalitet var koncentrationen af 4 PFAS dog under 40 ng/L. Kommunerne skal efter de eksisterende regler analysere for PFAS og andre miljøfarlige forurenede stoffer, hvis der er kendskab til forurenende kilder.

EU's

badevandsdirektiv stiller ikke krav til at EU-lande skal medtage PFAS i klassificeringen af badevand. Derfor findes der ikke en EU-opgørelse over situationen af PFAS i badevand. Miljøministeriet har oplyst andre EU-lande om, at Danmark måler for PFAS i badevandet til inspiration for, at andre lande kan lave lignende målinger og efterspørger viden omkring målinger for PFAS i badevand for at kunne sammenligne koncentrationen af PFAS i det danske badevand med andre turistedestinationer.

Overfladevand

I NOVANA-programmet overvåges PFAS i fisk i vandløb, søer og kystvande. Miljøstyrelsen har i 2021 og 2022 intensiveret overvågningen af miljøfarlige stoffer i overfladevand herunder overvågning af PFAS i det ferske vandmiljø.

Miljøstyrelsen iværksatte ud over det almindelige NOVANA-program i 2021 en screeningsundersøgelse for PFAS i fisk og vand fra vandløb nær brandøvelsespladser.

Miljøstyrelsen gennemfører desuden i 2022 og 2023 et projekt om opsporing af kilder til forurenende stoffer i et testoplund, herunder 22 PFAS.

Miljøstyrelsen er derudover ved at gennemføre et projekt, som skal belyse udvekslingen af PFAS mellem sediment og vand i et ferskvandsmiljø og mulige kilder til PFAS-forurening

Et dansk partnerskab med repræsentanter fra myndigheder, erhverv og organisationer arbejder frem mod 2024 bidrage til at identificere og prioritere de væsentligste miljøfarlige stoffer og kilderne til dem samt relevante virkemidler mod problematiske stoffer i vandmiljøet, herunder PFAS. Partnerskabet skal konkret bidrage med anbefalinger til en prioritering af stoffer, for hvilke der skal udarbejdes nye miljøkvalitetskrav og afdække kildeopsporingsbehov, teknologiudviklingsbehov og nye reguleringsbehov.

Havvand

PFOS er i de regionale havkonventioner HELCOM og OSPAR udpeget som indikatorstof. Det betyder at tilstanden for stoffet følges i hhv. Østersøen og Nordøst Atlanten. I HELCOM er der netop indgået en aftale om en regional handlingsplan, som spænder over de næste 10 år. Den indebærer blandt andet, at Danmark sammen med de andre lande omkring Østersøen samarbejder om at mindske brugen af PFAS i brandslukningsskum til havs samt fremme brugen af alternativer.

Spildevand

Miljøstyrelsen er i gang med at revidere vejledning om tilslutning af industrispildevand til offentlige spildevandsanlæg, hvilket blandt andet omfatter vejledende grænseværdier for en række miljøfarlige forurenende stoffer, herunder PFOS.

De vejledende grænseværdier tager udgangspunkt i miljøkvalitetskravene for overfladevand for det pågældende stof. Der er på nuværende tidspunkt ikke fastlagt miljøkvalitetskrav for andre per- og polyfluorerede stoffer end PFOS.

Miljøstyrelsen vil før sommeren 2023 desuden opdatere vejledningen til kommunerne vedrørende håndtering af miljøfarlige stoffer i spildevandet fra forsyningernes renseanlæg, herunder PFOS. Miljøstyrelsen

gennemfører sammen med DANVA en analyse af PFAS-data i indløb- og udløbsprøver fra 89 renseanlæg.

Miljøstyrelsen har i 2022 igangsat et toårigt innovationspartnerskab med fokus på udvikling af miljøteknologi, der kan reducere udledningen af miljøfarlige stoffer. Innovationspartnerskabet består af forsyninger, teknologileverandører, virksomheder med udledninger til offentlig eller eget renseanlæg, rådgivere, vidensinstitutioner og brancheforeninger.

Fisk i vandløb, søer og kystvande

I NOVANA-programmet overvåges for PFAS i fisk i vandløb, søer og kystvande. Der er siden 2017 blevet overvåget for 12 PFAS-stoffer i grundvand. Miljøstyrelsen iværksatte i 2021 en screeningsundersøgelse for PFAS i fisk og vand fra vandløb ved brandøvelsespladser. Der er iværksat ekstra overvågning af PFAS i fisk i 2022 på Fyn og Skjern Å)

Der er fokus på havvand og havskum, dels som årsag til forurening med PFAS på land, dels i forhold til betydningen for sundheden (havskum). Der er i 2022 iværksat et projekt om spredning af PFAS fra hav til land.

For at sikre viden om forurening med PFAS indsamlede Miljøstyrelsen i september 2022 prøver på 20 stationer i Nordsøen. Analyserne omfatter de 22 PFAS-forbindelser, som er undersøgt på de 50 badevandsstationer.

Luft

Sverige har gennemført et større studie af PFAS i affaldsstrømmen fra affaldsforbrændingsanlæg. Der blev målt på bundaske, flyveaske og kondensat. Konklusionen i rapporten var, at niveauerne generelt var lave, men der var enkelte værker, der havde højere værdier. På den baggrund har Vestforbrænding og Amager Ressource Center lavet en række målinger, hvor der ikke er påvist nogen af de 22 forskellige PFAS, som der er analyseret for.

Regnvand

TV 2 Nyhederne har fundet spor af PFAS i fire ud af fem regnvandsprøver, der blev indsamlet af TV 2 Vejret og analyseret af det akkrediterede laboratorium Eurofins. Højeste værdi var i Lyngby, hvor regnen indeholdt 1,5 nanogram PFAS pr. liter. Grænseværdien er 2 nanogram pr. liter. Miljøstyrelsen overvejer et midlertidigt måleprogram for regnvand.

Vildt

Miljøstyrelsen har i samarbejde med Naturstyrelsen og Danmarks Jægerforbund i 2022 indsamlet en mindre stikprøve af vildt til analyse for PFAS. Miljøstyrelsen har løbende i forbindelse med indsamling og efterfølgende analyser drøftet analyseresultaterne med Fødevarestyrelsen, der bl.a. har ansvaret for grænseværdier for PFAS i vildt.

Jord og sediment

Miljøstyrelsen har sænket jordkvalitetskriterier og det tilhørende grundvandsvandskriterie for PFAS. Ligeledes har Miljøstyrelsen udvidet antallet af PFAS i det allerede gældende sumkriterie for PFAS i jord og grundvand, så antallet af stoffer er hævet fra 12 til 22.

Miljøstyrelsens teknologipulje har i 2022 haft fokus på projekter om PFAS. Der er igangsat fire projekter med fokus på oprensning af PFAS i jord og grundvand, samt seks projekter om vidensopsamling, kildeopsporing og spredningsveje, deriblandt spredning af PFAS fra hav til land og diffus forurening med PFAS i jord.

Puljen udbydes igen i 2023, hvor der fortsat vil være fokus på PFAS, både i forhold til oprensningsteknologier, vidensopsamling, kildeopsporing og spredningsveje. Miljøministeriet vil derudover sikre, at der udarbejdes en plan for håndtering, bortskaffelse og oprensning af jord forurenede med PFAS.

Der er i dag ikke fastsat aktionsniveauer (koncentrationsniveauer) for PFAS i materiale, der skal genplaceres på havbunden (klapning). Miljøstyrelsen er i gang med at revidere den eksisterende vejledning om klapning. Revisionen vil bl.a. indeholde en gennemgang/servicetjek af de eksisterende aktionsniveauer.

Spildevandsslam

Der er i dag ikke fastsat grænseværdier for PFAS i spildevandsslam i affald til jord-bekendtgørelsen. Miljøstyrelsen har i oktober 2021 udsendt et brev til kommuner og interessenter om foreløbige vejledende grænseværdier for PFAS i spildevandsslam til jordbrugsformål. Den foreløbige vejledende grænseværdi for summen af 4 PFAS (PFOA, PFOS, PFNA og PFHxS) er 0,01 mg/kg tørstof, mens den foreløbige vejledende grænseværdi for summen af 22 PFAS-stoffer er 0,4 mg/kg tørstof. DCE på Århus Universitet er aktuelt ved at foretage en risikovurdering af Miljøstyrelsens vejledende grænseværdier, herunder forudsætningerne bag grænseværdierne.

Miljøstyrelsen har desuden fået foretaget en undersøgelse, hvor spildevandsslam blev analyseret for en række miljøfarlige stoffer, herunder PFAS. Sideløbende hermed har Miljøstyrelsen i efteråret 2022 igangsat et initiativ om analyse af fremtidig slamhåndtering til gavn for miljø og klima. Her undersøges teknologier til håndtering af PFAS-forurenede slam. Initiativet har til formål at afdække, hvordan spildevandsslam skal håndteres i fremtiden. Miljøstyrelsen forventer, at analyse af fremtidig slamhåndtering til gavn for miljø og klima er færdig primo 2023, og endelige tiltag og anbefalinger udarbejdes i løbet af 2023.

Miljøstyrelsen har yderligere en undersøgelse af PFAS og fluorstoffers skæbne ved forbrænding af slam under forberedelse til gennemførelse i 2023.

Der er derudover i 2022

givet støtte til et TUP-projekt om, hvorvidt udbringning af spildevandsslam på landbrugsjord kan medføre en uacceptabel påvirkning af grundvandet. Dette sker ved feltundersøgelser og analyser for primært PFAS. En del af undersøgelserne vil finde sted på KUs forsøgsmarker i Taastrup, hvor der gennem 20 år er lavet forsøg med spildevandsslam. Projektet forventes afsluttet ultimo 2023.

Affald

For at få viden om PFAS i forskellige bygge- og anlægsaffaldsfraktioner, har Miljøstyrelsen igangsat screeninger på en række områder. Dette gælder for deponerede vindmøllevinger, slagge fra affaldsforbrændingsanlæg og mineraluld. Resultaterne forventes offentliggjort i 1. halvår af 2023. Miljøstyrelsen er ligeledes ved at igangsætte yderligere analyser på området, herunder af beton, tegl, asfalt, samt ift. genbrug af møbler.

Derudover har Miljøstyrelsen igangsat en screeningsundersøgelse af udvaskningen af PFAS og andre miljøfarlige stoffer fra elektronikaffald. Resultaterne fra denne undersøgelse vil blive offentliggjort i første kvartal af 2023 sammen med forslag til mulige tiltag mhp. at håndtere udvaskning fra elektronikaffald.

Der er udarbejdet kommunikationsmateriale til kommunernes brug i forbindelse med, at borgerne fra 1. juli 2023 skal sortere tekstilaffald. Tekstilaffald, hvor der er stor risiko for indhold af PFAS f.eks. imprægneret overtøj og regntøj, skal ikke sorteres til genanvendelse jf. Vejledning om sorteringskriterier for husholdningsaffald.

Fødevarer og foderstoffer

Fødearestyrelsen gennemfører en vurdering af risici ift. PFAS samt håndtering af et indhold, der vurderes at udgøre en risiko i:

- fødevarer
- foderstoffer

Naturstyrelsen og Miljøstyrelsen i januar 2023 offentliggjorde en stikprøveundersøgelse af græs- og vandprøver. Prøverne var taget på arealer forvaltet af Naturstyrelsen og bortforpagtet til græsning og slet. Resultaterne viste, at græs på 60 ud af de 67 lokaliteter lå over Fødearestyrelsens PFAS indikationsværdier for kødkvæg, og her blev en opfølgende kontrol af græsningsdyrene iværksat.

Helbredseffekter af PFAS

Sundhedsstyrelsen nedsatte i efteråret 2021 en ekspertgruppe, der består af førende forskere samt repræsentanter fra de arbejds- og miljømedicinske afdelinger, Dansk Selskab for Almen Medicin, Styrelsen for Patientsikkerhed og Korsør Kogræsser- og Naturplejeforening. Ekspertgruppen har rådgivet Sundhedsstyrelsen i arbejdet med at klarlægge helbredseffekter af eksponering for PFAS. Derudover er der udarbejdet vejledningsmateriale til praktiserende læger samt borgere der har været eksponeret for PFAS. Der er desuden udarbejdet en rapport om helbredseffekter af PFOA, PFNA, PFOS og PFHxS.

4.2. Sikre viden- og erfaringsudveksling

Samarbejde med USA

Miljøministeriet har indledt et myndighedssamarbejde med USA om PFAS, herunder særligt Californien. Californien har stor fokus på PFAS og har bred erfaring med særligt overvågning og kildesporing samt risikovurdering og forbrugersikkerhed, og arbejder desuden også med teknologiudvikling.

MST konference

Miljøstyrelsen vil i 2023 afholde en større konference om PFAS med eksterne deltagere. Konferencen skal samle relevante forskere, myndigheder, virksomheder, rådgivere og eventuelle øvrige interessenter, der arbejder med PFAS i Danmark.

4.3. Begrænse brugen af PFAS i Danmark og EU

Forslag om EU-forbud mod anvendelse af PFAS

Danmark, Tyskland, Holland, Norge og Sverige indsendte den 13. januar 2023 et forslag til et EUforbud

mod PFAS til Det Europæiske Kemikalieagentur (ECHA). Forslaget kommer, efter at myndighederne i de fem lande siden 2020 har undersøgt anvendelsen af PFAS, alternativer til PFAS og stofferne kan påvirke mennesker og miljøet. Forslaget er fremsat under den generelle europæiske kemikaliereregulering, REACH, hvis begrænsningsproces giver medlemsstater mulighed for at fremsætte forslag til forbud mod fremstilling, markedsføring og anvendelse samt mulighed for undtagelser. Forslaget er det mest omfattende forslag til begrænsning af kemikalier i EU nogensinde. Det omfatter ca. 12.000 stoffer og en lang række anvendelsessektorer, herunder mange forskellige forbrugerprodukter, og en lang række anvendelser i industrien fx elektronik-, transport-, energi-, og fødevarersektoren. På grund af stoffernes brede anvendelse på tværs af sektorer, handel af produkter på tværs af grænser og forureningens grænseoverskridende karakter, så vil den bedste beskyttelse af miljø og sundhed samt de bedste rammevilkår for danske virksomheder opnås med fælles EU regler.

Forslaget bygger på:

- En bekymring om, at stofferne stort set ikke nedbrydes i miljøet, og at nogle af stofferne, efterhånden som der opnås mere viden om dem, har vist sig at have skadelige effekter på mennesker og miljø.
- Fastsættelse af overgangsperioder afhængigt af, hvor tilgængelige alternativerne er, samt om alternativerne har de nødvendige egenskaber. Der forventes en række tidsbegrænsede undtagelser for forbuddet, der vil finde anvendelse på forskellige tidspunkter efter ikrafttrædelsen. Derudover er der undtagelser for anvendelser, som er omfattet af anden lovgivning.

Forslaget skal nu behandles i Kemikalieagenturets videnskabelige ekspertkomitéer, herunder i 6 måneders offentlig høring. Når ekspertkomitéernes vurdering er klar sendes den til EUKommissionen. Forslaget forventes tidligst vedtaget i 2025. Da der er tale om en forordning, skal forbuddet ikke implementeres i dansk lovgivning, men vil være direkte gældende i hele EU, når forordningen træder i kraft.

PFOS i brandslukningsskum i den maritime industri

Ved forhandlinger i den Internationale Maritime Organisation (IMO) i foråret 2022 blev nuværende internationale regler revideret med henblik på et forbud mod brugen af PFOS til brandslukning i den maritime industri.

De nye regler træder i kraft pr.

1. januar 2026, såfremt vedtaget, dog med den undtagelse at eksisterende skibe først skal opfylde kravet ved førstkommende synsinterval efter 1. januar 2026.

Forslag om EU-forbud mod anvendelsen af PFAS i brandslukningsskum og mulighed for midlertidige nationale forbud

Det Europæiske Kemikalieagentur (ECHA) indsendte i 2022 forslag om EU-forbud mod PFAS i brandslukningsskum. Miljøministeriet har gennemført et projekt der undersøger anvendelsen af PFAS-holdigt brandslukningsskum på danske øvelsespladser, og resultaterne indgik i vurderingen af muligheden for tidligere national udfasning af denne anvendelse. Udkast til bekendtgørelse om forbud mod import, salg og anvendelse af PFAS-holdigt brandskum på øvelsespladser, [forventes][blev] sendt i høring i foråret 2023 med forventet ikrafttrædelse 1. januar 2024. Et markedsføringsforbud vil normalt stille danske og udenlandske virksomheder ens. Miljøministeren har sendt brev til øvelsespladserne med opfordring til tidligere frivillig udfasning. Forslaget til EU-forbud mod PFAS i brandslukningsskum er under behandling i ECHA's videnskabelige ekspertkomitéer.

I det forslag til EU-forbud mod PFAS, som Danmark, Nederlandene, Tyskland, Sverige og Norge har indsendt, indgår tekstiler.

Globalt forbud

PFAS'erne 'C9-C21 PFCA'er' er nomineret til optagelse under Stockholmkonventionen og er under vurdering i konventionens ekspertgruppe. Stofferne kan tidligst optages under konventionen på partsmødet i 2025. Danmark

PFAS er anerkendt som en stofgruppe af global bekymring i regi af FNs miljøprogram, UNEP, og i OECD, hvor indsatsen samlet skal bidrage til en global overgang til sikre alternativer.

4.4. Sikre at forvaltning og regulering understøtter at udledning af PFAS til miljøet begrænses

Der er i 2021 og 2022 gennemført en omfattende opsporing af punktkilder samt kvantificering af tilførsel af miljøfarlige forurenende stoffer fra diffuse kilder til vandmiljøet. Herudover er der udarbejdet en strategi for miljøfarlige stoffer i vand- og havmiljøet, som bl.a. skal skabe et bedre overblik over kilder til miljøfarlige stoffer, og hvilke virkemidler der skal til for at begrænse disse. Som en del af strategien er også nedsat et partnerskab for miljøfarlige stoffer på tværs af myndigheder og interessenter. Miljøstyrelsen har i 2021 kontrolleret for udvalgte PFAS'er i tekstiler og produkter som smøreolier, voks og polish og i 2022 i bl.a. håndbrandslukkere.

På baggrund af resultater fra kortlægning og overvågningen af PFAS-forureningen samt bedst tilgængelig viden om bl.a. spredningsveje, kilder og renseteknologiske løsninger mv. for PFAS vil regulering og forvaltning i Danmark løbende blive opdateret og justeret i forhold til at tage nødvendige skridt til at begrænse menneskelig eksponering.

5. Organisation

Miljøministeriet har det overordnede ansvar for gennemførelse og opfølgning på handlingsplanen for PFAS. I tilknytning til handlingsplanen nedsættes en taskforce bestående af

- en række ministerier med tilhørende styrelser, herunder Miljøministeriet, Sundhedsministeriet, Ministeriet for Fødevarer, Landbrug og Fiskeri
- Danske Regioner og Kommunernes Landsforening
- repræsentanter for de danske vandværker og spildevandssektoren
- repræsentanter fra de arbejds- og miljømedicinske klinikker.

Bæredygtigt Miljø og

Produktion

J.nr. 2023-625

Ref. HPE

Den 24. januar 2023

[Miljøministeriet]

Bilag x. Grænseværdier for PFAS i spildevandsslam

24. januar 2023

PFAS i spildevandsslam

Spildevandsslam bruges i dag som gødning i landbruget, da det bl.a. indeholder næringsstoffet fosfor, der er en begrænset, nødvendig og uerstattelig ressource. PFAS fra spildevandsslam udbragt på landbrugsjord kan belaste overfladevand, grundvand og jord. Herfra kan det optages i planter og på den måde spredes til foder og fødevarer. Ca. 90.000 ton spildevandsslam opgjort i tørstof blev i 2020 udbragt på landbrugsarealer, og landbrugere får betaling fra forsyningsselskaber herfor. Spildevandsslam kan dog indeholde PFAS fra anvendelse af stofferne i industri eller fra diffuse kilder i husholdninger. I affald til jord-bekendtgørelsen er fastsat grænseværdier for miljøskadelige stoffer, fx tungmetaller, som spildevandsslam skal overholde, hvis det skal anvendes som gødning på landbrugsarealer. Bekendtgørelsen indeholder for nuværende ikke grænseværdier for PFAS.

I dag er der udmeldt vejledende grænseværdier på baggrund af jordkvalitetskriterier. De er på henholdsvis 0,01 mg/kg tørstof for PFAS4, som er fire PFAS stoffer og 0,4 mg/kg tørstof for PFAS22, der dækker 22 stoffer.

Aarhus Universitet (AU) afleverer [primo februar] 2023 en faglig rapport til Miljøstyrelsen med grundlag for fastsættelse af grænseværdier. Rapporten vil belyse på hvilket niveau, der kan fastsættes grænseværdier i affald til jord-bekendtgørelsen, for at begrænse spredning af PFAS til henholdsvis jord, fødevarer og foder, overfladevand samt grundvand.

Grænseværdierne skal træde i kraft i løbet af 2023 efter implementering i affald til jord-bekendtgørelsen.

Implementering og lovgivning

Grænseværdierne implementeres i affald til jord-bekendtgørelsen.

Akt id. 398756
[For en del af de ekstraheringspligtige
oplysninger er der ekstraheret fra akt id.
398793 og 398599, som der henvises til]

[Miljøministeriet]

[Sundhedsministeriet]

[Klima-, Energi- og Forsyningsministeriet]

[Ministeriet for Fødevarer, Landbrug og Fiskeri]

[Erhvervsministeriet]

[Finansministeriet]

[Forsvarsministeriet]

National handlingsplan for PFAS

XX. januar 2023

PFAS er en stor gruppe af ca. 4.700 af syntetisk fremstillede fluorstoffer, der har været brugt siden begyndelsen af 1950'erne. Stofferne er svært nedbrydelige og er vand- og fedtskyende og mange en stor del akkumuleres i kroppen hos dyr og mennesker. og findes over alt i verden. PFAS har været brugt i bl.a. fødevareemballage, brandslukningsskum, overfladebehandling og imprægnering af fx tekstiler. Nogle Nogle PFAS-stoffer er bl.a. mistænkt for at være kræftfremkaldende og har skadelige effekter på organer og immunsystemet. Af den grund er Nogle enkelte PFAS-stoffer er i dag forbudt..

. De senere år er der målt PFAS forekomster mange steder i miljøet Danmark. I enkelte tilfælde har også mennesker været eksponeret for høje doser af stofferne. I en meget omtalt sag fra Korsør har en række borgere indtaget PFOS, som er ét specifikt PFAS stof, ved at spise kød fra kvæg, som har græsset i et område, der tidligere har været brugt til brandslukningsøvelser og derfor var forurenet med PFOS. Andre steder er der konstateret forurening af bl.a. søvand, drænvand, havskum, dyrevildt og økologiske æg.

Det fremgår af regeringsgrundlaget, ”Ansvar for Danmark”, at der skal fremlægges en national handlingsplan for PFAS, at regeringen vil arbejde for et forbud mod PFAS-stoffer på EU-plan og begrænse brugen i Danmark, samtog slutteligt se på kravene til rensning af spildevandet.

Det bemærkes, at der ikke forFor nuværende foreligger ikke en national handlingsplan for PFAS, idet idet den daværende miljøminister i august 2022 meldte ud, at S-regeringen ville ønskedehave en national strategi for PFAS-forurening, men ikke nåede at fremlægge en plan forud for valgudskrivelsen.

Både stat, regioner og kommuner er involveret i arbejdet med PFAS, jf. hvor de nuværende igangsatte initiativer er opsummeret i jf. boks 1.

Boks 1: Igangsatte initiativer vedr. PFAS

- ☐ National kortlægning af tidligere brandøvelsespladser (MIM, FMN, Regioner; Kommuner)
- ☐ Opsporing af punktkilder (MIM, FMN, Danske Regioner, Kommuner)
- ☐ Styrket overvågning af PFAS i drikkevand, badevand, vandløb, søer, fødevarer mv. (MIM, FVM, SUM)
- ☐ Sundhedsvurdering af badning i vand med PFAS-indhold (MIM)
- ☐ Skærpelse af kvalitetskravene for PFAS i drikkevand og jord (MIM)
- ☐ Ny strategi for miljøfarlige stoffer i vand- og havmiljøet (MIM)
- ☐ EU- forslag om at forbyde gruppen af PFAS-stoffer til al brug, som ikke er nødvendig (MIM)
- ☐ Grænseværdier for PFAS i visse animalske fødevarer (FVM)
- ☐ Forberedelse af grænseværdi for PFAS i spildevandsslam til jordbrugsformål (MIM)
- ☐ Nationalt forbud mod PFAS i brandslukningsskum på brandøvelsespladser (MIM)

Regionerne har ansvaret for indsatsen omkring jordforurening, herunder kortlægning af forurenede grunde samt oprensning af den kortlagte jordforurening.. I 2021 dag modtager prioriterede regionerne ca. 340430 430 mio. kr. årligt til jordforureningsopgaven ud af en ramme til regional udvikling på ca. 2,6 mia. kr. Regionerne og fik 20 mio. kr. ekstra årligt fra 2023 til opgavensfa. ændrede kvalitetskrav i jord og grundvand, som bla. har ført til, herunder til PFAS. De skærpede kvalitetskrav i jord og grundvand har ført til, at regionerne må revurdere allerede kortlagte grunde, hvor der kan forekomme forurening med PFAS. Regeringen prioriterede herudover 630 mio. kr. ifm. FL21med Finansloven for 2021 til understøttelse af

regionernes arbejde med oprensning af generationsforureningerne for 2021 til 2025.

Regionerne havde pr. maj 2022 kortlagt og systematisk undersøgt ca. 1200 af disse lokaliteter for PFAS. Af disse er cirka 900 grunde påvist forurenede med det giftige stof. Danske Regioner har oprenset [xx] af disse grunde. Grundet begrænset viden og øget fokus på mulig jordforurening med PFAS på boliggrunde, kan der blive behov for midler til at fremme en hurtigere indsats for boliggrunde, der er kortlagt pga. potentiel forurening med PFAS. Det antages, at omkring 2.500 boliggrunde er omfattet af regionernes kortlægning af potentielle PFAS-forureninger. I foråret 2022 var 36 af de 52 lokaliteter, hvor der er mistanke om PFAS-forurening fra brandøvelsespladser, er blevet undersøgt for forekomsten af PFAS. Danske Regioner har senest i januar 2023 meldt ud, at det kan koste op til 4,5 milliarder kroner at komme i bund med PFAS-problematikken.

Implementering

Miljøministeriet har det overordnede ansvar for den nationale handlingsplan for PFAS. For at sikre implementering af initiativerne i handlingsplanen nedsættes en taskforce bestående af Miljøministeriet, Sundhedsministeriet, Ministeriet for Fødevarer, Landbrug og Fiskeri, Danske Regioner, Kommunernes Landsforening, repræsentanter for de danske vandværker og spildevandssektoren samt repræsentanter fra universiteter samt de arbejds- og miljømedicinske klinikker, *jf. bilag 1*.

Akt id. 398734 **[For de ekstraheringspligtige oplysninger** **er der ekstraheret fra akt id. 398756, som** **der henvises til]**

Akt id. 398705 **[For en del af de ekstraheringspligtige** **oplysninger er der ekstraheret fra akt id.** **398793 og 398600, som der henvises til]**

Bilag 2

Bæredygtigt Miljø og
Produktion
J.nr. 2023-625
Ref. HPE
Den 6. februar 2023

Udgifter til national handlingsplan for PFAS i 2023

Bilag 3

Bæredygtigt Miljø og
Produktion
J.nr. 2023-625
Ref. HPE

Den 6. februar 2023

[Miljøministeriet]

Bilag x. Grænseværdier for PFAS i spildevandsslam

2. februar 2023

Akt id. 398682

[For en del af de ekstraheringspligtige oplysninger er der ekstraheret fra akt id. 398599, 398600 og 398793, som der henvises til]

Bilag 3

Bæredygtigt Miljø og
Produktion
J.nr. 2023-625
Ref. HPE
Den 6. februar 2023

Akt id. 398681

[For en del af de ekstraheringspligtige oplysninger er der ekstraheret fra akt id. 398600, som der henvises til]

Akt id. 398804

[For en del af de ekstraheringspligtige oplysninger er der ekstraheret fra akt id. 398600 og 398793, som der henvises til]

Bilag 2

Bæredygtigt Miljø og
Produktion
J.nr. 2023-625
Ref. HPE
Den 6. februar 2023

Bilag 3

Bæredygtigt Miljø og
Produktion
J.nr. 2023-625
Ref. HPE
Den 6. februar 2023

Akt id. 398803 **[For en del af de ekstraheringspligtige** **oplysninger er der ekstraheret fra akt id.** **398600 og 398599, som der henvises til]**

[Miljøministeriet]
[Indenrigs- og Sundhedsministeriet]
[Klima-, Energi- og Forsyningsministeriet]
[Ministeriet for Fødevarer, Landbrug og Fiskeri]
[Erhvervsministeriet]
[Finansministeriet]

Initiativer i national handlingsplan for PFAS i perioden 2024-2026

[[Miljøministeriet]
[Indenrigs- og Sundhedsministeriet]
[Klima-, Energi- og Forsyningsministeriet]
[Ministeriet for Fødevarer, Landbrug og Fiskeri]
[Erhvervsministeriet]
[Finansministeriet]

Initiativer i regeringens nationale handlingsplan for PFAS

Miljøministeriet]
[Indenrigs- og Sundhedsministeriet]
[Klima-, Energi- og Forsyningsministeriet]
[Ministeriet for Fødevarer, Landbrug og Fiskeri]
[Erhvervsministeriet]
[Finansministeriet]

Fortælling om national handlingsplan for PFAS

28. marts 2023



Miljøministeriet

Aktdetaljer

Akttitel: SV: Frist den 14. april 2023: Endeligt udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Aktnummer: 39

Akt ID: 398600

Dato: 14-04-2023 20:16:32

Type: Indgående

Dokumenter:

- [1] SV Frist den 14. april 2023 Endeligt udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag.eml
- [2] Bilag 1 - Fortælling om national handlingsplan for PFAS.docx
- [3] Bilag 2 - Initiativer i regeringens handlingsplan for PFAS.docx
- [4] Bilag 3 - Detaljeret beskrivelse initiativer og budget PFAS handlingsplan.docx
- [5] Bilag 4 - Regionernes indsats.docx
- [6] Cover - PFAS-handlingsplan.docx

Den 27. april 2023

Til: Helle Winther (■■■■@mim.dk), Paolo Drostby (■■■■@fvm.dk), ■■■■@fmn.dk (■■■■@fmn.dk), Anders Terp Bekhøj (■■■■@bm.dk), ■■■■@bm.dk (■■■■@bm.dk), Anitta Hilda Vandman Bugenhagen (■■■■@sm.dk), Kathrine Bløcher (■■■■@kefm.dk), Trine Vig Houe (■■■■@SUM.DK), Cecilie Solstad (EM-DEP (■■■■@em.dk), ■■■■@bm.dk (■■■■@bm.dk))

Cc: Kristine Raunkjær Stubdrup (■■■■@mim.dk), ■■■■@fvm.dk (■■■■@fvm.dk), Henrik Søren Larsen (■■■■@mim.dk), Janne Birk Nielsen (■■■■@mim.dk), Charlotte Brøndum (■■■■@mim.dk), Katrine Rafn (■■■■@mim.dk), Katrine Nissen (■■■■@mim.dk), Lea Frimann Hansen (■■■■@mim.dk), Nina Porst (■■■■@mim.dk), Ulrik Duus Gjessing (■■■■@mim.dk), Hans Prytz Henriksen (■■■■@fvm.dk), Daniel Atli Larsen (EM-DEP) (■■■■@em.dk), Maria Petersen Ølholm (■■■■@SUM.DK), Benedikte Zwicky Bønløkke (EM-DEP (■■■■@em.dk), Rasmus Mathorne Madsen (■■■■@kefm.dk)

Fra: ■■■■@fm.dk (■■■■@fm.dk)

Titel: SV: Frist den 14. april 2023: Endeligt udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Sendt: 14-04-2023 20:16

Bilag: Bilag 1 - Fortælling om national handlingsplan for PFAS.docx; Bilag 2 - Initiativer i regeringens handlingsplan for PFAS.docx; Bilag 3 - Detaljeret beskrivelse initiativer og budget PFAS handlingsplan.docx; Bilag 4 - Regionernes indsats.docx; Cover - PFAS-handlingsplan.docx;

Kære Helle

Tak for denne. Hermed bemærkninger fra FM. Jeg har ikke nået bilag om spildevandsslam. Det følger enten senere i aften eller i morgen.

Bemærk at jeg har ændret bilagsnumrene, da jeg ikke rigtig synes, at det giver mening at kalde cover for bilag 1.

Med venlig hilsen

Frederik



Frederik Olund Kirkegaard

Fuldmægtig

Center for Klima, Grøn Økonomi og EU (KGE)

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Du bedes venligst være opmærksom på, at Finansministeriet ved modtagelsen af din henvendelse behandler de personoplysninger om dig, der fremgår af beskeden. Dette sker som led i Finansministeriets myndighedsudøvelse. Du kan læse mere om, hvordan Finansministeriet behandler dine personoplysninger, og hvilke rettigheder du har som registreret mv. i ministeriets privatlivspolitik: <https://www.fm.dk/om-os/privatlivspolitik>

Fra: Helle Winther <■■■■@mim.dk>

Sendt: 31. marts 2023 11:32

Til: Paolo Drostby <■■■■@fvm.dk>; ■■■■@fmn.dk; Anders Terp Bekhøj <■■■■@bm.dk>; Louise Anker Pedersen <■■■■@bm.dk>; Anitta Hilda Vandman Bugenhagen <■■■■@sm.dk>; Frederik Olund Kirkegaard <■■■■@fm.dk>; Kathrine Bløcher <■■■■@kefm.dk>; Trine Vig Houe <■■■■@SUM.DK>; Cecilie Solstad (EM-DEP) <■■■■@em.dk>; Louise Anker Pedersen <■■■■@bm.dk>

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Emne: Frist den 14. april 2023: Endeligt udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære alle

Vedlagt finder i et sidste udkast til ØU-cover incl. bilag forud for endelig clearing.



Aktdetaljer

Akttitel: SV: Frist den 14. april 2023: Endeligt udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Aktnummer: 40

Akt ID: 398599

Dato: 15-04-2023 17:36:10

Type: Indgående

Dokumenter: [1] SV Frist den 14. april 2023 Endeligt udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag.eml

[2] Bilag 5 - Spildevandsslam.docx

Den 27. april 2023

Til: Helle Winther (■■■■@mim.dk), Paolo Drostby (■■■■@fvm.dk), ■■■■@fmn.dk (■■■■@fmn.dk), Anders Terp Bekhøj (■■■■@bm.dk), ■■■■@bm.dk (■■■■@bm.dk), Anitta Hilda Vandman Bugenhagen (■■■■@sm.dk), Kathrine Bløcher (■■■■@kefm.dk), Trine Vig Houe (■■■■@SUM.DK), Cecilie Solstad (EM-DEP (■■■■@em.dk), ■■■■@bm.dk (■■■■@bm.dk))

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Fra: ■■■■@fm.dk (■■■■@fm.dk)

Titel: SV: Frist den 14. april 2023: Endeligt udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Sendt: 15-04-2023 17:36

Bilag: Bilag 5 - Spildevandsslam.docx;

Kære Helle

Hermed også bilaget om spildevandsslam fra FM. Beklager forsinkelse.

Med venlig hilsen

Frederik



Frederik Olund Kirkegaard

Fuldmægtig

Center for Klima, Grøn Økonomi og EU (KGE)

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Fra: Helle Winther <■■■■@mim.dk>

Sendt: 31. marts 2023 11:32

Til: Paolo Drostby <■■■■@fvm.dk>; ■■■■@fmn.dk; Anders Terp Bekhøj <■■■■@bm.dk>; Louise Anker Pedersen <■■■■@bm.dk>; Anitta Hilda Vandman Bugenhagen <■■■■@sm.dk>; Frederik Olund Kirkegaard <■■■■@fm.dk>; Kathrine Bløcher <■■■■@kefm.dk>; Trine Vig Houe <■■■■@SUM.DK>; Cecilie Solstad (EM-DEP) <■■■■@em.dk>; Louise Anker Pedersen <■■■■@bm.dk>

Cc: Kristine Raunkjær Stubdrup <■■■■@mim.dk>; Patrick William Keith Vardy <■■■■@fvm.dk>; Henrik Søren Larsen <■■■■@mim.dk>; Janne Birk Nielsen <■■■■@mim.dk>; Charlotte Brøndum <■■■■@mim.dk>; Katrine Rafn <■■■■@mim.dk>; Katrine Nissen <■■■■@mim.dk>; Lea Frimann Hansen <■■■■@mim.dk>; Nina Porst <■■■■@mim.dk>; Ulrik Duus Gjessing <■■■■@mim.dk>; Hans Prytz Henriksen <■■■■@fvm.dk>; Daniel Atli Larsen (EM-DEP) <■■■■@em.dk>; Maria Petersen Ølholm <■■■■@SUM.DK>; Benedikte Zwicky Bønløkke (EM-DEP) <■■■■@em.dk>; Frederik Olund Kirkegaard <■■■■@fm.dk>; Rasmus Buchholt Mathorne <■■■■@kefm.dk>

Emne: Frist den 14. april 2023: Endeligt udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære alle

Vedlagt finder i et sidste udkast til ØU-cover incl. bilag forud for endelig clearing.

Sagen er godkendt af minister i MIM.

De vedlagte bilag er følgende:

Bilag 1: ØU-cover



Aktdetaljer

Akttitel: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Aktnummer: 43

Akt ID: 398793

Dato: 26-01-2023 11:07:00

Type: Udgående

Dokumenter:

- [1] Frist tirsdag den 31. januar kl. 15 Udkast til ØU-cover og national handlingsplan for PFAS.eml
- [2] Bilag1_ØU_Cover_PFAS_handlingsplan_012023.docx
- [3] Bilag2_PFAS_handlingsplan_012023.docx
- [4] Bilag3_oversigt_yderligere_initiativer_handlingsplan_012023.docx
- [5] Bilag 4_Bilag til ØU cover _Grænseværdi for PFAS i slam_udkast.docx

Den 27. april 2023

Til: Asbjørn Brink (■■■■@fm.dk), Trine Vig Houe (■■■■@SUM.DK), Cecilie Solstad (EM-DEP (■■■■@em.dk), Paolo Drostby (■■■■@fvm.dk), ■■■■@fmn.dk (■■■■@fmn.dk), Anders Terp Bekhøj (■■■■@bm.dk), ■■■■@bm.dk (■■■■@bm.dk), Anitta Hilda Vandman Bugenhagen (■■■■@sm.dk), ■■■■@fm.dk (■■■■@fm.dk)
Cc: Kristine Raunkjær Stubdrup (■■■■@mim.dk), ■■■■@em.dk (■■■■@em.dk), Maria Petersen Ølholm (■■■■@SUM.DK), ■■■■@fvm.dk (■■■■@fvm.dk), ■■■■@fvm.dk (■■■■@fvm.dk), Henrik Søren Larsen (■■■■@mim.dk), Janne Birk Nielsen (■■■■@mim.dk), Charlotte Brøndum (■■■■@mim.dk), Katrine Rafn (■■■■@mim.dk), Katrine Nissen (■■■■@mim.dk), Lea Frimann Hansen (■■■■@mim.dk), Nina Porst (■■■■@mim.dk), Ulrik Duus Gjessing (■■■■@mim.dk)
Fra: Helle Winther (■■■■@mim.dk)
Titel: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS
Sendt: 26-01-2023 11:08
Bilag: Bilag1_ØU_Cover_PFAS_handlingsplan_012023.docx; Bilag2_PFAS_handlingsplan_012023.docx; Bilag3_oversigt_yderligere_initiativer_handlingsplan_012023.docx; Bilag 4_Bilag til ØU cover _Grænseværdi for PFAS i slam_udkast.docx;

Kære alle

Jeg har vedlagt 1. udkast til ØU-cover samt national strategi for PFAS incl. bilag.

Særligt for SUM og FVM udestår, at der skal indskrives konkrete initiativer i både handlingsplan og ØU-cover (incl. økonomi). Der er udelukkende medtaget tekst fra SUM OG FVM fra tidligere indspil i 2022 (markeret med gult i udkast til handlingsplan).

Vi imødeser gerne jeres kommentarer (på kontorniveau) med frist tirsdag den 31. januar kl. 15.

Herefter vil vi indarbejde jeres bemærkninger mhp. at sagen forhåbentlig kan sendes til clearing ved udgangen af uge 5/primo uge 6.

I er meget velkomne til at ringe/skrive, hvis I har spørgsmål.

På forhånd tak for jeres tilbagemeldinger.

Hilsener fra Helle

Venlig hilsen

Helle Winther

Fuldmægtig | Bæredygtigt Miljø og Produktion
+45 22350167 | ■■■■@mim.dk

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Miljøministeriet

Departementet | Slotsholmsgade 12 | 1216 København K | Tlf. +45 38 14 21 42 | ■■■■@mim.dk | www.mim.dk
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Aktdetaljer

Akttitel: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Aktnummer: 49

Akt ID: 398758

Dato: 31-01-2023 15:55:44

Type: Indgående

Dokumenter: [1] SV Frist tirsdag den 31. januar kl. 15 Udkast til ØU-cover og national handlingsplan for PFAS.eml

Den 27. april 2023

Til: Helle Winther (■■■■@mim.dk)
Fra: ■■■■@fm.dk (■■■■@fm.dk)
Titel: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS
Sendt: 31-01-2023 15:55

Kære Helle

Beklager, at I ikke har modtaget noget fra FM endnu på denne. Vi skal lige have alle gode folk med, da sagen vedrører flere forskellige områder.

Med venlig hilsen

Frederik



Frederik Olund Kirkegaard
Fuldmægtig
Center for Klima, Grøn Økonomi og EU (KGE)
T 40434589
E ■■■■@fm.dk

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Fra: Helle Winther <■■■■@mim.dk>
Sendt: 26. januar 2023 11:08
Til: ■■■■@fm.dk; Trine Vig Houe <■■■■@SUM.DK>; Cecilie Solstad (EM-DEP) <■■■■@em.dk>; Paolo Drostby <■■■■@fvm.dk>; ■■■■@fmn.dk; Anders Terp Bekhøj <■■■■@bm.dk>; Louise Anker Pedersen <■■■■@bm.dk>; Anitta Hilda Vandman Bugenhagen <■■■■@sm.dk>; Frederik Olund Kirkegaard <■■■■@fm.dk>
Cc: Kristine Raunkjær Stubdrup <■■■■@mim.dk>; ■■■■@em.dk; Maria Petersen Ølholm <■■■■@SUM.DK>; Sebastian Rønsdal <■■■■@fvm.dk>; Patrick William Keith Vardy <■■■■@fvm.dk>; Henrik Søren Larsen <■■■■@mim.dk>; Janne Birk Nielsen <■■■■@mim.dk>; Charlotte Brøndum <■■■■@mim.dk>; Katrine Rafn <■■■■@mim.dk>; Katrine Nissen <■■■■@mim.dk>; Lea Frimann Hansen <■■■■@mim.dk>; Nina Porst <■■■■@mim.dk>; Ulrik Duus Gjessing <■■■■@mim.dk>
Emne: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Kære alle

Jeg har vedlagt 1. udkast til ØU-cover samt national strategi for PFAS incl. bilag.

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I er meget velkomne til at ringe/skrive, hvis I har spørgsmål.

På forhånd tak for jeres tilbagemeldinger.

Hilsener fra Helle

Venlig hilsen

Helle Winther

Fuldmægtig | Bæredygtigt Miljø og Produktion
+45 22350167 | [REDACTED]@mim.dk

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Aktdetaljer

Akttitel: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Aktnummer: 50

Akt ID: 398757

Dato: 31-01-2023 16:11:00

Type: Udgående

Dokumenter: [1] SV Frist tirsdag den 31. januar kl. 15 Udkast til ØU-cover og national handlingsplan for PFAS.eml

Den 27. april 2023

Til: [REDACTED]@fm.dk ([REDACTED]@fm.dk)
Fra: Helle Winther ([REDACTED]@mim.dk)
Titel: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS
Sendt: 31-01-2023 16:11

Kære Frederik

Ok. Tak for melding. Blot skal jeg gerne have noget i morgen, da vi skal have en ny version klar af dokumenterne inden weekenden.

Hilsen fra Helle

Venlig hilsen

Helle Winther
Fuldmægtig | Bæredygtigt Miljø og Produktion
+45 22350167 | [REDACTED]@mim.dk

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[Facebook](#) | [Twitter](#) | [Instagram](#) | [LinkedIn](#)

Fra: Frederik Olund Kirkegaard <[REDACTED]@fm.dk>
Sendt: 31. januar 2023 15:56
Til: Helle Winther <[REDACTED]@mim.dk>
Emne: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Kære Helle

Beklager, at I ikke har modtaget noget fra FM endnu på denne. Vi skal lige have alle gode folk med, da sagen vedrører flere forskellige områder.

Med venlig hilsen

Frederik



Frederik Olund Kirkegaard
Fuldmægtig
Center for Klima, Grøn Økonomi og EU (KGE)
T 40434589
E [REDACTED]@fm.dk

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Fra: Helle Winther <[REDACTED]@mim.dk>
Sendt: 26. januar 2023 11:08
Til: [REDACTED]@fm.dk; Trine Vig Houe <[REDACTED]@SUM.DK>; Cecilie Solstad (EM-DEP) <[REDACTED]@em.dk>; Paolo Drostby <[REDACTED]@fvm.dk>; [REDACTED]@fmn.dk; Anders Terp Bekhøj <[REDACTED]@bm.dk>; Louise Anker Pedersen <[REDACTED]@bm.dk>; Anitta Hilda Vandman Bugenhagen <[REDACTED]@sm.dk>; Frederik Olund Kirkegaard <[REDACTED]@fm.dk>
Cc: Kristine Raunkjær Stubdrup <[REDACTED]@mim.dk>; [REDACTED]@em.dk; Maria Petersen Ølholm <[REDACTED]@SUM.DK>; Sebastian Rønsdal <[REDACTED]@fvm.dk>; Patrick William Keith Vardy <[REDACTED]@fvm.dk>; Henrik Søren Larsen

<[REDACTED]@mim.dk>; Janne Birk Nielsen <[REDACTED]@mim.dk>; Charlotte Brøndum <[REDACTED]@mim.dk>; Katrine Rafn <[REDACTED]@mim.dk>; Katrine Nissen <[REDACTED]@mim.dk>; Lea Frimann Hansen <[REDACTED]@mim.dk>; Nina Porst <[REDACTED]@mim.dk>; Ulrik Duus Gjessing <[REDACTED]@mim.dk>

Emne: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Kære alle

Jeg har vedlagt 1. udkast til ØU-cover samt national strategi for PFAS incl. bilag.

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Hilsener fra Helle

Venlig hilsen

Helle Winther

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Aktdetaljer

Akttitel: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Aktnummer: 51

Akt ID: 398756

Dato: 31-01-2023 17:36:11

Type: Indgående

Dokumenter: [1] SV Frist tirsdag den 31. januar kl. 15 Udkast til ØU-cover og national handlingsplan for PFAS.eml
[2] Bilag 1 - PFAS-handlingsplan.docx
[3] Bilag 2 - Oversigt over initiativer.docx
[4] Bilag 3 - Grænseværdi for PFAS i spildevandsslam.docx
[5] Cover - PFAS-handlingsplan.docx

Den 27. april 2023

Til: Helle Winther (■■■■@mim.dk)
Cc: Kristine Raunkjær Stubdrup (■■■■@mim.dk), Henrik Søren Larsen (■■■■@mim.dk), Janne Birk Nielsen (■■■■@mim.dk), Charlotte Brøndum (■■■■@mim.dk), Katrine Rafn (■■■■@mim.dk), Katrine Nissen (■■■■@mim.dk), Lea Frimann Hansen (■■■■@mim.dk), Nina Porst (■■■■@mim.dk), Ulrik Duus Gjessing (■■■■@mim.dk), Andreas Steen Elkjær (■■■■@fm.dk), Magnus Storm Rasmussen (■■■■@fm.dk)
Fra: ■■■■@fm.dk (■■■■@fm.dk)
Titel: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS
Sendt: 31-01-2023 17:36
Bilag: Bilag 1 - PFAS-handlingsplan.docx; Bilag 2 - Oversigt over initiativer.docx; Bilag 3 - Grænseværdi for PFAS i spildevandsslam.docx; Cover - PFAS-handlingsplan.docx;

Kære Helle

Tak for sagen, som jeg her vedlægger Finansministeriets bemærkninger til. Jeg beklager, at vi har overskredet fristen.

I er velkomne til at tage fat i os, hvis der er behov for, at vi uddyber nogle af dem.

Med venlig hilsen

Frederik



FINANSMINISTERIET

Frederik Olund Kirkegaard

Fuldmægtig

Center for Klima, Grøn Økonomi og EU (KGE)

T 40434589

E ■■■■@fm.dk

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Fra: Helle Winther <■■■■@mim.dk>

Sendt: 26. januar 2023 11:08

Til: ■■■■@fm.dk; Trine Vig Houe <■■■■@SUM.DK>; Cecilie Solstad (EM-DEP) <■■■■@em.dk>; Paolo Drostby <■■■■@fvm.dk>; ■■■■@fmn.dk; Anders Terp Bekhøj <■■■■@bm.dk>; Louise Anker Pedersen <■■■■@bm.dk>; Anitta Hilda Vandman Bugenhagen <■■■■@sm.dk>; Frederik Olund Kirkegaard <■■■■@fm.dk>

Cc: Kristine Raunkjær Stubdrup <■■■■@mim.dk>; ■■■■@em.dk; Maria Petersen Ølholm <■■■■@SUM.DK>; Sebastian Rønsdal <■■■■@fvm.dk>; Patrick William Keith Vardy <■■■■@fvm.dk>; Henrik Søren Larsen <■■■■@mim.dk>; Janne Birk Nielsen <■■■■@mim.dk>; Charlotte Brøndum <■■■■@mim.dk>; Katrine Rafn <■■■■@mim.dk>; Katrine Nissen <■■■■@mim.dk>; Lea Frimann Hansen <■■■■@mim.dk>; Nina Porst <■■■■@mim.dk>; Ulrik Duus Gjessing <■■■■@mim.dk>

Emne: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Kære alle

Jeg har vedlagt 1. udkast til ØU-cover samt national strategi for PFAS incl. bilag.

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5/primu uge 6.

I er meget velkomne til at ringe/skrive, hvis I har spørgsmål.

På forhånd tak for jeres tilbagemeldinger.

Hilsener fra Helle

Venlig hilsen

Helle Winther

Fuldmægtig | Bæredygtigt Miljø og Produktion
+45 22350167 | ████@mim.dk

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Aktdetaljer

Akttitel: Ang: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Aktnummer: 54

Akt ID: 398744

Dato: 01-02-2023 07:18:04

Type: Udgående

Dokumenter: [1] Ang SV Frist tirsdag den 31. januar kl. 15 Udkast til ØU-cover og national handlingsplan for PFAS.eml

Den 27. april 2023

Til: [redacted]@fm.dk ([redacted]@fm.dk)
Fra: Helle Winther ([redacted]@mim.dk)
Titel: Ang: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS
Sendt: 01-02-2023 07:18

Kære Frederik

Tak for input. Vi integrerer kommentarer og input i dag og i morgen og forventer at sende nyt udkast ud på fredag.
Hilsen Helle

Venlig hilsen

Helle Winther

Fuldmægtig | Bæredygtigt Miljø og Produktion
[+45 22350167](tel:+4522350167) | [redacted]@mim.dk

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Fra: Frederik Olund Kirkegaard <[redacted]@fm.dk>

Dato: 31. januar 2023 kl. 17.36.11 CET

Til: Helle Winther <[redacted]@mim.dk>

Cc: Kristine Raunkjær Stubdrup <[redacted]@mim.dk>, Henrik Søren Larsen <[redacted]@mim.dk>, Janne Birk Nielsen <[redacted]@mim.dk>, Charlotte Brøndum <[redacted]@mim.dk>, Katrine Rafn <[redacted]@mim.dk>, Katrine Nissen <[redacted]@mim.dk>, Lea Frimann Hansen <[redacted]@mim.dk>, Nina Porst <[redacted]@mim.dk>, Ulrik Duus Gjessing <[redacted]@mim.dk>, Andreas Steen Elkjær <[redacted]@fm.dk>, Magnus Storm Rasmussen <[redacted]@fm.dk>

Emne: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Kære Helle

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Med venlig hilsen

Frederik



Frederik Olund Kirkegaard

Fuldmægtig
Center for Klima, Grøn Økonomi og EU (KGE)
T 40434589
E [redacted]@fm.dk

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Fra: Helle Winther <[redacted]@mim.dk>

Sendt: 26. januar 2023 11:08

Til: [redacted]@fm.dk; Trine Vig Houe <[redacted]@SUM.DK>; Cecilie Solstad (EM-DEP) <[redacted]@em.dk>; Paolo Drostby <[redacted]@fvm.dk>; [redacted]@fmn.dk; Anders Terp Bekhøj <[redacted]@bm.dk>; Louise Anker Pedersen <[redacted]@bm.dk>; Anitta Hilda Vandman Bugenhagen <[redacted]@sm.dk>; Frederik Olund Kirkegaard <[redacted]@fm.dk>
Cc: Kristine Raunkjær Stubdrup <[redacted]@mim.dk>; [redacted]@em.dk; Maria Petersen Ølholm <[redacted]@SUM.DK>; Sebastian Rønsdal <[redacted]@fvm.dk>; Patrick William Keith Vardy <[redacted]@fvm.dk>; Henrik Søren Larsen <[redacted]@mim.dk>; Janne Birk Nielsen <[redacted]@mim.dk>; Charlotte Brøndum <[redacted]@mim.dk>; Katrine Rafn <[redacted]@mim.dk>; Katrine Nissen <[redacted]@mim.dk>; Lea Frimann Hansen <[redacted]@mim.dk>; Nina Porst <[redacted]@mim.dk>; Ulrik Duus Gjessing <[redacted]@mim.dk>
Emne: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Kære alle

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På forhånd tak for jeres tilbagemeldinger.

Hilsener fra Helle

Venlig hilsen

Helle Winther

Fuldmægtig | Bæredygtigt Miljø og Produktion
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Aktdetaljer

Akttitel: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Aktnummer: 57

Akt ID: 398734

Dato: 01-02-2023 10:46:53

Type: Indgående

Dokumenter: [1] SV Frist tirsdag den 31. januar kl. 15 Udkast til ØU-cover og national handlingsplan for PFAS.eml
[2] Cover - PFAS-handlingsplan.docx

Den 27. april 2023

Til: Helle Winther (■■■■@mim.dk)
Cc: Kristine Raunkjær Stubdrup (■■■■@mim.dk), Henrik Søren Larsen (■■■■@mim.dk), Janne Birk Nielsen (■■■■@mim.dk), Charlotte Brøndum (■■■■@mim.dk), Katrine Rafn (■■■■@mim.dk), Katrine Nissen (■■■■@mim.dk), Lea Frimann Hansen (■■■■@mim.dk), Nina Porst (■■■■@mim.dk), Ulrik Duus Gjessing (■■■■@mim.dk), Andreas Steen Elkjær (■■■■@fm.dk), Magnus Storm Rasmussen (■■■■@fm.dk)
Fra: ■■■■@fm.dk (■■■■@fm.dk)
Titel: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS
Sendt: 01-02-2023 10:46
Bilag: Cover - PFAS-handlingsplan.docx;

Kære Helle

I senest fremsendte version var der ved en fejl enkelte af vores bemærkninger, der ikke var kommet med. Jeg eftersender derfor en ny version her med enkelte yderligere forslag/bemærkninger.

Med venlig hilsen

Frederik



Frederik Olund Kirkegaard
Fuldmægtig
Center for Klima, Grøn Økonomi og EU (KGE)
T 40434589
E ■■■■@fm.dk

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Fra: Frederik Olund Kirkegaard
Sendt: 31. januar 2023 17:36
Til: Helle Winther <■■■■@mim.dk>
Cc: Kristine Raunkjær Stubdrup <■■■■@mim.dk>; Henrik Søren Larsen <■■■■@mim.dk>; Janne Birk Nielsen <■■■■@mim.dk>; Charlotte Brøndum <■■■■@mim.dk>; Katrine Rafn <■■■■@mim.dk>; Katrine Nissen <■■■■@mim.dk>; Lea Frimann Hansen <■■■■@mim.dk>; Nina Porst <■■■■@mim.dk>; Ulrik Duus Gjessing <■■■■@mim.dk>; Andreas Steen Elkjær <■■■■@fm.dk>; Magnus Storm Rasmussen <■■■■@fm.dk>
Emne: SV: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Kære Helle

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Frederik



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Fuldmægtig

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Fra: Helle Winther <████@mim.dk>

Sendt: 26. januar 2023 11:08

Til: ████@fm.dk; Trine Vig Houe <████@SUM.DK>; Cecilie Solstad (EM-DEP) <████@em.dk>; Paolo Drostby <████@fvm.dk>; ████@fmn.dk; Anders Terp Bekhøj <████@bm.dk>; Louise Anker Pedersen <████@bm.dk>; Anitta Hilda Vandman Bugenhagen <████@sm.dk>; Frederik Olund Kirkegaard <████@fm.dk>

Cc: Kristine Raunkjær Stubdrup <████@mim.dk>; ████@em.dk; Maria Petersen Ølholm <████@SUM.DK>; Sebastian Rønsdal <████@fvm.dk>; Patrick William Keith Vardy <████@fvm.dk>; Henrik Søren Larsen <████@mim.dk>; Janne Birk Nielsen <████@mim.dk>; Charlotte Brøndum <████@mim.dk>; Katrine Rafn <████@mim.dk>; Katrine Nissen <████@mim.dk>; Lea Frimann Hansen <████@mim.dk>; Nina Porst <████@mim.dk>; Ulrik Duus Gjessing <████@mim.dk>

Emne: Frist tirsdag den 31. januar kl. 15: Udkast til ØU-cover og national handlingsplan for PFAS

Kære alle

Jeg har vedlagt 1. udkast til ØU-cover samt national strategi for PFAS incl. bilag.

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Hilsener fra Helle

Venlig hilsen

Helle Winther

Fuldmægtig | Bæredygtigt Miljø og Produktion
+45 22350167 | ████@mim.dk

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Aktdetaljer

Akttitel: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Aktnummer: 64

Akt ID: 398713

Dato: 08-02-2023 10:56:13

Type: Indgående

Dokumenter: [1] SV Frist onsdag den 8. februar kl. 15 Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag.eml

Den 27. april 2023

Til: Helle Winther (■■■■@mim.dk)
Fra: ■■■■@fm.dk (■■■■@fm.dk)
Titel: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag
Sendt: 08-02-2023 10:56

Kære Helle

Har du mulighed for at sende en version, hvor der er svaret på de spørgsmål, vi stillede i første runde?

Med venlig hilsen

Frederik



Frederik Olund Kirkegaard

Fuldmægtig
Center for Klima, Grøn Økonomi og EU (KGE)
T 40434589
E ■■■■@fm.dk

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Fra: Helle Winther <■■■■@mim.dk>

Sendt: 6. februar 2023 17:40

Til: ■■■■@fm.dk; Trine Vig Houe <■■■■@SUM.DK>; Cecilie Solstad (EM-DEP) <■■■■@em.dk>; Paolo Drostby <■■■■@fvm.dk>; ■■■■@fmn.dk; Anders Terp Bekhøj <■■■■@bm.dk>; Louise Anker Pedersen <■■■■@bm.dk>; Anitta Hilda Vandman Bugenhagen <■■■■@sm.dk>; Frederik Olund Kirkegaard <■■■■@fm.dk>; Kathrine Bløcher <■■■■@kefm.dk>

Cc: Kristine Raunkjær Stubdrup <■■■■@mim.dk>; ■■■■@em.dk; Maria Petersen Ølholm <■■■■@SUM.DK>; Sebastian Rønsdal <■■■■@fvm.dk>; Patrick William Keith Vardy <■■■■@fvm.dk>; Henrik Søren Larsen <■■■■@mim.dk>; Janne Birk Nielsen <■■■■@mim.dk>; Charlotte Brøndum <■■■■@mim.dk>; Katrine Rafn <■■■■@mim.dk>; Katrine Nissen <■■■■@mim.dk>; Lea Frimann Hansen <■■■■@mim.dk>; Nina Porst <■■■■@mim.dk>; Ulrik Duus Gjessing <■■■■@mim.dk>

Emne: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære alle

Tak for alle jeres input og kommentarer til det første udkast af ØU-cover og bilag vedr. national handlingsplan for PFAS.

Jeg har vedlagt revideret udkast til ØU-cover vedr. national strategi for PFAS incl. bilag.

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Herefter forventer vi at sagen kan sendes i clearing ultimo uge 6/primo uge 7 med henblik på FØ den 28. februar 2023 og ØU den 9.marts 2023.

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På forhånd tak for jeres tilbagemeldinger.

Hilsener fra Helle

Venlig hilsen

Helle Winther

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Aktdetaljer

Akttitel: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Aktnummer: 65

Akt ID: 398712

Dato: 08-02-2023 11:25:00

Type: Udgående

Dokumenter: [1] SV Frist onsdag den 8. februar kl. 15 Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag.eml

Den 27. april 2023

Til: [REDACTED]@fm.dk ([REDACTED]@fm.dk)
Fra: Helle Winther ([REDACTED]@mim.dk)
Titel: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag
Sendt: 08-02-2023 11:25

Kære Frederik

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Hilsener fra helle

Venlig hilsen

Helle Winther
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Fra: Frederik Olund Kirkegaard <[REDACTED]@fm.dk>
Sendt: 8. februar 2023 10:56
Til: Helle Winther <[REDACTED]@mim.dk>
Emne: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære Helle

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Med venlig hilsen

Frederik



Frederik Olund Kirkegaard
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Fra: Helle Winther <[REDACTED]@mim.dk>
Sendt: 6. februar 2023 17:40
Til: [REDACTED]@fm.dk; Trine Vig Houe <[REDACTED]@SUM.DK>; Cecilie Solstad (EM-DEP) <[REDACTED]@em.dk>; Paolo Drostby <[REDACTED]@fvm.dk>; [REDACTED]@fmn.dk; Anders Terp Bekhøj <[REDACTED]@bm.dk>; Louise Anker Pedersen <[REDACTED]@bm.dk>; Anitta Hilda Vandman Bugenhagen <[REDACTED]@sm.dk>; Frederik Olund Kirkegaard <[REDACTED]@fm.dk>; Kathrine Bløcher <[REDACTED]@kefm.dk>

Cc: Kristine Raunkjær Stubdrup <[REDACTED]@mim.dk>; [REDACTED]@em.dk; Maria Petersen Ølholm <[REDACTED]@SUM.DK>; Sebastian Rønsdal <[REDACTED]@fvm.dk>; Patrick William Keith Vardy <[REDACTED]@fvm.dk>; Henrik Søren Larsen <[REDACTED]@mim.dk>; Janne Birk Nielsen <[REDACTED]@mim.dk>; Charlotte Brøndum <[REDACTED]@mim.dk>; Katrine Rafn <[REDACTED]@mim.dk>; Katrine Nissen <[REDACTED]@mim.dk>; Lea Frimann Hansen <[REDACTED]@mim.dk>; Nina Porst <[REDACTED]@mim.dk>; Ulrik Duus Gjessing <[REDACTED]@mim.dk>

Emne: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære alle

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Hilsener fra Helle

Venlig hilsen

Helle Winther

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Aktdetaljer

Akttitel: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Aktnummer: 66

Akt ID: 398711

Dato: 08-02-2023 11:26:16

Type: Indgående

Dokumenter: [1] SV Frist onsdag den 8. februar kl. 15 Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag.eml

Den 27. april 2023

Til: Helle Winther (■■■■@mim.dk)
Fra: ■■■■@fm.dk (■■■■@fm.dk)
Titel: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag
Sendt: 08-02-2023 11:26

Kære Helle

Så skal I nok forvente, at vi stiller samme spørgsmål igen og forventer svar, inden I skal videre på regeringsudvalg.

Med venlig hilsen

Frederik



Frederik Olund Kirkegaard
Fuldmægtig
Center for Klima, Grøn Økonomi og EU (KGE)
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E ■■■■@fm.dk

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Fra: Helle Winther <■■■■@mim.dk>
Sendt: 8. februar 2023 11:25
Til: Frederik Olund Kirkegaard <■■■■@fm.dk>
Emne: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære Frederik

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Hilsener fra helle

Venlig hilsen

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Fra: Frederik Olund Kirkegaard <■■■■@fm.dk>
Sendt: 8. februar 2023 10:56
Til: Helle Winther <■■■■@mim.dk>
Emne: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære Helle

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Med venlig hilsen

Frederik



Frederik Olund Kirkegaard

Fuldmægtig

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Fra: Helle Winther <helle.winther@mim.dk>

Sendt: 6. februar 2023 17:40

Til: frederik.olund@fm.dk; Trine Vig Houe <trine.vig@sum.dk>; Cecilie Solstad (EM-DEP) <cecilie.solstad@em.dk>; Paolo Drostby <paolo.drostby@fvm.dk>; anders.terp@fmn.dk; Anders Terp Bekhøj <anders.terp@bm.dk>; Louise Anker Pedersen <louise.anker@bm.dk>; Anitta Hilda Vandman Bugenhagen <anitta.hilda@sm.dk>; Frederik Olund Kirkegaard <frederik.olund@fm.dk>; Kathrine Bløcher <kathrine.bløcher@kefm.dk>

Cc: Kristine Raunkjær Stubdrup <kristine.raunkjaer@mim.dk>; cecilie.solstad@em.dk; Maria Petersen Ølholm <maria.petersen@sum.dk>; Sebastian Rønsdal <sebastian.ronsdal@fvm.dk>; Patrick William Keith Vardy <patrick.william@fvm.dk>; Henrik Søren Larsen <henrik.soren@mim.dk>; Janne Birk Nielsen <janne.birk@mim.dk>; Charlotte Brøndum <charlotte.brondum@mim.dk>; Katrine Rafn <katrine.rafn@mim.dk>; Katrine Nissen <katrine.nissen@mim.dk>; Lea Frimann Hansen <lea.frimann@mim.dk>; Nina Porst <nina.porst@mim.dk>; Ulrik Duus Gjessing <ulrik.duus@mim.dk>

Emne: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære alle

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Hilsener fra Helle

Venlig hilsen

Helle Winther

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Aktdetaljer

Akttitel: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Aktnummer: 67

Akt ID: 398710

Dato: 08-02-2023 11:29:00

Type: Udgående

Dokumenter: [1] SV Frist onsdag den 8. februar kl. 15 Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag.eml

Den 27. april 2023

Til: [redacted]@fm.dk ([redacted]@fm.dk)
Fra: Helle Winther ([redacted]@mim.dk)
Titel: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag
Sendt: 08-02-2023 11:29

Kære Frederik

Som sagt, så er der gennemført et stort arbejde med at integrere svar på hovedparten af kommentarerne i teksten. Det håber jeg, at I kan se afspejlet.

Hilsener fra Helle

Venlig hilsen

Helle Winther
Fuldmægtig | Bæredygtigt Miljø og Produktion
+45 22350167 | [redacted]@mim.dk

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Fra: Frederik Olund Kirkegaard <[redacted]@fm.dk>
Sendt: 8. februar 2023 11:26
Til: Helle Winther <[redacted]@mim.dk>
Emne: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære Helle

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Med venlig hilsen

Frederik



Frederik Olund Kirkegaard
Fuldmægtig
Center for Klima, Grøn Økonomi og EU (KGE)
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Fra: Helle Winther <[redacted]@mim.dk>
Sendt: 8. februar 2023 11:25
Til: Frederik Olund Kirkegaard <[redacted]@fm.dk>
Emne: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære Frederik

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Hilsener fra helle

Venlig hilsen

Helle Winther

Fuldmægtig | Bæredygtigt Miljø og Produktion
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Fra: Frederik Olund Kirkegaard <████@fm.dk>

Sendt: 8. februar 2023 10:56

Til: Helle Winther <████@mim.dk>

Emne: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære Helle

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Med venlig hilsen

Frederik



FINANSMINISTERIET

Frederik Olund Kirkegaard

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Center for Klima, Grøn Økonomi og EU (KGE)
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Fra: Helle Winther <████@mim.dk>

Sendt: 6. februar 2023 17:40

Til: ████@fm.dk; Trine Vig Houe <████@SUM.DK>; Cecilie Solstad (EM-DEP) <████@em.dk>; Paolo Drostby <████@fvm.dk>; ████@fmn.dk; Anders Terp Bekhøj <████@bm.dk>; Louise Anker Pedersen <████@bm.dk>; Anitta Hilda Vandman Bugenhagen <████@sm.dk>; Frederik Olund Kirkegaard <████@fm.dk>; Kathrine Bløcher <████@kefm.dk>

Cc: Kristine Raunkjær Stubdrup <████@mim.dk>; ████@em.dk; Maria Petersen Ølholm <████@SUM.DK>; Sebastian Rønsdal <████@fvm.dk>; Patrick William Keith Vardy <████@fvm.dk>; Henrik Søren Larsen <████@mim.dk>; Janne Birk Nielsen <████@mim.dk>; Charlotte Brøndum <████@mim.dk>; Katrine Rafn <████@mim.dk>; Katrine Nissen <████@mim.dk>; Lea Frimann Hansen <████@mim.dk>; Nina Porst <████@mim.dk>; Ulrik Duus Gjessing <████@mim.dk>

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Kære alle

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Venlig hilsen

Helle Winther

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Aktdetaljer

Akttitel: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Aktnummer: 72

Akt ID: 398705

Dato: 08-02-2023 15:59:01

Type: Indgående

Dokumenter:

- [1] SV Frist onsdag den 8. februar kl. 15 Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag.eml
- [2] Bilag 1 - PFAS handlingsplan del 1 2023.docx
- [3] Bilag 2 - Udgifter 2023.docx
- [4] Bilag 3 - Initiativer - udgifter 2024-2026.docx
- [5] Bilag 4 - Spildevandsslam.docx
- [6] Bilag 5 - Regionernes indsats PFAS.docx
- [7] Cover - PFAS.docx

Den 27. april 2023

Til: Helle Winther (■■■■@mim.dk)
Fra: ■■■■@fm.dk (■■■■@fm.dk)
Titel: SV: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag
Sendt: 08-02-2023 15:59
Bilag: Bilag 1 - PFAS handlingsplan del 1 2023.docx; Bilag 2 - Udgifter 2023.docx; Bilag 3 - Initiativer - udgifter 2024-2026.docx; Bilag 4 - Spildevandsslam.docx; Bilag 5 - Regionernes indsats PFAS.docx; Cover - PFAS.docx;

Kære Helle

Hermed fra Finansministeriet. Vi bliver nødt til at eftersende bud på modeller, finansiering og tabelopstilling.

Med venlig hilsen

Frederik



Frederik Olund Kirkegaard
Fuldmægtig
Center for Klima, Grøn Økonomi og EU (KGE)
T 40434589
E ■■■■@fm.dk

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Fra: Helle Winther <■■■■@mim.dk>
Sendt: 6. februar 2023 17:40
Til: ■■■■@fm.dk; Trine Vig Houe <■■■■@SUM.DK>; Cecilie Solstad (EM-DEP) <■■■■@em.dk>; Paolo Drostby <■■■■@fvm.dk>; ■■■■@fmn.dk; Anders Terp Bekhøj <■■■■@bm.dk>; Louise Anker Pedersen <■■■■@bm.dk>; Anitta Hilda Vandman Bugenhagen <■■■■@sm.dk>; Frederik Olund Kirkegaard <■■■■@fm.dk>; Kathrine Bløcher <■■■■@kefm.dk>
Cc: Kristine Raunkjær Stubdrup <■■■■@mim.dk>; ■■■■@em.dk; Maria Petersen Ølholm <■■■■@SUM.DK>; Sebastian Rønsdal <■■■■@fvm.dk>; Patrick William Keith Vardy <■■■■@fvm.dk>; Henrik Søren Larsen <■■■■@mim.dk>; Janne Birk Nielsen <■■■■@mim.dk>; Charlotte Brøndum <■■■■@mim.dk>; Katrine Rafn <■■■■@mim.dk>; Katrine Nissen <■■■■@mim.dk>; Lea Frimann Hansen <■■■■@mim.dk>; Nina Porst <■■■■@mim.dk>; Ulrik Duus Gjessing <■■■■@mim.dk>
Emne: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Kære alle

Tak for alle jeres input og kommentarer til det første udkast af ØU-cover og bilag vedr. national handlingsplan for PFAS.

Jeg har vedlagt revideret udkast til ØU-cover vedr. national strategi for PFAS incl. bilag.

Vi imødeser gerne jeres eventuelle kommentarer – KC-godkendte - med frist onsdag den 8. februar 2023 kl. 15.

Herefter forventer vi at sagen kan sendes i clearing ultimo uge 6/primo uge 7 med henblik på FØ den 28. februar 2023 og ØU den 9.marts 2023.

I er meget velkomne til at ringe/skrive, hvis I har spørgsmål.

På forhånd tak for jeres tilbagemeldinger.

Hilsener fra Helle

Venlig hilsen

Helle Winther

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Aktdetaljer

Den 27. april 2023

Akttitel: ØU-sag PFAS-handlingsplan Aktnummer: 73

Akt ID: 398704
Dato: 09-02-2023 10:31:48
Type: Udgående
Dokumenter: [1] ØU-sag PFAS-handlingsplan.eml



Aktdetaljer

Den 27. april 2023

Akttitel: SV: ØU-sag PFAS-handlingsplan Aktnummer: 74

Akt ID: 398703

Dato: 09-02-2023 15:18:15

Type: Indgående

Dokumenter: [1] SV ØU-sag PFAS-handlingsplan.eml
[2] Skitse til finansieret PFAS-handlingsplan.docx



Aktdetaljer

Den 27. april 2023

Akttitel: Ang: SV: ØU-sag PFAS-handlingsplan
Aktnummer: 75

Akt ID: 398702

Dato: 09-02-2023 15:21:40

Type: Udgående

Dokumenter: [1] Ang SV ØU-sag PFAS-handlingsplan.eml



Aktdetaljer

Den 27. april 2023

Akttitel: SV: ØU-sag PFAS-handlingsplan Aktnummer: 85

Akt ID: 398682

Dato: 17-02-2023 13:31:10

Type: Udgående

Dokumenter:

- [1] SV ØU-sag PFAS-handlingsplan.eml
- [2] Bilag 4 - Spildevandsslam.docx
- [3] Bilag 5 - Regionernes indsats PFAS.docx
- [4] Bilag1_PFAS_handlingsplan_1del_2023_022023.docx
- [5] Nyt bilag 2 - Initiativer - udgifter 2023-2026.docx
- [6] Revideret_ØU_cover_PFAS_10022023.docx



Aktdetaljer

Den 27. april 2023

Akttitel: SV: ØU-sag PFAS-handlingsplan Aktnummer: 86

Akt ID: 398681

Dato: 20-02-2023 15:36:06

Type: Indgående

Dokumenter: [1] SV ØU-sag PFAS-handlingsplan.eml
[2] Cover - PFAS-handlingsplan.docx



Aktdetaljer

Den 27. april 2023

Akttitel: SV: ØU-sag PFAS-handlingsplan
Aktnummer: 88

Akt ID: 398660

Dato: 21-02-2023 16:58:10

Type: Indgående

Dokumenter: [1] SV ØU-sag PFAS-handlingsplan.eml

Til: Helle Winther (■■■■@mim.dk)
Cc: ■■■■@fm.dk (■■■■@fm.dk), Kristine Raunkjær Stubdrup (■■■■@mim.dk), Nina Porst (■■■■@mim.dk)
Fra: ■■■■@fm.dk (■■■■@fm.dk)
Titel: SV: ØU-sag PFAS-handlingsplan
Sendt: 21-02-2023 16:58

Kære Helle

Mine frister for at kunne få PFAS-sagen på FØ den 28. februar nærmer sig hastigt. Hvis I har noget foreløbigt, I kan sende over, og som vi kan læse med på i aften, vil det være meget hjælpsomt. Også i lyset af, at andre ministerier skal kunne nå at forholde sig til sagen. I kan eventuelt markere de steder, hvor der er udeståender, hvis der er behov for at tage højde for det.

Med venlig hilsen

Frederik



FINANSMINISTERIET

Frederik Olund Kirkegaard

Fuldmægtig

Center for Klima, Grøn Økonomi og EU (KGE)

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Fra: Helle Winther <■■■■@mim.dk>

Sendt: 20. februar 2023 16:25

Til: Frederik Olund Kirkegaard <■■■■@fm.dk>

Cc: Christine Aggerstrøm Hansen <■■■■@fm.dk>; Kristine Raunkjær Stubdrup <■■■■@mim.dk>; Nina Porst <■■■■@mim.dk>

Emne: SV: ØU-sag PFAS-handlingsplan

Tak, Frederik. Vi kigger på dem og jeg vender tilbage i morgen, tirsdag.

Hilsen fra Helle

Venlig hilsen

Helle Winther

Fuldmægtig | Bæredygtigt Miljø og Produktion

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Fra: Frederik Olund Kirkegaard <■■■■@fm.dk>

Sendt: 20. februar 2023 15:36

Til: Helle Winther <■■■■@mim.dk>

Cc: Christine Aggerstrøm Hansen <■■■■@fm.dk>; Kristine Raunkjær Stubdrup <■■■■@mim.dk>; Nina Porst <■■■■@mim.dk>

Jeg er opmærksom på, at Frederik har sendt bemærkninger og varslet assistance med tabeller mv. Det sætter vi pris på. Måske en af jer kunne give mig et ring, så vi ikke arbejder forbi hinanden?

Pft.

Bh Nina

Venlig hilsen

Nina Porst

Kontorchef | Grøn Omstilling
+45 20 37 38 43 | [REDACTED]@mim.dk

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Aktdetaljer

Den 27. april 2023

Akttitel: Initiativ i handleplan for PFAS på ISMs område Aktnummer: 90

Akt ID: 398658
Dato: 23-02-2023 12:45:11
Type: Indgående
Dokumenter: [1] Initiativ i handleplan for PFAS på ISMs område.eml

Til: Helle Winther ([REDACTED]@mim.dk)
Fra: Magnus Storm Rasmussen ([REDACTED]@fm.dk)
Titel: Initiativ i handleplan for PFAS på ISMs område
Sendt: 23-02-2023 12:45

Hej Helle

Jeg sidder i FM med sundhedsområdet og har lige læst med på sagen om handlingsplan for håndtering af PFAS. Vil gerne lige have lidt baggrund for, at ISM nævner, at de kan finansiere deres initiativ indenfor egen ramme. Har du en kontakt i ISM?

Bedste hilsner



FINANSMINISTERIET

Magnus Storm Rasmussen
Fuldmægtig
Velfærdspolitisk Center (VPC)
M: 29 10 67 17
E: [REDACTED]@fm.dk

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Aktdetaljer

Den 27. april 2023

Akttitel: Procesmelding PFAS-handlingsplan Aktnummer: 91

Akt ID: 398657
Dato: 23-02-2023 17:12:00
Type: Udgående
Dokumenter: [1] Procesmelding PFAS-handlingsplan.eml

Til: [REDACTED]@fm.dk ([REDACTED]@fm.dk), Esben Tikjøb Mogensen (EM-DEP ([REDACTED]@em.dk), Hans Prytz Henriksen ([REDACTED]@fvm.dk), Maria Petersen Ølholm ([REDACTED]@SUM.DK), Rasmus Mathorne Madsen ([REDACTED]@kefm.dk)
Fra: Helle Winther ([REDACTED]@mim.dk)
Titel: Procesmelding PFAS-handlingsplan
Sendt: 23-02-2023 17:12

Kære alle

Vi har desværre været nødt til at udskyde FØ og sigter nu definitivt efter FØ i uge 10 (tirsdag den 7. marts) og ØU uge 12 (torsdag den 23. marts).

Jeg vender tilbage med et nyt udkast til ØU-sagen snarest muligt.

Hilsen fra Helle

Venlig hilsen

Helle Winther
Fuldmægtig | Bæredygtigt Miljø og Produktion
+45 22350167 | [REDACTED]@mim.dk

Du kan få nyheder om ny miljøteknologi og MUDP-ansøgningsrunder direkte i din mailboks.
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Aktdetaljer

Den 27. april 2023

Akttitel: SV: Procesmelding PFAS-handlingsplan Aktnummer: 92

Akt ID: 398656
Dato: 27-02-2023 09:15:41
Type: Indgående
Dokumenter: [1] SV Procesmelding PFAS-handlingsplan.eml

Til: Helle Winther (■■■■@mim.dk)
Fra: ■■■■@fm.dk (■■■■@fm.dk)
Titel: SV: Procesmelding PFAS-handlingsplan
Sendt: 27-02-2023 09:15

Kære Helle

Vi er nødt til at se et udkast til en sag senest i løbet af i dag, hvis FØ den 7. marts skal være en mulighed. Det må I derfor meget gerne arbejde efter.

Med venlig hilsen

Frederik



Frederik Olund Kirkegaard
Fuldmægtig
Center for Klima, Grøn Økonomi og EU (KGE)
T 40434589
E ■■■■@fm.dk

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Fra: Helle Winther <■■■■@mim.dk>
Sendt: 23. februar 2023 17:12
Til: Frederik Olund Kirkegaard <■■■■@fm.dk>; Esben Tikjøb Mogensen (EM-DEP) <■■■■@em.dk>; Hans Prytz Henriksen <■■■■@fvm.dk>; Maria Petersen Ølholm <■■■■@SUM.DK>; Rasmus Buchholt Mathorne <■■■■@kefm.dk>
Emne: Procesmelding PFAS-handlingsplan

Kære alle

Vi har desværre været nødt til at udskyde FØ og sigter nu definitivt efter FØ i uge 10 (tirsdag den 7. marts) og ØU uge 12 (torsdag den 23. marts).

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Hilsen fra Helle

Venlig hilsen

Helle Winther
Fuldmægtig | Bæredygtigt Miljø og Produktion
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Aktdetaljer

Akttitel: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Aktnummer: 96

Akt ID: 398804

Dato: 06-02-2023 17:39:00

Type: Udgående

Dokumenter:

- [1] Frist onsdag den 8. februar kl. 15 Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag.eml
- [2] Revideret_ØU_cover_PFAS_022023.docx
- [3] Bilag1_PFAS_handlingsplan_1del_2023_022023.docx
- [4] Bilag2_udgifter_2023.docx
- [5] Bilag3_initiativer_udgifter_2024_2026.docx
- [6] Bilag4_spildevandsslam_022023.docx
- [7] Bilag5_regionernes_indsats_PFAS_022023.docx

Den 27. april 2023

Til: Asbjørn Brink (■■■■@fm.dk), Trine Vig Houe (■■■■@SUM.DK), Cecilie Solstad (EM-DEP (■■■■@em.dk), Paolo Drostby (■■■■@fvm.dk), ■■■■@fmn.dk (■■■■@fmn.dk), Anders Terp Bekhøj (■■■■@bm.dk), ■■■■@bm.dk (■■■■@bm.dk), Anitta Hilda Vandman Bugenhagen (■■■■@sm.dk), ■■■■@fm.dk (■■■■@fm.dk), Kathrine Bløcher (■■■■@kefm.dk)

Cc: Kristine Raunkjær Stubdrup (■■■■@mim.dk), ■■■■@em.dk (■■■■@em.dk), Maria Petersen Ølholm (■■■■@SUM.DK), ■■■■@fvm.dk (■■■■@fvm.dk), ■■■■@fvm.dk (■■■■@fvm.dk), Henrik Søren Larsen (■■■■@mim.dk), Janne Birk Nielsen (■■■■@mim.dk), Charlotte Brøndum (■■■■@mim.dk), Katrine Rafn (■■■■@mim.dk), Katrine Nissen (■■■■@mim.dk), Lea Frimann Hansen (■■■■@mim.dk), Nina Porst (■■■■@mim.dk), Ulrik Duus Gjessing (■■■■@mim.dk)

Fra: Helle Winther (■■■■@mim.dk)

Titel: Frist onsdag den 8. februar kl. 15: Revideret udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Sendt: 06-02-2023 17:39

Bilag: Revideret_ØU_cover_PFAS_022023.docx; Bilag1_PFAS_handlingsplan_1del_2023_022023.docx; Bilag2_udgifter_2023.docx; Bilag3_initiativer_udgifter_2024_2026.docx; Bilag4_spildevandsslam_022023.docx; Bilag5_regionernes_indsats_PFAS_022023.docx;

Kære alle

Tak for alle jeres input og kommentarer til det første udkast af ØU-cover og bilag vedr. national handlingsplan for PFAS.

Jeg har vedlagt revideret udkast til ØU-cover vedr. national strategi for PFAS incl. bilag.

Vi imødeser gerne jeres eventuelle kommentarer – KC-godkendte - med frist onsdag den 8. februar 2023 kl. 15.

Herefter forventer vi at sagen kan sendes i clearing ultimo uge 6/primo uge 7 med henblik på FØ den 28. februar 2023 og ØU den 9.marts 2023.

I er meget velkomne til at ringe/skrive, hvis I har spørgsmål.

På forhånd tak for jeres tilbagemeldinger.

Hilsener fra Helle

Venlig hilsen

Helle Winther
Fuldmægtig | Bæredygtigt Miljø og Produktion
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Aktdetaljer

Akttitel: Frist den 14. april 2023: Endeligt udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag

Aktnummer: 97

Akt ID: 398803

Dato: 31-03-2023 11:32:00

Type: Udgående

Dokumenter:

- [1] Frist den 14. april 2023 Endeligt udkast til ØU-cover vedr. national handlingsplan for PFAS incl. bilag.eml
- [2] Bilag6_Spildevandsslam_032023.docx
- [3] Bilag5_Regionernes_indsats_032023.docx
- [4] Bilag4_Detaljeret_beskrivelse_initiativer_og_budget_PFAS_handlingsplan_032023.docx
- [5] Bilag 3_Initiativer i regeringens handlingsplan for PFAS_032023.docx
- [6] Bilag 2_Fortælling om national handlingsplan for PFAS_032023.docx
- [7] Bilag1_ØU_cover_PFAS_handlingsplan_032023.docx

Den 27. april 2023

Til: Jesper Gamst ([REDACTED]@eurofins.dk)
Fra: Esben Tikjøb Mogensen (EM-DEP) ([REDACTED]@em.dk)
Titel: Brev fra erhvervsministeren
Sendt: 24-02-2023 13:45
Bilag: Brev fra erhvervsministeren.pdf;

Kære Jesper Gamst

Se venligst vedhæftede brev fra erhvervsministeren.

Med venlig hilsen
Esben Mogensen



ESBEN TIKJØB MOGENSEN (EM-DEP)

Fuldmægtig
Område 4

Slotsholmsgade 10-12

1216 København K

[REDACTED]@em.dk

Tlf. 33 92 33 50

Mobil 91 33 71 15



EAN 5798000026001

Erhvervsministeriet er ansvarlig for behandlingen af de personoplysninger, vi modtager om dig. Du kan læse mere om, hvordan vi behandler dine personoplysninger på vores hjemmeside <https://em.dk/privatlivspolitik>.

Erhvervsministeriet gør opmærksom på, at denne e-mail og eventuelle vedhæftede filer er fortrolige. Hvis du ikke er den tilsigtede modtager, bedes du straks underrette afsenderen ved at besvare denne e-mail og derefter slette e-mailen. Hvis du har modtaget denne e-mail ved en fejl, skal vi gøre klart, at enhver form for kopiering, offentliggørelse eller distribution af denne e-mail kan være ulovlig.



Jesper Gamst
Eurofins Environment Testing Denmark
Ladelundvej 85
6600 Vejen
[redacted]@eurofins.dk

ERHVERVSMINISTEREN

24. februar 2023

Kære Jesper

Mange tak for den venlige lykønskning.

Som erhvervs- og forbrugernes minister ser jeg, på lige fod med Eurofins, alvorligt på PFAS-problematikken. Det er også baggrunden for, at regeringen har besluttet at fortsætte arbejdet med en national handlingsplan for PFAS.

Den nationale handlingsplan skal bidrage til at afværge, inddæmme og oprense PFAS-forureninger. På den baggrund vil jeg foreslå jer at kontakte miljøministeren, som er ansvarlig for det videre arbejde med den nationale PFAS-handlingsplan.

Bedste hilsner,


Morten

ERHVERVSMINISTERIET

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1216 København K

Tlf. 33 92 33 50
Fax. 33 12 37 78
CVR-nr. 10092485
EAN nr. 5798000026001
[redacted]@em.dk
www.em.dk

Kære Morten Bødskov

I Eurofins vil vi gerne ønske dig stort tillykke med udnævnelsen til erhvervsminister og dermed både erhvervets og forbrugernes minister. Eurofins er en dansk laboratoriesammenslutning, som har specialiseret sig i tests for en lang række giftstoffer herunder også bl.a. tests for PFAS i forbrugerprodukter.

Vores laboranter arbejder dagligt med at analysere PFAS i forbrugernære produkter, og vi har derfor både data og erfaringerne til at kunne sige, at vi på dette område desværre blot har skrabt i overfladen af problemet.

Vi har med bekymring kunne iagttage og måle, hvordan PFAS udgør en stadig stigende udfordring med den drastiske udbredelse af de kræftfremkaldende evighedskemikalier i vores drikkevand, natur og mange af de produkter, vi benytter som forbrugere hver dag. Blandt andet har vi for nyligt set, hvordan brug af paptallerkener eller muffinforme drastisk kan forhøje indtagelsen af PFAS.

Derfor er vi særdeles positive over, at den nye regering vil sikre den tidligere regerings arbejde med en national handlingsplan for PFAS samt ønsker at begrænse brugen af kemikalierne i Danmark. I Eurofins bidrager vi meget gerne med vores ekspertviden om opsporing og tests af PFAS i produkter, så danske børn fx ikke skal kunne købe gummistøvler, der indeholder kræftfremkaldende kemi.

PFAS er et udbredt problem i naturen og i mange produkter

PFAS er et industrielt fremstillet kemisk stof, der udmærker sig ved at være særdeles effektivt som vandafviser. Derfor har det i mange år også været brugt i industrien, der har ledt til en spredning i naturen, hvor Danske Regioner senest har anslået, at 15.000 grunde i Danmark kan være forurenet. Omfanget kan dog være væsentligt højere, da PFAS-kemikalierne er svært nedbrydelige og yderst mobile.

I dag bruges PFAS fortsat til en lang række produkter, hvor fugt bør afvises. Det er fx regntøj, maling, tæpper og pizzapakker. PFAS er kræftfremkaldende, kan påvirke reproduktionen og er mistænkt for at være hormon- og immunforstyrrende.

Eurofins vil på baggrund af vores arbejde og erfaringer med farlig kemi gerne bidrage til regeringens arbejde og har samlet en række konkrete forslag til den nationale handlingsplan.

Hvis du har tid og lyst, så vil vi meget gerne mødes, så du har mulighed for at høre mere om konsekvenserne for forbrugerne ved den fortsatte brug af PFAS i en række produkter.

Jeg glæder mig til at høre fra dig – og endnu en gang tillykke med ministerposten.

Med venlig hilsen,
Jesper Gamst
Adm. direktør, Eurofins

Til: LEDS post ([REDACTED]@em.dk)
Fra: Jesper Gamst ([REDACTED]@eurofins.dk)
Titel: Vedr. PFAS
Sendt: 24-01-2023 08:15
Bilag: Eurofins - Brev til Bødskov.pdf;

Kære Morten Bødskov

Stort tillykke med ministerudnævnelsen. I laboratoriesammenslutningen Eurofins er vi førende i at teste og analysere de giftige PFAS-kemikalier, hvis forurening vi i øjeblikket ser massiv omtale af.

Vores laboranter, der arbejder med PFAS til daglig, ved, at vi kun har set toppen af isbjerget. Såfremt du har mulighed for det, vil vi meget gerne mødes med dig for at drøfte problematikken samt forelægge en række af vores løsningsforslag.

Se vedlagte brev for detaljer.

Jeg ser frem til at høre fra dig.

Best regards,

Jesper Gamst
Managing Director

Eurofins Environment Testing Denmark
Ladelundvej 85
DK-6600 Vejen
Mobile: +45 6134 8688
E-mail: [REDACTED]@eurofins.dk

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Til: Johan Amby (EM-DEP) (████████@em.dk)
Cc: Seemab Ghazal Sheikh (EM-DEP) (████████@em.dk)
Fra: Brian Wessel (EM-DEP) (████████@em.dk)
Titel: VS: Kort opfølgning fra samtalen i dag vedrørende: Meeting request to discuss unintended consequences of a possible PFAS use ban (under REACH) currently under preparation by your country [RL-WSDOCS.FID1329787]
Sendt: 26-10-2021 14:26
Bilag: Letter Brian Wessel - Denmark.pdf;

Kære Johan

Tror jeg sendte denne til dig tidligere – vil du følge op?
Tak



BRIAN WESSEL (EM-DEP)
Erhvervsjuridisk direktør
Område 2

Slotsholmsgade 10-12
1216 København K
████████@em.dk
Tlf. 33 92 33 50
Mobil 91 33 72 45

EAN 5798000026001

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Fra: Betina Wichmann <████████@lundgrens.dk>
Sendt: 26. oktober 2021 14:24
Til: Brian Wessel (EM-DEP) <████████@em.dk>
Emne: Kort opfølgning fra samtalen i dag vedrørende: Meeting request to discuss unintended consequences of a possible PFAS use ban (under REACH) currently under preparation by your country [RL-WSDOCS.FID1329787]

Kære Brian Wessel
Mange tak for din tilbagemelding på mobil i dag. Som jeg oplyste ved samtalen har Honeywell bedt mig om at følge op i forhold til deres vedlagte henvendelse til Erhvervsministeriet.

Jeg vil være taknemmelig, hvis du vil holde mig orienteret i forhold til status på henvendelsen fra Honeywell.

Med venlig hilsen

Betina Wichmann
Advokat

LUNDGREN S

.....

Tel +45 3525 2535
Mob +45 2524 5132

..... E-mail Confidentiality and Data Protection Notice

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Fra: Vandezande, Marleen <[REDACTED]@honeywell.com>

Sendt: 7. oktober 2021 14:06

Til: [REDACTED]@em.dk

Cc: Soulet, Julien <[REDACTED]@Honeywell.com>; Walsh, Mary B <[REDACTED]@Honeywell.com>

Emne: Meeting request to discuss unintended consequences of a possible PFAS use ban (under REACH) currently under preparation by your country

Letter sent on behalf of Julien Soulet.

Kind regards,

Marleen Vandezande
Assistant to Julien Soulet

Vice President and General Manager
Fluorine Products EMEA
Advanced Materials EMEA

Managing Director
Honeywell Belgium N.V.
Honeywell Fluorine Products Europe B.V.
Office: [REDACTED]
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Honeywell Fluorine Products Europe B.V.

Stationsplein Zuid-West 961
1117 CE Schiphol-Oost
The Netherlands
Tel. [REDACTED]
www.honeywell.com

Ministry of Industry, Business and Financial Affairs
Attn.: Brian Wessel
CEO, Regulation of Business and International Relations

[REDACTED]@em.dk

Dear Mr Wessel,

We are writing you in relation to the PFAS REACH restriction proposal that was entered into the registry of restriction intentions of the European Chemicals Agency (ECHA) on 15 July 2021 by five EU/EEA countries and the unintended impact that this restriction may have on the Danish economy and on achieving the objectives under the Paris Agreement and the EU Green Deal. Decarbonization and the reduction of the emission of greenhouse gases (thereby limiting global warming to less than 2 degrees centigrade) are key interlinked global policy objectives.

Honeywell is a strong supporter of these objectives, and we believe that we make an important contribution to achieving them. For example, to date, the use of our Solstice HFO refrigerants and blowing agents has helped avoid the release of nearly 250 million metric tons of CO₂e¹ into the atmosphere so far, an equivalent to removing over 50 million cars from the road, more than all passenger cars registered in Germany. Furthermore:

- Honeywell is a recognized and established B2B supplier of innovative chemicals to various enterprises in Denmark.
- Our customers use our products to manufacture various *high added value* final products (including air-conditioning and refrigeration systems, medical packaging and devices, various electronics, building insulation foams, etc.). Our business partners in Denmark are leading suppliers and manufactures including SMEs and start-ups.
- Honeywell's products contribute to the important innovative downstream projects in sectors such as pharmaceuticals, automotive (incl. electric vehicles), refrigeration, renewable energy, construction, as well as electronics.

The expected approach of the proposing countries, confirmed in the recent registration of the intent, is to expand the current definition of what constitute a PFAS, and to regulate thousands of substances never before considered as PFAS as one single group. In our view, this approach does not sufficiently consider the recently issued OECD guidelines, which emphasizes that PFAS is a broad, general, nonspecific term, which does not inform whether a compound is harmful and is not a basis for regulation.²

The new definition would, amongst others, include HFOs (a refrigerant with low global warming potentials that are used in applications such as refrigeration, air conditioning, building insulation, personal and household care) and PCTFE (a fluoropolymer that is used in high-barrier pharmaceutical packaging). In our view, capturing these two substances under the definition of PFAS is not scientifically justified, because they do not pose a risk to human health or the environment. The total costs for society should such a blanket ban be enacted would be extremely high (particularly for SMEs) and disproportionate to the alleged health and environmental risks which are being used to justify this future possible restriction.

¹ HFO Climate Impact (fluorineproducts-honeywell.com)

² OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris.

The proposed restriction would prohibit Honeywell from continuing to supply any HFOs and PCTFE to their partners and customers in Denmark. It could consequently have a negative impact on the businesses of these customers and (consequently) on the employment provided by these customers in Denmark.

Most importantly we believe the restriction could negatively impact the ability of Europe and its countries to achieve the ambitious decarbonisation and energy efficiency objectives already agreed in particular in the Paris Agreement and the EU Green Deal. For example, it would lead to the replacement of HFOs by alternatives with a greater environmental impact from reliability or safety issues and often with more indirect emissions, resulting largely from the energy used.

As we know these matters are important to you, we would very much value the opportunity to discuss the impact of the PFAS REACH restriction proposal on the Danish economy and on achieving the objectives set out in the Paris Agreement and the EU Green Deal with you.

Kind regards,

A handwritten signature in black ink, appearing to read 'Julien Soulet', with a stylized flourish at the end.

Julien Soulet
Vice President and General Manager for Advanced Materials EMEA

Til: Johan Munk Wolfhagen ([REDACTED]@mim.dk)
Fra: Johan Amby (EM-DEP) ([REDACTED]@em.dk)
Titel: SV: Spørgsmål ang. forbud mod brug af kemiske stoffer på EU-plan
Sendt: 02-11-2021 14:49

Kære Johan

Har i fundet en relevant kollega til denne?

Mvh
Johan



JOHAN AMBY (EM-DEP)

fuldmægtig

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Fra: Johan Munk Wolfhagen <[REDACTED]@mim.dk>
Sendt: 26. oktober 2021 14:47
Til: Johan Amby (EM-DEP) <[REDACTED]@em.dk>
Emne: SV: Spørgsmål ang. forbud mod brug af kemiske stoffer på EU-plan

Kære Johan

Jeg finder lige en relevant kollega, der kan tage fat i dig!

Mvh Johan

Johan Munk Wolfhagen

Fuldmægtig | Rent drikkevand og sikker kemi

| +45 21 78 05 69 | [REDACTED]@mim.dk

Miljøministeriet

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Fra: Johan Amby (EM-DEP) <[REDACTED]@em.dk>
Sendt: 26. oktober 2021 14:42
Til: Johan Munk Wolfhagen <[REDACTED]@mim.dk>

Emne: Spørgsmål ang. forbud mod brug af kemiske stoffer på EU-plan

Kære Johan

Jeg kontakter dig, da jeg er usikker på hvem i MIM, som er mest oplagt ift. denne. Vores AC har modtaget et brev fra Honeywell, en producent af kølemidler mv., som gerne vil drøfte PFAS REACH-forslaget fra juni 2021. Da det omhandler forbud mod brug af kemiske stoffer vil jeg høre om den ikke ligger bedre hos jer og om der evt. er en AC, som Brian kan henvise til hos jer?

Mvh
Johan



JOHAN AMBY (EM-DEP)

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Til: [REDACTED]@mst.dk ([REDACTED]@mst.dk)
Cc: Mikkel Aaman Sørensen ([REDACTED]@mim.dk)
Fra: Johan Amby (EM-DEP) ([REDACTED]@em.dk)
Titel: SV: Spørgsmål fra Honeywell ang. forbud mod brug af kemiske stoffer på EU-plan (PFAS)
Sendt: 04-11-2021 16:35
Bilag: Letter Brian Wessel - Denmark.pdf;

Kære Toke

Lægger i op til en drøftelse med Honeywell? Vi kan godt give bidrag og evt. tage med.

Hvordan ser i på deres argumentation ift. kølemidlerne og PFAS-forbuddet (at definitionen er for bred)?

Mvh
Johan



JOHAN AMBY (EM-DEP)
fuldmægtig

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Fra: Mikkel Aaman Sørensen <[REDACTED]@mim.dk>
Sendt: 3. november 2021 15:49
Til: Johan Amby (EM-DEP) <[REDACTED]@em.dk>
Cc: Rikke Donchil Holmberg <[REDACTED]@mim.dk>; Dorte Bjerregaard Lerche <[REDACTED]@mim.dk>; Johan Munk Wolfhagen <[REDACTED]@mim.dk>; Toke Winther <[REDACTED]@mst.dk>
Emne: Spørgsmål fra Honeywell ang. forbud mod brug af kemiske stoffer på EU-plan (PFAS)

Kære Johan Amby,

Allerførst undskyld at vi har været så længe om at svare dig.

Det nævnte REACH forslag er stadigvæk i en teknisk afklaringsfase. Derfor behandles alle henvendelser som udgangspunkt af Miljøstyrelsen.

Jeg har sat Toke Winther, som har arbejdet med forslaget som Cc på denne mail.

Venlig hilsen

Mikkel Aaman Sørensen

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