What you need to know about the updated PFAS restriction dossier

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Introduction

This summary sets out the main points of the Background Document for the proposed universal PFAS restriction under the REACH Regulation. The Background Document describes the environmental and human health risks associated with the use of PFASs and assesses the appropriateness (proportionality) of different restriction options to address them.

The Background Document is an update of the Annex XV report[1] first published in March 2023, incorporating information from more than 5 600 consultation answers submitted in the consultation on the Annex XV report (March to September 2023). The update led to the inclusion of eight additional sectors[2], resulting in 23 sectors being assessed in the Background Document.

What are PFASs?

PFASs – per and polyfluoroalkyl substances – are a group of over 10,000 man-made substances widely used in the EU across many sectors and applications. They do not break down under environmental conditions and can have a negative effect on human health and the environment.

The Background Document - like this summary - has been prepared by the national authorities of the five countries - Germany, the Netherlands, Denmark, Sweden and Norway (called the 'Dossier Submitters') - that compiled the original Annex XV report. It is now being evaluated by the European Chemicals Agency's scientific committees for Risk Assessment and Socio-Economic Analysis. The opinions of the committees – together with the Background Document – will form the basis for decision-making by the European Commission and EU Member States on the proposal.

This document summarises the extensive Background Document, which runs to over 3,300 pages, into an accessible overview of its main content, highlighting major changes compared to the March 2023 Annex XV report - such as details of the various additional sectors that have been assessed or changes to proposed derogations made based on improved knowledge of the suitability of alternatives to PFASs in specific sectors.

[1] *Under the EU REACH Regulation, an Annex XV report is the formal document prepared by a Member State competent authority or ECHA to propose a restriction or other regulatory action on a substance. It contains evidence on hazards, risks, uses, and socio-economic impacts, following a specific format defined in Annex XV of the REACH Regulation.*

[2] *To manage the large number of applications in and for which PFAS are being used, the Dossier Submitters opted to organize its dossier based on sectors. A sector is in that case a group of (economic) activities and/or industrial areas in which PFAS are used in a similar way or related purposes across supply chains, and that is sufficiently recognizable to stakeholders. Some applications of PFAS are used in many sectors in a similar way, e.g., in sealings, machinery, technical textiles, applications of fluorinated gases. In those cases the Dossier Submitter opted to cover those as an overarching application applicable to several sectors. Under which sector a specific application or use falls depends on where a product's end use is. A coated screw could for example fall under construction, transport or machinery, depending on the purpose for which it is used..*

The purpose of this summary is to allow stakeholders to readily identify the parts of the Background Document, and key updates to the restriction draft proposal, that are relevant to them. Whilst this summary is intended as a useful starting point, it is not an exhaustive account of the restriction dossier. The full Background Document is available on the website of the European Chemicals Agency (ECHA): https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas.

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

Legend

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

Figure 1 – Illustration of the range of tonnages and emissions for manufacture and use groups assessed in the background document based on data for 2020

This summary focuses on:

- the substances included in the proposed restriction (chemical scope);
- the PFAS concern (hazard and risk assessment);

- the different sectors of PFASs assessed (including their resulting emissions to the environment);
- the different restriction options considered and their associated socio-economic impacts (for each of the 23 sectors considered).

the main conclusions of the assessment, such as those relating to the proportionality[3] of the different restriction options.

Conclusion

All PFASs in the scope of the background document are either very persistent themselves or degrade into very persistent PFASs in the environment. As a consequence, if releases are not minimised, humans and other organisms will be exposed to progressively increasing amounts of PFASs. The resulting damage to the environment and human health is expected to last for long periods (decades to centuries). Even if further releases of PFASs were immediately prevented, existing technical and environmental stocks would continue to be a source of exposure for generations to come.

Even though not all PFASs are PBT substances, the concerns raised for them compare with the concerns for PBT/vPvB substances. Additional concerns regard mobility and long-range transport potential of PFASs. The Dossier Submitters therefore conclude that PFASs should be treated as non-threshold substances for the purpose of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment and environmental monitoring data regarded as a proxy for an unacceptable risk.

In accordance with previous restriction proposals on non-threshold substances, it is concluded that every emission to the environment increases the likelihood of adverse effects. Therefore, current and future emissions have to be minimized. According to the Dossier Submitters' assessment this can best be achieved with a group-based restriction under REACH.

The 2023 consultation on the Annex XV report resulted in over 5 600 comments from stakeholders, including among others information on uses, emissions, availability of alternatives and socio-economic impacts. Information from these comments has been used to update the dossier and resulted in the inclusion of eight additional sectors, with a complete assessment of the use of non-polymeric and polymeric PFASs in 23 sectors. For the European Economic Area, the Dossier Submitters estimate a yearly amount of 186 000 to 340 000 t of PFASs being introduced to the market (based on data from 2020), which – due to the expected economic growth in relation to several sectors – is expected to increase further under the baseline scenario.

Over a 30-year period (2025 – 2055) the expected mean PFAS tonnage used in the European Economic Area is 27 million tonnes, leading to emissions of about 4.7 million tonnes during the manufacture of products containing PFAS, the use phase and the end-of-life phase when no action is taken.

[3] *Proportionality refers to whether a restriction option is suitable and necessary to achieve the intended level of protection, without going beyond what is needed. It balances health and environmental protection with socio-economic impacts.*

The impacts of up to three different restriction options (full ban, restriction with time-limited derogations, continued use under certain conditions) are assessed on a sector level by the Dossier Submitters. In order to provide information on the appropriateness (proportionality) of the different restriction options, the Dossier Submitters take into account the costs associated with a restriction (among other criteria the existence of alternatives and time required before they could be implemented served as a proxy for the costs) as well as the effectiveness (emission reduction potential) of each of the restriction options.

Overall, a restriction for the assessed sectors with use-specific derogations (RO2) will reduce emissions by 83%. In comparison, a full ban will reduce emissions by around 96%. Costs under RO2 are generally found to be lower than under RO1 (full ban), rendering RO2 an option that is preferable over RO1 as it mitigates adverse socio-economic impacts through time-limited and unlimited derogations for uses for which it is not feasible to substitute PFASs within 18 months after entry-into-force. An exception to this is the manufacturing of PFAS, where a continued use under controlled conditions with releases not exceeding limit values is proposed to ensure the supply of PFASs for derogated uses.

Chemical scope, hazard, risk and main concerns

The chemical scope, hazard, risk and main concerns are described in Section 1.1 of the Main report of the Background Document.

These aspects have not changed compared to the original Annex XV report.

Substances covered

The Background Document defines PFASs as substances containing at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom in their molecular structure, with no H, Cl, Br and I atoms attached to that carbon. This definition is consistent with that developed by the Organisation for Economic Co-operation and Development (OECD) in 2021[4].

The scope includes both non-polymeric (e.g., perfluoroalkyl carboxylic acids, perfluorocarbons) and polymeric PFASs (e.g., fluoropolymers, perfluoropolyethers). The proposed restriction addresses all PFASs within scope irrespective of whether they are substances on their own, are constituents in another substance (including as an impurity or additive) or are present in mixtures or in articles.

The common chemical property underpinning all substances within this scope is their potential for very high environmental persistence (see below). Therefore, certain PFASs whose molecular structures are indicative of relatively rapid degradation in the environment (unlikely to meet the REACH Annex XIII criteria for persistence) are excluded from the scope.

Why PFASs are a concern for health and the environment

The concern for all of the PFASs within scope is predominantly their very high persistence in the environment, which by far exceeds the 'very persistent' (vP) criterion in Annex XIII of the REACH

[4] *https://www.oecd.org/content/dam/oecd/en/publications/reports/2021/07/reconciling-terminology-of-the-universe-of-per-and-polyfluoroalkyl-substances_a7fbcba8/e458e796-en.pdf*

Regulation. Their persistence is due to exceptionally strong carbon-fluorine bonds, leading to negligible degradation and environmental half-lives spanning decades to centuries.

In addition to the common property of persistence, a range of PFASs within the scope of the proposed restriction have been associated with concerns linked to their bioaccumulation, high mobility, long-range transport potential, accumulation in plants, global warming potential and/or (eco)toxicological effects.

A number of well-studied PFASs have harmonised or self-classifications for human health and/or environmental hazards. The absence of classifications for other PFASs is considered to reflect data gaps rather than a lack of hazard.

PFASs are released to the environment throughout their whole lifecycle. Information on the environmental fate of PFASs (Annex B.4 of the Background Document) highlights that PFASs are ubiquitous in air, water (including surface water, groundwater and drinking water), soil, sediment and biota. Human exposure occurs via (i) dietary intake, e.g., contaminated fish, meat, dairy and vegetables, (ii) drinking water, (iii) inhalation/dermal contact of/with indoor dust, air and consumer products and (iv) occupational exposure. Serum levels in the general population range from 1–10 ng/mL, with levels up to 100 ng/mL reported near contaminated sites. Combined exposure to PFAS mixtures exceeds health-based guidance values (e.g., EFSA's tolerable weekly intake of 4.4 ng/kg body weight), increasing the risk of liver, immune, and reproductive effects (see Annex B.5 of the Background Document).

Because of the concerns of PFASs, the Dossier Submitters consider the PFASs within the scope of the restriction dossier to pose a risk that is not adequately controlled. The Dossier Submitters conclude that it is not possible or appropriate to set a safe concentration limit of PFASs in the environment, given their persistence. Therefore, the Dossier Submitters consider that the objective of risk management should be to minimise future releases of PFASs in order to minimise the likelihood of adverse effects.

Regulatory approach and considered restriction options

The regulatory approach – the justification for an EU-wide restriction measure – and restriction scenarios are presented in the Main report of the Background Document in sections 1.2 and 2.3, respectively. The results of the assessments of the different restriction options (ROs) can be found in section 2.4.4.1 "Comparison of different restriction options" and in Tables 10 and 11 in the Main report.

A REACH restriction- the best way to minimise the risk

The Dossier Submitters conclude that a REACH restriction is the most effective way to control the identified risk due to:

- **Possibility to use a group-based approach**: Prevents regrettable substitution by targeting all PFASs.
- **Source control**: Addresses manufacture, use, and placing on the market, including imports.

Other legislative options are concluded to be less appropriate. For example, harmonised classification according to the CLP regulation and REACH authorisation are concluded to not be appropriate due to their focus on single substances. In addition, the high number of substances and uses would not be possible to manage under REACH authorisation because of the large number and diversity of different supply chains that would be affected. Also, for most sectors applicable sector-specific legislation is not considered sufficient as it does in many cases not aim at minimising emissions to the environment.

Three different restriction options are investigated

With a view to minimise emissions of PFASs, three restriction options (ROs) are assessed by the Dossier Submitters:

1. **RO1**: Full ban after an 18-month transitional period for all uses: as outlined in the Annex XV report (March 2023), RO1 offers the greatest potential for emission reduction but is considered **not to be proportionate** due to the high socio-economic costs that would arise because of the current lack of suitable alternatives for many sectors in such a short timeline.

2. **RO2**: Ban with time-limited derogations (6.5 or 13.5 years in duration) for uses with sufficiently strong evidence that suitable alternatives would not be available at 'entry into force' (termed – low substitution potential). The length of the derogation proposed is determined based on standardised criteria relating to status of development of alternatives and the time required to implement them.

3. **RO3**: Continued use of PFASs with strict emission limits, or additional emission controls to increase the effectiveness of an RO2[5].

The uses of PFASs and their emissions

The uses and emissions are reported in Annex A and Annex B of the Background Document, respectively. All uses of PFASs (except firefighting foams which are addressed in a separate restriction[6]) are within scope of the restriction.

Sectors that have been investigated

PFASs are currently used in a wide variety of uses. Based on information received across the various consultations[7], these uses were categorised by the Dossier Submitters into a series of distinct sectors, each with a clearly defined scope. In comparison to the original Annex XV report, the Background Document contains eight additional sectors, addressing either newly identified sectors or sectors that have been taken out of already assessed sectors. These additional sectors are:

- Printing applications,
- Sealing applications,
- Machinery applications,

[5] *RO3 options are considered for a limited number of sectors, based on whether relevant information was provided in the consultation on the Annex XV report.*

[6] *https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1856e8ce6*

[7] *Call for evidence: May – July 2020; 2nd Stakeholder consultation: July – Oct. 2021; Consultation on Annex XV report: March – Sept. 2023*

- Other medical applications (falling outside the scopes of active pharmaceutical ingredients and medical devices),
- Explosives,
- Military applications,
- Technical textiles and
- Broader industrial uses (e.g. solvents and catalysts used in industrial settings).

The number and breadth of the sectors considered, ensures that all current uses of PFASs, even if a specific use was not reported to the Dossier Submitters, could be categorised into one of these use groups. In this way, the Background Document is considered to provide clarity on the impacts of each of the restriction options assessed (i.e., RO1, RO2, etc.). The scope of each sector, including details of the specific uses contained within them, is described in Annex A of the Background Document. An overview of each of the sectors assessed, including an overview of their respective scope, is furthermore provided in Figure 2 and in Annex 1 of this summary document.

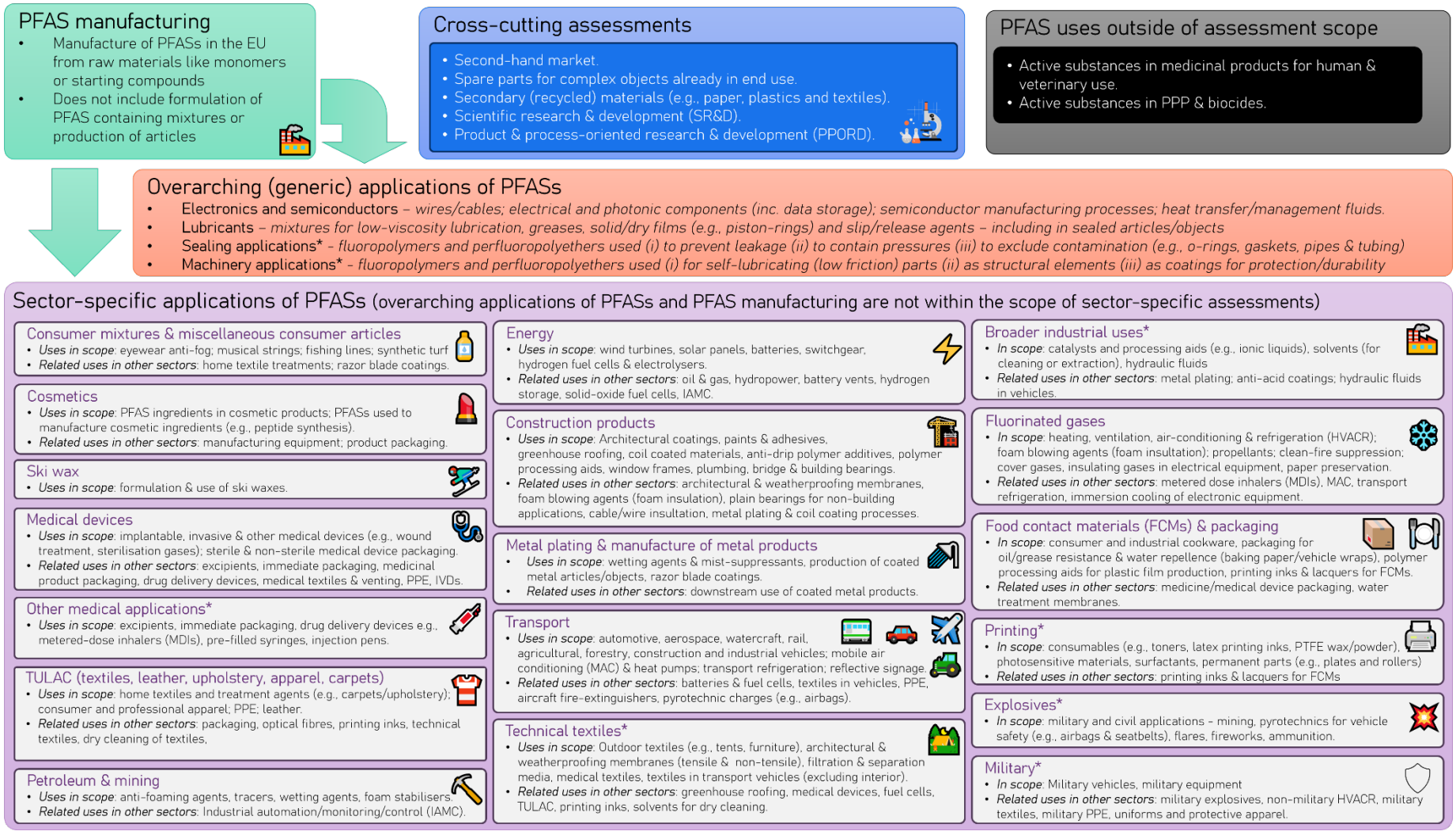

Figure 2 – Use map for the different sectors addressed in the Background Document. For further details see Annex 1.

Total volumes and emissions from the use of PFASs

The tonnage of PFASs used on a sector level is estimated by the Dossier Submitters based on the information provided in the 2023 consultation on the Annex XV report as well as preceding consultations[7] organised during the preparation phase of the dossier, combined with information from public sources (e.g. registration databases, scientific literature, permits). **The estimated volumes in the updated Background Document increased significantly in most of the sectors compared to the information available before the 2023 consultation.** This indicates the gained knowledge among stakeholders about their use of PFASs.

The Dossier Submitters estimate that approximately 190 000 – 340 000 tonnes of PFASs were introduced to the European Economic Area in 2020 (Table 3 in Main report of the Background Document). The volumes of the different PFAS groups are:

- Polymeric PFASs (mainly fluoropolymers): 84 000 to 199 000 tonnes.
- Fluorinated gases: 92 000 to 102 000 tonnes.
- PFAAs and PFAA precursors (non-polymeric PFASs): 11 000 to 41 000 tonnes.

The total amount of PFASs forecasted to be used in the EEA over a 30-year period (2022-2055) is estimated to be 27.1 million tonnes in the absence of a restriction (baseline scenario), with corresponding emissions of 4.7 million tonnes (Table 13, in Main report of the Background Document).

Emissions of PFASs (on which further information is provided in Annex B.9 of the Background Document) occur during the following lifecycle stages:

- **Manufacturing** of PFASs.
- **Production** of PFAS-containing products and mixtures.
- **Use phase**: Emissions from consumer and professional products (e.g., cosmetics and textiles) and industrial processes (e.g., leaks from heating, ventilation, air conditioning, and refrigeration equipment).
- **Waste stage**: Landfill leachates, incineration emissions, emissions from recycling and recovery and emissions from wastewater treatment, incl. sludge.

Emissions from the manufacture of PFASs are primarily estimated based on tonnage information provided during the consultation, combined with information on the effectiveness of abatement techniques, scientific publications, emission permits of production facilities, etc.

For the production and use phase, available information on use-specific emissions was used to estimate emissions. As specific (i.e., measured) information on emissions was typically lacking, generic release factors based on environmental release categories (ERCs) were predominantly used to estimate emissions, following applicable ECHA Guidance[8]. For emissions during the waste management phase, use-specific information on emissions was used if available although, similarly to the production and use lifecycle stages, this information was generally not available. In those cases, release estimates were based on generic emission factors from literature for incineration destruction

[8] *Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation*

efficiencies[9]. Distribution of waste between the main waste management routes was based on specific information on a sector level or general information from the Eurostat database.

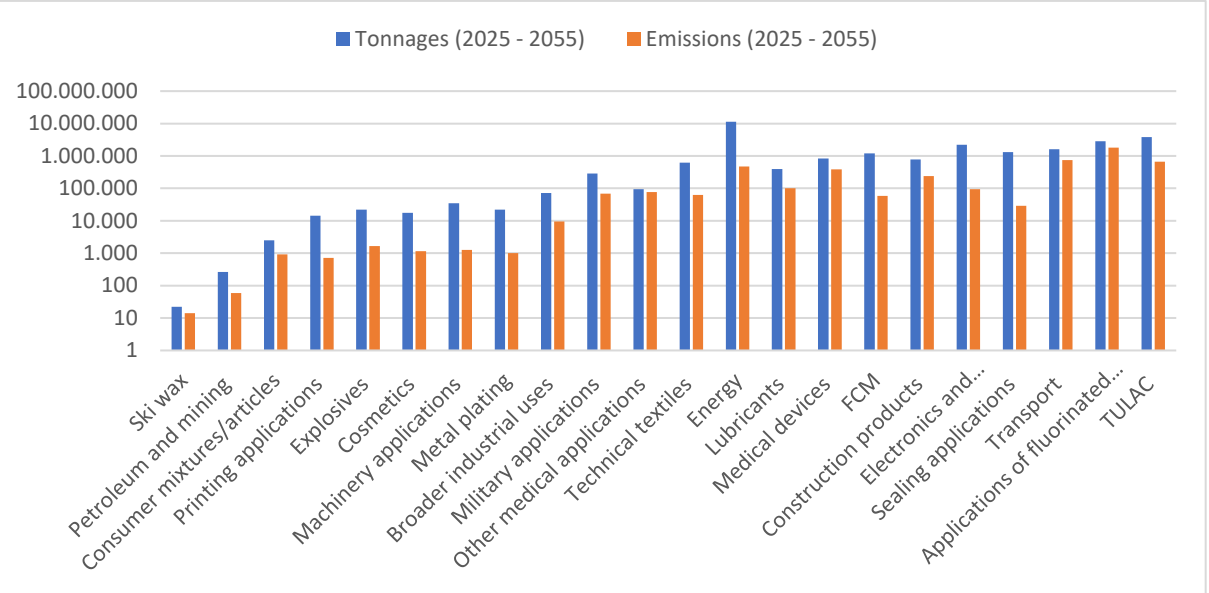

Figure 3 – Tonnage and Emissions over the assessment period 2025 - 2055 for the different PFAS use groups assessed in the Background Document (logarithmic scale).

Impact assessment for the sectors – methodological approach

The impact assessment is reported in Annex E.2 of the Background Document.

With a view of concluding on the appropriateness (i.e. proportionality) of each of the restriction options, a detailed impact assessment is conducted for each of the sectors listed in Annex 1 to this document.

The methodological approach (described in Annex E.2) consists of a structured semi-quantitative framework to evaluate the costs (negative impacts), benefits (positive impacts) and ultimately proportionality of the different restriction options at a use group level. A semi-quantitative cost-effectiveness approach that compares costs to the expected emission reduction is used. This approach is chosen recognising that PFASs should be treated as non-threshold substances for the purpose of risk assessment (see Section 1.1.6 in the Main report of the Background Document) and that emissions should as a result be minimised as all emissions pose a risk and adverse impacts for society cannot be ruled out below a specific threshold. A cost-effectiveness analysis, aiming to estimate the cost per avoided tonne of emissions, is a commonly applied approach for evaluating regulatory options for non-threshold substances (in the absence of defined response functions).

Quantification of the costs and benefits is attempted in all cases and quantified estimates have been provided whenever possible based on the information available to the Dossier Submitters as a result

[9] *99% assumed for non-hazardous waste incineration, 99.99% for hazardous waste incineration), or generic release factors for landfills (see Annex B.9.26*

of stakeholder consultations[7] as well as complementary research conducted by the Dossier Submitters. However, in light of data gaps in relation to various elements (particularly in relation to costs), a quantitative assessment is not feasible and/or meaningful in many cases as any estimate would have been associated with unacceptably high uncertainties.

The absence of quantitative cost estimates for most sectors prohibits the estimation of the cost per avoided tonne of emissions in quantitative terms. Instead, a semi-quantitative approach that compares the costs (categorised from 'very low' to 'very high' across five categories) to the emission reduction (in percentage terms) relative to the situation without a restriction (the baseline) is employed.

Qualitative information on the existence of suitable alternatives, i.e. alternatives with a better hazard profile that are technically and economically feasible and available in sufficient quantities, and the time required to implement them is considered to be a useful proxy for the costs associated with a ban on placing on the market and use. For example, where suitable alternatives are concluded not to exist at entry-into-force, the impacts of a full ban of PFASs (after a transition period of 18 months) would likely be associated with comparatively high costs for society (compared to uses where there are suitable alternatives). The existence of alternatives, therefore, is one (but not the only) criterion considered for the categorisation of costs. Further details of the methodology applied are provided in Annex E.2 of the Background Document. Along with a five-category scale for assessing the effectiveness (emission reduction potential) of each of the restriction options, this qualitative cost scale allows a 'proportionality matrix' to be plotted that visualises the likelihood that a restriction option would be considered proportionate:

Effectiveness: emission reduction [%]	**Costs**				
	Very low	**Low**	**Moderate**	**High**	**Very high**
Very Low (<70%)	Not effective enough to achieve the desired minimum effectiveness level				
Low (70 – 79%)					
Moderate (80 –89%)					
High (90 - 98%)					
Very high (≥99%)					Very effective, very high costs

Figure 4 - Proportionality matrix used in the Background Document to visualize the proportionality of the different restriction options considered. The coloring in the matrix reflects the conclusions on the likelihood of a restriction option to be proportionate. Dark green coloring implies that the restriction option can be considered 'proportionate', while light green coloring implies that it is 'likely proportionate'. Red coloring implies that the restriction option is 'not proportionate', while pink coloring means that the restriction option is 'likely not proportionate'. Yellow coloring implies that the restriction option is very effective but associated with very high costs. In this case it is advisable to consider a restriction option associated with lower costs.

A reduction of emissions is ultimately associated with wider societal benefits (on which further information is provided in the Main report of the Background Document in Sections 2.4.2 and 2.4.4). This includes:

- Avoided negative human health impacts;

- Avoided impacts on ecosystem functioning and the so-called ecosystem services provided to society by such ecosystems, e.g. food and water provision, climate regulation and recreation;
- Loss of property value in polluted areas; and
- Avoided remediation costs incurred in attempts to avoid or minimize the aforementioned impacts.

Overall, a restriction with use-specific derogations (RO2) is estimated to reduce emissions by 83% compared to the baseline scenario over the assessment period of 2025-2055. In comparison, a full ban (RO1) is estimated to reduce emissions by around 96%. Costs under RO2 are generally found to be lower than under RO1. For all assessed sectors, conclusions on the expected level of costs and expected emission reduction as well as the proportionality of different restriction options are summarised in the table below. For some sectors, an RO3 is assessed, considering sector specific conditions that could be implemented. For the manufacture of PFASs, the Dossier Submitters consider an RO3 to be the most proportionate measure (see Table 1 below).

All **derogations proposed** (based on conclusions that the respective RO2 is the most proportionate option) and the **changes in derogations** compared to the Annex XV report published in March 2023 can be found in Annex 2 to this document. Therefore, specific derogations associated with each sector under RO2 are not listed in the table below. Further details can be found in the Background document in Annex E.2 and Section 2.4 in the Main report.

Table 1 – Overview of tonnages, emissions, expected emission reduction under the different restriction options as well as expected costs and the proportionality over the assessment period of 2025 – 2055 of the different PFAS use groups assessed in the Background Document

Sector	PFAS use (tonnes) in the absence of a restriction 2025-2055	Emissions in the absence of a restriction (tonnes, with end-of-life emissions) 2025-2055	Emission reduction (%) 2025-2055	Costs	Proportionality
Total	**27 085 126**	**4 745 333**	**RO1: 96% (High)** **RO2: 83% (Moderate)**		
TULAC	3 780 157	664 871	RO1: 95% (High) RO2: 95% (High)	RO1: Very high RO2: Moderate	RO1: Likely not proportionate RO2: Likely proportionate
Food contact materials and packaging	1 198 801	58 804	RO1: 97% (High) RO2: 96% (High)	RO1: Very high RO2: Moderate	RO1: Likely not proportionate RO2: Likely proportionate
Metal plating and manufacture of metal products	22 337	1 013	RO1: 94% (High) RO2: 91% (High)	RO1: High to very high RO2: Low to moderate	RO1: Likely not proportionate RO2: Likely proportionate
Consumer mixtures and miscellaneous consumer articles	2 496	912	RO1: 94% (High)	RO1: Low	RO1: Deemed proportionate
Cosmetics	17 475	1 165	RO1: 94% (High)	RO1: Low	RO1: Deemed proportionate
Ski wax	22	14	RO1: 90% (High)	RO1: Very low	RO1: Deemed proportionate
Applications of fluorinated gases	2 837 008	1 804 914	RO1: 95% (High) RO2: 83% (Moderate)	RO1: Very high RO2: Low	RO1: Likely not proportionate RO2: Likely proportionate
Medical devices	829 278	387 686	RO1: 97% (High) RO2: 97% (High)	RO1: Very high RO2: Moderate	RO1: Likely not proportionate RO2: Likely proportionate
Transport	1 606 016	738 478	RO1: 94% (High) RO2: 61% (Very low) RO3: 64% (Very low)	RO1: Very high RO2: Moderate RO3: High	RO1: Likely not proportionate RO2: Not effective enough RO3: Not effective enough
Electronics and semiconductors	2 199 106	94 277	RO1: 98% (High) RO2: 79% (Low) RO3: 72% (Low)	RO1: Very high RO2: Moderate RO3: Moderate	RO1: Likely not proportionate

Sector	PFAS use (tonnes) in the absence of a restriction 2025-2055	Emissions in the absence of a restriction (tonnes, with end-of-life emissions) 2025-2055	Emission reduction (%) 2025-2055	Costs	Proportionality
					RO2: Likely proportionate RO3: Likely proportionate
Energy	11 243 057	470 246	RO1: 99% (High) RO2: 90% (High) RO3: Not quantified (Lower)	RO1: Very high RO2: Moderate RO3: Not estimated, possibly lower than RO1 and RO2	RO1: Likely not proportionate RO2: Likely proportionate RO3: Likely proportionate (but this depends on the treatment methods at the waste stage)
Construction products	787 293	241 400	RO1: 96% (High) RO2: 95% (High)	RO1: Very high RO2: Moderate	RO1: Likely not proportionate RO2: Likely proportionate
Lubricants	392 568	100 108	RO1: 96% (High) RO2: 62% (Very low)	RO1: Very high RO2: Moderate	RO1: Likely not proportionate RO2: Likely proportionate
Petroleum and mining	264	59 (without EoL)	RO1: 94% (High) RO2: 94% (High)	RO1: High RO2: Low	RO1: Likely not proportionate RO2: Deemed proportionate
Printing applications	14 461	722	RO1: 96% (High) RO2: 80% (Moderate)	RO1: High RO2: Moderate	RO1: Likely not proportionate RO2: Likely proportionate
Sealing applications	1 317 296	29 086	RO1: 96% (High) RO2: 66% (Very low) RO3: 10% (Very low)	RO1: Very high RO2: Moderate RO3: Low	RO1: Likely not proportionate RO2: Not effective enough RO3: Not effective enough
Machinery applications	34 432	1 265	RO1: 96% (High) RO2: 66% (Very low) RO3: 42% (Very low)	RO1: Very high RO2: Moderate RO3: Low	RO1: Likely not proportionate RO2: Not effective enough RO3: Not effective enough
Other medical applications	94 518	76 626	RO1: 91% (High) RO2: 74% (Low)	RO1: Very high RO2: Moderate	RO1: Likely not proportionate RO2: Likely proportionate

Sector	PFAS use (tonnes) in the absence of a restriction 2025-2055	Emissions in the absence of a restriction (tonnes, with end-of-life emissions) 2025-2055	Emission reduction (%) 2025-2055	Costs	Proportionality
Military applications[10]	284 297	69 099	RO1: 97% (High) RO2: 72% (Low)	RO1: Very high RO2: Moderate	RO1: Likely not proportionate RO2: Likely proportionate
Explosives	22 009	1 664	RO1: 96% (High) RO2: 95% (High)	RO1: Not available RO2: Not available	RO1: No conclusion possible RO2: No conclusion possible
Technical textiles	614 665	62 464	RO1: 97% (High) RO2: 84% (Moderate) RO3: 76% (Low)	RO1: Very high RO2: Moderate RO3: Low to moderate	RO1: Likely not proportionate RO2: Likely proportionate RO3: Likely proportionate
Broader industrial uses	71 867	9 618	RO1: 96% (High) RO2: 68% (Very low)	RO1: High RO2: Moderate	RO1: Likely not proportionate RO2: Likely proportionate

[10] *Tonnage and emissions for military applications reported for the sake of completeness, but not included in the total to avoid double counting as the sub-uses are covered under other sectors.*

Manufacture of PFASs

The impacts on the manufacture of PFASs are assessed in Annex E.2.1 of the Background Document. For the manufacture of PFASs, an RO3 is proposed as the most appropriate restriction option. This RO3 allows continued manufacturing of PFASs for derogated uses and export under strictly controlled conditions. Emissions of PFASs may not exceed 0.01% of the tonnage produced in a year at a facility (unless stricter EU or national legislation applies) and this should be achieved 6.5 years after entry into force of the restriction. For fluoropolymer manufacturing processes where polymerisation aid technology is used (either fluorinated or non-fluorinated polymerisation aids), the emissions may not exceed 0.0036% of the tonnage produced per year at a facility (unless stricter EU or national legislation applies) as of the end of 2030. This is estimated to result in an emission reduction of 90 to 93% over 30 years (2025-2055) compared to the baseline scenario. At the same time, it ensures that derogated uses will have access to necessary (starting materials) for their products/uses.

Derogations for second-hand articles, spare parts and recycling

A restriction on the manufacture, use and placing on the market of PFASs as substances on their own and their placing on the market in (i) another substance, as a constituent, (ii) a mixture or (iii) an article would also impact the placing on the market of second-hand articles, spare parts and potentially products made of recycled material (depending on whether those comply with the proposed concentration limits). With a view of determining whether a full ban with a transition period of 18 months (RO1) with the considered concentration limits can be considered proportionate or whether specific derogations are advisable, the impacts of such a restriction option are assessed in Annex E.3 of the Background Document. **These aspects were not discussed in detail in the original Annex XV report but are newly introduced in Background Document.** On the basis of the assessment, the following conclusions are drawn:

Second-hand articles: The restriction impacts the second-hand market, particularly for textiles, apparel, and electronics containing PFASs. Items like PFAS-treated carpets or clothing could be restricted from resale if the concentration of PFASs exceeded the proposed concentration limits (e.g., 0.1 mg/kg for total PFASs in textiles). This could reduce market value and availability, affecting low-income consumers who rely on second-hand goods. Stakeholders highlight enforcement challenges, as testing second-hand items is impractical, potentially leading to informal markets or waste diversion. Therefore, the Background Document proposes a derogation from the restriction for placing on the market of articles which were already in end-use in the Union.

Spare parts: A potential restriction of PFASs in spare parts, such as replacement seals or other components in machinery or vehicles, would lead to premature disposal and obsolescence of PFAS-containing complex objects. Therefore, the Dossier Submitters propose a derogation from the restriction for spare parts to maintain safety and functionality (e.g., in medical devices or transport). Manufacturers report that PFAS-free alternative spare parts are not yet suitable for all relevant uses of PFASs, potentially increasing costs or safety risks during transition periods (e.g., 12–24 months proposed).

Impacts on recycling and circular economy: Based on the information submitted to the consultation on the Annex XV report, the Dossier Submitters have identified four main types of material recycling that may be impacted by a restriction, namely (i) plastics, (ii) paper/cardboard, (iii) textile and (iv)

metals. The term 'material recycling' is interpreted in accordance with Directive 2008/98/EC on waste. Based on the information provided by stakeholders, the Dossier Submitters conclude that there is sufficiently strong evidence that **recycled metals** will meet the proposed concentration limits for PFASs and that, therefore, the proposed restriction would not have disproportionate impacts on metal recycling activities. However, with respect to (i) plastics, (ii) paper and cardboard and (iii) textiles, the Dossier Submitters conclude that it is not proportionate to require recyclers to adhere to the concentration limits set out in the proposed restriction as this would largely lead to a need to abandon recycling activities.

Other important topics in the Background Document

Information on the following topics can be found in the Background Document in the explanatory note as well as in section 2.5 in Main report as well as in Annex E.4.1.

Review of proposed derogations

The proposed derogations are based on the expected substitution potential (with no derogations being proposed where the substitution potential is high (18 months after entry-into-force of a restriction). A derogation of 13.5 years is generally proposed when research and development efforts so far did not identify possible PFAS-free alternatives or where certification processes of known alternatives require more than 6.5 years. The Dossier Submitters consider this timeframe to normally be sufficient for industry to take benefit from technical progress and to carry out scientific research and development activities to find and deploy technically and economically feasible alternatives. As research and development processes have yet to start in many cases, uncertainties are generally high for 13.5-year derogations (e.g., fluoropolymers in sealings, lubricants, and batteries). A review clause could avoid socio-economic impacts if alternatives are not developed in time, but it is in the European Commission's remit to implement this.

Approach to the upstream supply chain for derogated uses

Derogations implicitly include the use of PFASs in the upstream supply chain (as starting materials, intermediates, final substances) for derogated uses, covering substances, mixtures, and articles, but not PFASs in equipment, solvents, or auxiliary chemicals not contained in the final product. This approach has been proposed as specific PFASs are required for derogated uses, necessitating production from PFAS-based materials.

Product and Process Oriented Research and Development (PPORD)

A time-unlimited PPORD derogation for derogated uses is proposed, ceasing when the specific derogation ends. This has been proposed to not hinder the development process in which also lower amounts of PFAS may be achieved for certain processes or products.

Scientific research and development

REACH Article 67(1) generally exempts scientific research and development from restrictions. This involves lab-scale experimentation (<1 tonne/year), including synthesis, testing, and quality control. The Dossier Submitters consider that this covers PFASs (polymeric and non-polymeric) in scientific

research and development products (like reagents, solvents, filter membranes, seals, lubricants) for sample preparation, diagnostics, and analysis.

Practicability and Monitorability

A restriction has to be implementable and enforceable. This is assessed by the Dossier Submitters in section 2.5 of the Main report of the Background Document and Annex E.4 of the Background Document.

No major changes were introduced compared to the initial Annex XV report.

The main aspects to consider with regard to practicability are, among others, analytical methods, monitorability and challenges.

Analytical methods: Analytical methods have been described. Concentration limits were proposed above which manufacture, use, and placing on the market is prohibited:

- 25 ppb for individual non-polymeric PFASs,
- 250 ppb for sum of non-polymeric PFASs,
- 50 ppm for total fluorine (including polymeric PFASs).

Practicability: RO2 and RO3 are feasible with derogations and reporting, though research and development for alternatives and supply chain adjustments pose challenges.

Monitorability: Industry reports, customs data, and environmental sampling (50 EEA sites) support compliance, but gaps in isomer detection and import tracing persist (monitoring costs estimated to be €10–100 million/year).

Challenges: Data gaps in PFAS inventories and illegal imports require enhanced monitoring.

Reporting requirements and site-specific management plans

Reporting requirements for manufacturers, importers of PFASs and PFAS-containing products, and formulators, are discussed in the explanatory note and in section 2.5 of the Main report as well as in Annex E.4.1 of the Background Document. They are proposed for derogations with a duration of 13.5 years or time-unlimited as well as for all applications of fluorinated gases, with a view of creating an understanding of the magnitude of continuing emissions as well as the progress made in relation to substitution. This could help the European Commission to gather data on the use of these substances in these sectors and to monitor any changes. In the event that data reveals any concerns for the sector, further actions can be initiated on European Commission level.

Manufacturers, importers and downstream users of fluoropolymers and perfluoropolyethers making use of any derogation should prepare a site-specific management plan, outlining which PFASs are used in which quantities and in which products. These plans are a tool to ensure users of fluoropolymers and perfluoropolyethers adequately assess all life cycle stages of their PFAS-containing products during the transitional period and support the implementation of suitable risk management measures and operational conditions, and allows enforcement to monitor this.

Annex 1 – Scope of the sectors assessed in the Background Document

The following table summarises the scope of each of the different sectors assessed in the Background Document. For the full scope, please refer to the Background Document.

Sectors	Uses assessed withing sector	Uses assessed elsewhere
PFAS manufacturing	• Manufacture of PFASs in the EU from raw materials like monomers or starting compounds.	• Further processing of PFAS containing mixtures or articles (e.g., blending, purification, compounding, moulding, milling, grinding, drying, sintering, machining, cutting; (covered in respective use/application sections)). • Use of PFAS in various applications (covered in respective use/application sections). • Imported PFAS volumes (final uses assessed in use groups).
TULAC (Textiles, Upholstery, Leather, Apparel, Carpets)	• Home textiles (e.g., carpets, seat covers including in vehicles and public settings like hospitals and public transport). • Consumer apparel. • Professional apparel and personal protective equipment (PPE). • Leather. • Home fabric treatments.	• Packaging (see food contact materials and packaging, A.3.4). • Optical fibre weaving solutions for lighting applications (e.g., in health, apparel, automotive, safety, communication, architecture, industrial applications; see electronics and semiconductors, A.3.12). • Latex printing inks for textiles (see printing applications, A.3.17). • Industrial applications relevant for production processes of the textile industry (e.g., conveyor belts, dyeing machinery; covered in machinery applications or other relevant sectors). • Technical textiles (covered separately, A.3.23). • Solvents for dry-cleaning of textiles (see applications of fluorinated gases, RCOM).
Food contact materials and packaging	• Packaging for oil/grease resistance and water repellence (e.g., baking papers, vehicle wraps). • PFAS as processing aids in plastic film/sheet production. • Consumer cookware/appliances with non-stick surfaces. • Industrial food/feed production for non-stick surfaces and polymer processing additives (e.g., emulsifiers).	• Industrial equipment with fluoropolymers (e.g., sealings, gaskets, piping, conveyor belts) in food/feed production, except non-stick coated cookware (see sealing applications, A.3.18 and machinery applications, A.3.19). • Primary packaging for pharmaceuticals and non-sterilised medical devices (see medical devices, A.3.10). • Membranes/filtration materials for drinking water treatment (see technical textiles, A.3.23).

	• f-HDPE (fluorinated high-density polyethylene) packaging. • Other packaging applications.	• Non-intentionally added substances (NIAS) in recycled packaging (covered in recycling section). • Lubricants in industrial settings (see lubricants, A.3.15). • PFAS production and end-of-life material management (see PFAS manufacturing, A.2.1).
Metal plating and manufacture of metal products	• PFAS in metal plating as wetting agents and mist/fume suppressants. • Fluoropolymers in production of metal products used in buildings, construction, transport, energy, etc. • Razor blade coatings. • Solvents in metal manufacturing	• PFAS for engine parts and technical components (see transport, A.3.11). • PFAS in machinery parts and industrial applications (e.g., sealings; see sealing applications, A.3.18 and machinery applications, A.3.19). • PFAS in military equipment parts (see military applications, A.3.21). • Coil coating of metals (see construction products, A.3.14). • PFAS as cover gases in magnesium casting (see applications of fluorinated gases, A.3.9). • Other uses not listed (assessed in relevant sectors or separately if identified). • End-of-life (EoL) lifecycle stage (assessed in specific use groups).
Consumer mixtures and miscellaneous consumer articles	• Anti-fogging agents for spectacles/goggles. • PVDF strings for musical instruments. • Fishing lines. • Synthetic turf.	• Cosmetics, ski wax, and home fabric treatments (see sections on cosmetic (A.3.7), ski wax (A.3.8) and TULAC (A.3.3). • Razor blade coatings (see metal plating and manufacture of metal products, A.3.5). • Electrical components for musical instruments (see electronics and semiconductors, A.3.12). • Strings for musical instruments as spare parts (see spare parts, E.3.3).
Cosmetics	• PFAS in cosmetic products. • PFAS in manufacturing of cosmetic ingredients (e.g., peptide synthesis).	• PFAS in manufacturing equipment for cosmetics (e.g., sealing applications; see sealing applications, A.3.18 and machinery applications (A.3.19)). • Packaging of cosmetic products (see FCM and Packaging, A.3.4). • Analytical equipment in cosmetics sector (see explanatory note in main report).
Ski wax	• Ski wax.	• None specified.
Applications of fluorinated gases	• Heating, ventilation, air conditioning, and refrigeration (HVACR).	• Metered dose inhalers (MDIs; see Other medical applications A.3.20)

	• Foam blowing agents (foam insulation). • Propellants. • Cover gases. • Clean fire suppressants. • Insulating gases in electrical equipment. • Preservation of cultural paper-based materials.	• Mobile air conditioning (MAC; use, emissions and alternatives are reported as an application of fluorinated gases; impact assessment is reported in transport, A.3.11). • Transport refrigeration (use, emissions and alternatives are reported as an application of fluorinated gases; impact assessment is reported in transport, A.3.11). • Immersion cooling for IT hardware/batteries (see electronics and semiconductors, A.3.12). • Semiconductor manufacturing (see electronics and semiconductors, A.3.12). • Solvents for cleaning in semiconductor manufacturing and carrier solvents for lubricants (see electronics and semiconductors, A.3.12; broader industrial uses, A.3.24; lubricants, A.3.15). • Fluoropolymers in equipment containing fluorinated gases (e.g., o-rings, gaskets; see sealing applications, A.3.18). • Military applications of fluorinated gases (see military applications, A.3.21).
Medical devices	• Implantable medical devices. • Invasive medical devices. • Non-implantable/non-invasive medical devices (e.g., coatings, wound treatment, sterilisation gases). • Packaging for terminally sterilised and non-sterilised medical devices (PCTFE-based packaging fully assessed).	• Electronic equipment for medical imaging (see electronics and semiconductors, A.3.12). • Diagnostic laboratory testing (see scientific research and development, explanatory note). • Excipients, immediate packaging, and drug delivery devices (e.g., pMDIs, pre-filled syringes, injection pens, autoinjectors, on-body delivery systems; see other medical applications, A.3.20). • Medical textiles and membranes for venting (see technical textiles, A.3.23). • Personal protective equipment (e.g., clothing, drapes; see TULAC, A.3.3). • Analytical equipment (e.g., valves, tubing, connectors; see Sealing Applications, explanatory note in main report). • Trifluoroacetic acid (TFA) in laboratory uses/measuring devices (see explanatory note in main report). • TFA in manufacturing (see PFAS manufacturing, A.3.1). • Sealing applications, bearings, cables/wires for medical equipment (see sealing applications, A.3.18; machinery applications, A.3.19; electronics and semiconductors, A.3.12).

		• Packaging for medicines (see other medical applications, A.3.20). • Non-medical device packaging (see FCM & Packaging, A.3.4). • *In vitro* diagnostic medical devices (IVD; see Scientific Research and Development, explanatory note in main report).
Transport	• Automotive vehicles (e.g., motorcycles, cars, vans, lorries, buses, utility vehicles). • Aerospace vehicles (e.g., aircraft, drones, spacecraft). • Watercraft (e.g., boats, ships, ferries, submarines). • Rail vehicles (e.g., locomotives, passenger coaches, freight wagons). • Agricultural/forestry vehicles (e.g., tractors, harvesters, mowers and sprayers e.g. those falling under the European vehicle category T). • Construction/industrial vehicles (e.g., bulldozers, forklifts, cranes). • Transport-related infrastructure (e.g., reflective coatings for signage). • Horizontal use categories: body/hull/fuselage (e.g., foam mouldings), combustion engine, hydraulic fluids, coatings/liners/finishes, HVACR in transport vehicles (impact assessment only), aerospace-specific applications (e.g., hose linings), other transport uses (e.g., flotation fluids).	• Sealing applications, such as o-rings, gasket, valve seals, tubing, tank linings, etc. (see sealing applications, A.3.18) • Machinery applications, such as self-lubricating/low-friction components/coatings (see machinery applications, A.3.19). • Lubricants (see lubricants, A.3.15). • Mist suppressants in metal plating processes (see metal plating and manufacture of metal products, A.3.5). • Electronic components, optical fibres, sensors, immersion cooling (see electronics and semiconductors, A.3.12). • Batteries and fuel cells (see energy, A.3.13). • Textiles in engine bays (see technical textiles, A.3.23). • Interior textile treatments (see TULAC, A.3.3). • Personal protective equipment (e.g., life jackets; see TULAC, A.3.3). • Anti-drip additives in polymers (see electronics and semiconductors, A.3.12). • Acrylic foam tape (see sealing applications, A.3.18). • Fire extinguishers for aircraft (see applications of fluorinated gases, A.3.9). • Propellants for spray biocides in aircraft (see applications of fluorinated gases, A.3.9). • Pyrotechnic charges (e.g., airbags, seatbelt pretensioners; see explosives, A.3.22). • Spare parts (see spare parts, E.3.3). • Mobile air conditioning (MAC; use, emissions and alternatives are reported as an application of fluorinated gases; impact assessment is reported in transport, A.3.11. • Transport refrigeration (use, emissions and alternatives are reported as an application of fluorinated gases; impact assessment is reported in transport, A.3.11).

Electronics and semiconductors	• Wires and cables (excl. optical fibres). • Insulation material of electronic components (excl. wires/cables). • Coating/film of electronic components (excl. photonics). • Electronic components (e.g., printed circuit boards, antennas, piezoelectric devices, sensors). • Photonics (e.g., optical fibres, OLED, LCD, optical coatings). • Plastic additives (incl. anti-drip agents). • Heat transfer fluids (immersion cooling, cold plate cooling), including battery cooling. • Vapor phase soldering/condensation soldering. • Electronic data storage (excl. lubricants). • Semiconductor manufacturing (photolithography, etching, deposition, engineered fluids, equipment, advanced packaging, MEMS). • Other uses (e.g., medical imaging, power electronics, IAMC, telecommunication infrastructure, electrical heat tracing).	• Sealing applications (e.g., pipe linings, tubing, o-rings, gaskets; see sealing applications, A.3.18). • Machinery/equipment applications (e.g., conveyor systems, robotic arms; see machinery applications, A.3.19). • Membranes, vents and filters (see technical textiles, A.3.23). • Lubricants for magnetic recording media (see lubricants, A.3.15). • Electrical insulating gases (see applications of fluorinated gases, A.3.9). • Industrial precision cleaning (see broader industrial uses, A.3.24, except for specific uses in chemical vapor deposition/etch cleaning). • Refrigerants (chillers) in electronics (see A.3.9). • Non-electronic parts of sensors (e.g., liners, filters, membranes, gaskets; see sealing applications, machinery applications, technical textiles). • Spare parts (see Spare Parts, E.3.3). • Capacitors (assessed in Electronics and Semiconductors, except double layer capacitors in Energy, A.3.13).
Energy	• Renewable energy generation (wind, solar). • Hydrogen technology (e.g. PEM fuel cells, electrolysers). • Batteries. • Electrical grids (e.g., PTFE nozzles in switchgear, circuit breakers). • Manufacture of chemicals via electrolysis.	• Sealing applications (e.g., pipe linings, o-rings, gaskets; see sealing applications, A.3.18, except for fuel cell/electrolyser MEAs). • Machinery/equipment applications (e.g., conveyor systems, bearings; see machinery applications, A.3.19). • Lubricants e.g. for wind turbines (A.3.15). • Hydropower (see sealing applications (A.3.18), machinery applications (A.3.19)). • Anti-drip additives in polymers (see electronics and semiconductors, A.3.12). • Power plants (fossil fuel, nuclear, waste-to-energy; see sealing applications (A.3.18), machinery applications (A.3.19), electronics and semiconductors (A.3.12), lubricants (A.3.15)). • Oil and gas applications (see, petroleum and mining, A.3.16). • Membranes (e.g., HEPA filters, H2/zinc-air battery membranes; see technical textiles (A.3.23), except fuel cell/electrolyser membranes).

		• Solid oxide electrolyser/fuel cells (SOEC/SOFC; see sealing applications, A.3.18). • Hydrogen storage, refuelling, transport (see sealing applications (A.3.18), machinery applications (A.3.19)). • Solvents for cleaning (see electronics and semiconductors (A.3.12), broader industrial uses (A.3.24). • Electrical grids (except PTFE nozzles in switchgear/circuit breakers; see sealing applications (A.3.18), machinery applications (A.3.19), electronics and semiconductors (A.3.12), lubricants (A.3.15), applications of fluorinated Gases (A.3.9)). • Industrial Automation Monitoring and Control (IAMC; see sealing applications (A.3.18), machinery applications (A.3.19), electronics and semiconductors (A.3.12)). • Wires, cables and electronic components in e.g. photovoltaic panels (A.3.12). • Spare parts (see Spare Parts, E.3.3).
Construction products	• Architectural coatings and paints. • Coil coated product used in construction. • Polymer additives for fire safety. • Film/foil for greenhouses. • Processing aids for non-PFAS polymers/plastics. • Bridge and building bearings. • Window frames. • Plumbing applications. • Surface protection. • Wetting/levelling agents in coatings, paints, adhesives.	• Mist suppressants in metal plating processes (see metal plating and manufacture of metal products, A.3.5). • Coil coating of metal products (see metal plating and manufacture of metal products, A.3.5). • Architectural membranes (see technical textiles, A.3.23). • Flexible solar panels (see energy, A.3.13). • Foam blowing agents in roofing (see applications of fluorinated gases, A.3.9). • Weatherproofing membranes, vapour barriers (see technical textiles, A.3.23). • Coated fabric, fiberglass coating (see technical textiles, A.3.23). • Cables and wire insulation (see electronics and semiconductors, A.3.12). • Renewable energy systems (see energy, A.3.13). • Sealings, thread sealing tape, valves, pipes (see sealing applications, A.3.18). • Plain bearings for non-building applications (energy systems, cranes, lifts, elevators) in machinery/equipment(see machinery applications, A.3.19).

		• Lubricants in manufacturing PEX-pipes for underfloor heating (see lubricants, A.3.15). • Electrochromic functionalities in glazing (see electronics and semiconductors, A.3.12). • Film/coating of wind turbines/solar cells (see energy, A.3.13).
Lubricants	• Industrial use such as machinery, plastic/rubber products, electronics, food, paper, chemical industry, offshore/oil & gas, metal/steel, water/wastewater treatment, nuclear energy. • Professional use such as automotive, aerospace, rail/sea transport, watchmaking, test/monitoring equipment, medical devices, aviation, renewable energy, machinery outside factories, military applications, diving equipment, printing applications. Examples of specific uses: Dry lubrication for piston rings, slip/release agents for moulds, lubrication of assembly of medical devices, lubrication of syringes, carrier solvents for lubricant dispersions such as epilame mixtures for watchmaking.	• Lubricants for bike chains, zippers, piano keys, instrument strings, PTFE spray for door hinges (see consumer mixtures and miscellaneous consumer articles, A.3.6). • Articles and complex objects such as bearings, bearing liners, pumps are assessed in Machinery, c.f. A.3.19. • Low-friction sealing as an inherent property of fluoropolymers (see sealing applications, A.3.18). • Solvents for cleaning see applications of fluorinated gases (A.3.9), electronics and semiconductors (A.3.12) and broader industrial uses (A.3.24)). • EEE specialist equipment (see Electronics and Semiconductors, A.3.12). • Hydraulic oils (see transport, A.3.11).
Petroleum and mining	• Fluorinated siloxanes as anti-foaming agents. • Fluorinated alkanes as tracers in reservoirs (petroleum industry). • Wetting agents to leach ores (mining). • Acid mist suppressing agents in surface treatment baths (mining). • Foam stabilisers for metal salt separation in flotation (mining).	• Fluoropolymer applications (e.g., sealants, membranes; see sealing applications, E.2.13; machinery applications, E.2.17; technical textiles, E.2.22).
Printing applications	• Consumables: toners, latex printing inks, PTFE wax, pigments/colourants, PTFE powders, photosensitive materials, surfactants in printing equipment. • Permanent parts: electrophotographic press units, kinetic printing components, printing plates (offset/letterpress), rollers.	• Printing inks, lacquers, coatings for food contact materials (see food contact materials and packaging, A.3.4). • Solvents for 3D printing (see applications of fluorinated gases, A.3.9). • Lubricants (see lubricants, A.3.15). • Printed circuit boards, sensors (see electronics and semiconductors, A.3.12). • Sealing components in printing machinery (see sealing applications, A.3.18).

Sealing applications	• Fluoropolymers (FPs) and perfluoropolyethers (PFPEs) to prevent leakage, contain pressure, exclude contamination (e.g., pipes, o-rings, gaskets). • Applications in food production/handling, metal plating, cosmetics production, HVACR equipment, medical devices (except specific coatings), transport vehicles (except hoses in combustion engines and hose linings for aerospace), electronics/semiconductors, including production facilities (except cable liners, component coatings, vents), energy (except specific uses in fuel cells/electrolysers and PTFE nozzles used in switchgear), construction (except consumer sealants, threshold seals, specific tapes), petroleum/mining.	• Food contact materials and packaging (e.g., grease-proof paper, non-stick cookware coatings; see FCM & Packaging, A.3.4). • Metal plating (e.g., surface tension modifiers; see metal plating, A.3.5). • Medical device coatings (e.g., needles, stents, endoscopes, ePTFE devices; see medical devices, A.3.10). • Transport hoses in combustion engines, aerospace hose linings (see Transport, A.3.11). • Electronic component coatings, cable liners, vents for electronics/semiconductors (see electronics and semiconductors, A.3.12; technical textiles, A.3.23). • Energy-specific uses (e.g., wind-turbine blade coatings, PV module front/back sheets, fuel cell MEAs, PTFE nozzles in switchgear; see energy, A.3.13). • Consumer sealants, threshold seals, specific construction tapes (see construction products, A.3.14). • Lubrication of dynamic seals (see lubricants, A.3.15). • Spare parts (see Spare Parts, E.3.3).
Machinery applications	• Fluoropolymers (FPs) and perfluoropolyethers (PFPEs) in machinery (stationary/portable, portable machinery that is not already within the scope of the transport sector) for self-lubricating/low-friction components, structural elements, coatings for protection/durability. • Applications in food production, metal plating, cosmetics production, transport vehicle production, electronics/semiconductors manufacturing, energy equipment, petroleum/mining (e.g., bearings, skidways), textile industry (e.g., conveyor belts).	• Electronics/semiconductors component coatings, cable liners, vents (see electronics and semiconductors, A.3.12; technical textiles, A.3.23). • Energy-specific uses (e.g., wind-blade coatings, PTFE nozzles in switchgear; see energy, A.3.13). • Food contact materials (e.g., non-stick cookware coatings; see FCM and packaging, A.3.4). • Metal plating (e.g., surface tension modifiers; see metal plating, A.3.5). • Sealing applications (see sealing applications, A.3.18). • Lubricant mixtures (except self-lubricating materials like PTFE bearings; see lubricants, A.3.15). • Technical textiles (e.g., diaphragms, membranes; see technical textiles, A.3.23). • Spare parts (see Spare Parts, E.3.3).
Other medical applications	• Excipients • Immediate packaging	• None specified, other than Medical devices.

	• Drug delivery devices (e.g., pMDIs, pre-filled syringes, injection pens, autoinjectors, on-body delivery systems).	
Military applications	• PFAS (fluoropolymers, fluorinated gases) for military use (e.g., military vehicles, equipment).	• Uses of fluorinated gases not specifically for military applications (see applications of fluorinated gases, A.3.9). • PFASs in military vehicles/aerospace (except fluorinated gases for HVAC; see transport, A.3.11). • Electronic and electrical components for military applications (e.g., coatings, cabling; see electronics and semiconductors, A.3.12). • Sealing applications in military equipment/vehicles (see sealing applications, A.3.18). • Military explosives (see explosives, A.3.22). • Military textiles (e.g., tents, parachutes, medical textiles; see technical textiles, A.3.23). • Military PPE, uniforms, protective garments (see TULAC, A.3.3).
Explosives	• Fluoropolymers/fluoroelastomers in explosives for military and civil applications, mining/blasting, transport safety systems (e.g., airbags, seatbelts), professional/consumer activities (e.g., flares, ammunition, fireworks).	• Explosives in petroleum/mining equipment (see explosives, not Petroleum and Mining, A.3.16). • Explosives in transport safety systems (see Explosives, not Transport, A.3.11). • Construction demolition explosives (no substantive information received).
Technical textiles	• Outdoor technical textiles[11] (e.g., camping tents, cover sheets, outdoor furniture, moveable shade structures). • Architectural membranes, other tensile fabrics, other construction applications[12] (e.g., load-bearing architectural elements, both textiles/membranes and comparable non-textile structures, shading, sails). • Filtration and separation media, including comparable non-textile applications. • Removable covers for industrial process equipment.	• ETFE film/foil in greenhouses (see construction products, E.2.13). • Ancillary uses in filtration/separation (e.g., pipework, o-rings, pumps; see sealing applications (A.3.18), machinery applications (A.3.19)). • Wound treatment products and medical implants (see medical devices, A.3.10). • Braided packing for sealing applications, textiles used for flange protection and fabric expansion joints (see sealing applications, A.3.18).

[11] *The 'outdoor technical textiles' use comprises technical textiles in moveable structures that are not permanently exposed to environmental conditions, e.g. as they are only used for short periods of time but at regular intervals or can be moved indoors in seasons with harsher environmental conditions.*

[12] *The 'architectural membranes, other tensile fabrics and other construction applications' use comprises all technical textiles used for structures that are permanently incorporated or attached to buildings and other permanent infrastructure installations as well as other technical textile applications requiring tensile strength.*

	• Medical applications (e.g., surgical gowns, drapes), including comparable non-textile applications. • Technical textiles for transport vehicles.	• Textiles used for self-lubricating/low-friction purposes, e.g. as surface for seal of dryers, self-lubricating bearing cloths, PTFE-reinforced fabrics in wear strips and track liners (see machinery applications, A.3.19). • Textiles used for anti-adhesive/release purposes, e.g. in rubber production and during curing (see machinery applications, A.3.19). • Fuel-cell membranes (proton exchange membranes) and ion-exchange membranes, also when consisting of carbon fibres or being reinforced with PTFE fibres (see energy, A.3.13). • Home textiles and comparable uses in public settings, consumer/professional apparel, professional apparel and PPE, leather, home fabric treatments (see TULAC, A.3.3). • Packaging (see food contact materials and packaging, A.3.4). • Optical fibre weaving solutions for lighting applications (see electronics and semiconductors, A.3.12). • Latex printing inks for textiles (see printing applications, A.3.17). • Industrial applications relevant for production processes of the textile industry (e.g., conveyor belts, dyeing machinery; covered in machinery applications or other relevant sectors). • Solvents for dry-cleaning of textiles (see applications of fluorinated gases, RCOM).
Broader industrial uses	• Hydraulic fluids (not covered in Transport). • Solvents for precision cleaning, extraction, 3D printing. • Catalysts and processing aids (e.g., catalytic reaction media, ionic liquids).	• Precision cleaning in electronics/semiconductor manufacturing (see electronics and semiconductors, A.3.12). • Hydraulic fluids in transport (see Transport, A.3.11). • Analytical/laboratory applications (e.g., extraction fluids, calibration fluids; see scientific research and development explanatory note in the main report). • Engineered fluids for lubrication (see lubricants, A.3.15). • Heat transfer fluids for immersion cooling, medical lasers (see applications of fluorinated Gases (A.3.9), electronics and Semiconductors (A.3.12)). • Engineered fluids for diagnostic laboratory applications (see Scientific Research and Development, explanatory note in the main report). • Anti-acid coatings for metals (see metal plating and manufacture of metal products, A.3.5).

Annex 2 – Comparison of derogations in the Annex XV report as published in 2023 and the Background Document as published in 2025

Sector/topic	Paragraph in Draft entry text[13]		Remark	Proposed transition period
	Background Document (2025)	**Annex XV** report **(2023)**		
Biocidal products	4.a - Active substances in biocidal products within the scope of Regulation (EU) 528/2012	4.a - Active substances in biocidal products within the scope of Regulation (EU) 528/2012	No change	Indefinite
Plant protection products	4.b - Active substances in plant protection products within the scope of Regulation (EC) 1107/2009	4.b - Active substances in plant protection products within the scope of Regulation (EC) 1107/2009	No change	Indefinite
Human and Veterinary Medicinal Products	4.c - Active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC	4.c - Active substances in human and veterinary medicinal products within the scope of Regulation (EC) No 726/2004, Regulation (EU) 2019/6 and Directive 2001/83/EC	No change	Indefinite
Second-hand articles	4.d - Articles which were already in end-use in the Union	N.A.	Newly added	Indefinite
Spare parts	4.e - Spare parts intended to replace PFAS-containing articles in articles or complex objects	N.A.	Newly added	20 years after the last date the complex article was allowed to be placed on the market or until the end of service life,

[13] *Paragraph 4 contain exclusions from the restriction; paragraph 5 are (time-limited) derogations for all PFASs and paragraph 6 are derogations for fluoropolymers and PFPEs only. Some of the derogations are conditional on other provisions, e.g. reporting or a site-specific management plan.*

Sector/topic	Paragraph in Draft entry text[13] Background Document (2025)	Annex XV report (2023)	Remark	Proposed transition period
				whichever is shorter.
Spare parts	4.f - Spare parts used in articles or complex objects for which legal obligations related to the use of specific spare parts exist	N.A.	Newly added	Until the end of service life
Upstream supply chain	4.g - Starting materials and intermediates in PFAS manufacture for a use listed under paragraphs 4, 5, or 6.	N.A.	Newly added	Indefinite
Upstream supply chain	4.h - Production of PFAS-containing mixtures or articles in upstream supply chain for a use listed under paragraphs 4, 5, or 6.	N.A.	Newly added	Indefinite
PPORD	4.i - Product and process orientated research and development (PPORD)	N.A.	Newly added	Indefinite
Recycling	4.j - Paper and board articles containing recovered material, with the exception of food-contact material and packaging	N.A.	Newly added	Indefinite
Recycling	4.k - Textile articles containing recovered material, with the exception of toys as defined in Directive 2009/48/EC	N.A.	Newly added	13.5 years after EiF
Recycling	4.l - Plastic articles containing recovered material, with the exception of food-contact material and food-contact packaging and toys as defined in Directive 2009/48/EC	N.A.	Newly added	23.5 years after EiF
Manufacture of PFASs	4.m - Production of PFASs not exceeding specified emission limits to air, water and soil	N.A.	Newly added	Indefinite

Sector/topic	Paragraph in Draft entry text[13] Background Document (2025)	Annex XV report (2023)	Remark	Proposed transition period
TULAC	5.a - Personal protective equipment (PPE) intended to protect users against risks as specified in Regulation (EU) 2016/425, Annex I)	5.b – 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)	Scope extended to all PPE intended to protect users against risks as specified in Annex I of Regulation (EU) 2016/425, Annex I	13.5 years after EiF
TULAC	5.b - Personal protective equipment (PPE) specifically designed for armed forces, the maintenance of law and order and other emergency response workers	5.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)	Scope extended to cover armed forces, law enforcement, and emergency response workers.	13.5 years after EiF
TULAC	5.c - Impregnation agents for re-impregnation of articles referred to in paragraph 5a and 5b	5.d - Impregnation agents for re-impregnation of articles referred to in paragraph 5b and 5c	No change	13.5 years after EiF
Metal plating and manufacture of metal products	5.d - Hard chrome plating	[5.v - Hard chrome plating]	Potential derogation confirmed based on information from the consultation on the Annex XV report	6.5 years after EIF
Applications of fluorinated gases	5.e - Refrigerants in low temperature refrigeration below -50 °C	5.f - Refrigerants in low temperature refrigeration below -50 °C	No change	6.5 years after EIF
Applications of fluorinated gases	5.f - Refrigerants in laboratory test and measurement equipment	5.g - Refrigerants in laboratory test and measurement equipment	No change	13.5 years after EiF
Applications of fluorinated gases	5.g - Refrigerants in refrigerated centrifuges	5.h - Refrigerants in refrigerated centrifuges	No change	13.5 years after EiF
Applications of fluorinated gases	5.h - Refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives	5.j - Refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives	No change	Indefinite
Applications of fluorinated gases	5.i - Foam blowing agents in thermal insulation foam	[5.w - Foam blowing agents in expanded foam sprayed on site for building insulation]	Potential derogation confirmed based on information from the consultation on the Annex XV report. Scope broadened and proposed transition period prolonged.	13.5 years after EiF

Sector/topic	Paragraph in Draft entry text[13] Background Document (2025)	Annex XV report (2023)	Remark	Proposed transition period
Applications of fluorinated gases	5.j - Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required. The derogation does not apply to products intended for entertainment and decorative purposes for the general public;	[5.z - Propellants for technical aerosols for applications where non-flammability and high technical performance of spray quality are required]	Potential derogation confirmed based on information from the consultation on the Annex XV report. Entertainment/decorative products for the general public excluded from scope.	13.5 years after EiF
Applications of fluorinated gases	5.k - Fluorinated gases used as clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health	5.m - Clean fire suppressing agents where current alternatives damage the assets to be protected or pose a risk to human health	No change except for specification that the derogation applies to fluorinated gases, only.	13.5 years after EiF
Applications of fluorinated gases	5.l - Preservation of cultural paper-based materials	[5.aa - Preservation of cultural paper-based materials]	Potential derogation confirmed based on information from the consultation on the Annex XV report.	13.5 years after EiF
Applications of fluorinated gases	5.m - Insulating gases in high-voltage switchgear (>145 kV)	5.r - Insulating gases in high-voltage switchgear (>145 kV)	No change	6.5 years after EiF
Applications of fluorinated gases	5.n - Refrigerants, clean fire-suppressing agents and insulation gases for maintenance and refilling of existing HVACR, fire-suppressing and switchgear equipment put on the market before 18 months (or placed on the market after 18 months after EiF based on an applicable derogation)	5.i - Maintenance and refilling of existing HVACR equipment put on the market before [18 months after EiF] and for which no drop-in alternative exist.	Scope expanded to include fire-suppressing and switchgear equipment placed on the market before 18 months after EIF or after 18 months after EIF based on applicable derogations.	13.5 years after EiF
Applications of fluorinated gases	[5.o - Fluorinated gases at the CERN research installation]	N.A.	Newly added	13.5 years after EiF
Applications of fluorinated gases	N.A.	[5.dd - use as refrigerants and for mobile air conditioning in vehicles in military applications	Potential derogation marked for reconsideration; now covered under 5.ll - Military applications	N.A.
Medical Devices	N.A.	[5.bb - Cleaning and heat transfer: engineered fluids for medical devices]	Potential derogation marked for reconsideration; now partly covered	N.A.

Sector/topic	Paragraph in Draft entry text[13] Background Document (2025)	Annex XV report (2023)	Remark	Proposed transition period
			under 5.vv - Solvents used in industrial uses and 6.g - Heat transfer fluids for industrial and professional use of vapor phase soldering for electronics	
Medical Devices	N.A.	[5.cc - Membranes used for venting of medical devices]	Potential derogation marked for reconsideration; now covered under 5.nn - Sound-permeable and vent filters for electrical and electronic equipment or 6.e - Packaging for medical devices	N.A.
Transport	5.p - Additives to hydraulic fluids in transport vehicles	5.o - Additives to hydraulic fluids for anti-erosion/anti-corrosion in hydraulic systems (incl. control valves) in aircraft and aerospace industry aircraft and aerospace	Scope expanded to all hydraulic fluids and all transport vehicles	13.5 years after EiF
Transport	5.q - Refrigerants in mobile air conditioning systems and heat pump systems	5.p - Refrigerants in mobile air conditioning systems in combustion engine vehicles with mechanical compressors	Scope expanded to all vehicles and to heat pump systems	6.5 years after EiF for light duty electrical vehicles 13.5 years after EiF for all other vehicles
Transport	5.r - Refrigerants in transport refrigeration other than in marine applications	5.q - Refrigerants in transport refrigeration other than in marine applications	No change	6.5 years after EiF
Electronics and Semiconductors	5.s - Coatings and films on displays and lenses of electronic complex objects	N.A.	Newly added	6.5 years after EiF
Electronics and Semiconductors	5.t - Printed circuit boards and antennas	N.A.	Newly added	13.5 years after EiF
Electronics and Semiconductors	5.u - Photonics	N.A.	Newly added	13.5 years after EiF
Electronics and Semiconductors	5.v - Heat transfer fluids for 2-phase immersion cooling	N.A.	Newly added	13.5 years after EiF

Sector/topic	Paragraph in Draft entry text[13] Background Document (2025)	Annex XV report (2023)	Remark	Proposed transition period
Electronics and Semiconductors	5.w - Semiconductor manufacturing	[5.ee – The semiconductor manufacturing process]	Potential derogation confirmed based on information from the consultation on the Annex XV report.	13.5 years after EiF
Electronics and Semiconductors	5.x - Coatings and films of electronic components (excluding displays and lenses)	N.A.	Newly added	13.5 years after EiF
Energy	5.y - Binders and electrolytes in batteries	N.A.	Newly added	13.5 years after EiF
Construction	5.z - Polymer additives used for fire safety purposes in construction products	N.A.	Newly added	13.5 years after EiF
Lubricants	5.aa - Industrial and professional uses of lubricants or lubricant additives	N.A.	In the 2023 dossier, a derogation was named 'lubricants where the use takes place under harsh conditions or the use is needed for safe functioning and safety of equipment	13.5 years after EiF
Petroleum and mining	5.bb - Gas and oil tracers	N.A.	Newly added	13.5 years after EiF
Printing applications	5.cc - Toners	N.A.	Newly added	13.5 years after EiF
Printing applications	5.dd - Latex printing inks	N.A.	Newly added	13.5 years after EiF
Printing applications	5.ee - Electrophotographic press units	N.A.	Newly added	13.5 years after EiF
Printing applications	5.ff - Kinetic printing components	N.A.	Newly added	13.5 years after EiF
Printing applications	5.gg - Photosensitive materials	N.A.	Newly added	13.5 years after EiF
Printing applications	5.hh - Toners for use in existing equipment put on the market until 13.5 years after EiF	N.A.	Newly added	Indefinite
Printing applications	5.ii - Latex printing inks for use in existing equipment put on the market until 13.5 years after EiF	N.A.	Newly added	Indefinite
Printing Applications	N.A.	[5.x - Industrial and professional use of solvent-based debinding systems in 3D printing]	Potential derogation marked for reconsideration; now partly covered	N.A.

Sector/topic	Paragraph in Draft entry text[13] Background Document (2025)	Annex XV report (2023)	Remark	Proposed transition period
			under 5.vv - Solvents used in industrial uses	
Printing Applications	N.A.	[5.y – Industrial and professional use of smoothing agents for polymer 3D printing]	Potential derogation marked for reconsideration; now partly covered under 5.ww - Catalysts and processing aids in industrial uses	N.A.
Other Medical Applications	5.jj - Excipients in medicinal products for ophthalmic and dermatological therapies	N.A.	Newly added	13.5 years after EiF
Other Medical Applications	5.kk - Propellants in pressurized metered-dose inhalers (pMDIs)	N.A.	Newly added	6.5 years after EiF
Military Applications	5.ll - Military applications	N.A.	Newly added	13.5 years after EiF
Technical textiles	5.mm - HEPA (H 13-14) and ULPA (U 15-17) filters (according to EN 1822:2009) and in industrial uses for filtration and separation of air and other gases (excluding general ventilation uses)	5.e 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 until 6.5 years after EiF	Derogation split into several separate derogations	13.5 years after EiF
Technical textiles	5.nn - Sound-permeable and vent filters for electrical and electronic equipment		Derogation split into several separate derogations	6.5 years after EiF
Technical textiles	5.oo - Oxygen-permeable membranes in zinc-air batteries and other types of alkaline metal-air batteries		Derogation split into several separate derogations	13.5 years after EiF
Technical textiles	5.pp - Industrial use as media in liquid-liquid separation		Derogation split into several separate derogations	13.5 years after EiF
Technical textiles	5.qq - Technical textiles in engine bays of transport vehicles for noise, vibration and harshness (NVH) insulation and ignition protection	[5.u - textiles for the use in engine bays for noise and vibration insulation used in the automotive industry]	Potential derogation confirmed based on information from the consultation on the Annex XV report. Scope broadened.	13.5 years after EiF

Sector/topic	Paragraph in Draft entry text[13]		Remark	Proposed transition period
	Background Document (2025)	**Annex XV** report **(2023)**		
Technical textiles	5.rr - Technical textiles for noise, vibration and harshness (NVH) insulation outside engine bay	[5.u - textiles for the use in engine bays for noise and vibration insulation used in the automotive industry]	Potential derogation confirmed based on information from the consultation on the Annex XV report. Scope broadened.	6.5 years after EiF
Technical textiles	5.ss - Woven, knitted and nonwoven re-usable medical textiles as specified in Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795	N.A.	Newly added	13.5 years after EiF
Technical textiles	5.tt - Impregnation agents for re-impregnation of articles referred to in paragraph 5ss	N.A.	Newly added	13.5 years after EiF
Broader industrial uses	5.uu - Ionic liquids in industrial uses	N.A.	Newly added	6.5 years after EiF
Broader industrial uses	5.vv – Solvents used in industrial uses	N.A.	Newly added	13.5 years after EiF
Broader industrial uses	5.ww - Catalysts and processing aids in industrial uses	N.A.	Newly added	13.5 years after EiF
Food contact materials and packaging	6.a - Polymer processing aids in flexible plastic film extrusion	N.A.	Newly added	6.5 years after EiF
Food contact materials and packaging	6.b - Non-stick coatings in industrial bakeware	[6.g - non-stick coatings in industrial and professional bakeware until 6.5 years after EiF];	Potential derogation confirmed based on information from the consultation on the Annex XV report. Scope narrowed down to industrial uses.	6.5 years after EiF
Medical devices	6.c - Implantable medical devices (including medical implants and meshes) until 13.5 years after EiF;	6.b - Implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF	Scope broadened to include all implantable medical devices	13.5 years after EIF

Sector/topic	Paragraph in Draft entry text[13] Background Document (2025)	Annex XV report (2023)	Remark	Proposed transition period
		[6.h – Hernia meshes]	Potential derogation confirmed based on information from the consultation on the Annex XV report.	
Medical devices	6.d - Invasive medical devices (e.g. tubes and catheters) until 13.5 years after EiF;	6.b - Tubes and catheters in medical devices until 13.5 years after EiF	Scope broadened to include all invasive medical devices	13.5 years after EIF
Medical devices	6.e - Packaging for medical devices	[6.l - PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics]	Potential derogation confirmed for medical devices based on information from the consultation on the Annex XV report. Scope broadened to include also other PFASs.	13.5 years after EiF
Medical Devices	N.A.	6.i - Wound treatment products	Potential derogation marked for reconsideration not confirmed.	N.A.
Medical Devices	N.A.	6.j - Coating applications for medical devices	Potential derogation marked for reconsideration; now covered under 6.c - Implantable medical devices or other specific medical applications (e.g. 6.r, 6.t, 6.u, 6.v, etc.)	N.A.
Medical Devices	N.A.	[6.k - Rigid gas permeable contact lenses and ophthalmic lenses until 13.5 years after EiF];	Potential derogation marked for reconsideration; now covered under 5.jj - Excipients in medicinal products for ophthalmic and dermatological therapies	N.A.
Medical Devices	N.A.	[6.m - PTFE in ophthalmic solutions packaging]	Potential derogation marked for reconsideration; now covered under 6.e - Packaging for medical devices	N.A.
Medical Devices	N.A.	[6.n - Packaging of terminally sterilised medical devices]	Potential derogation marked for reconsideration; now covered under 6.e - Packaging for medical devices	N.A.
Transport	6f. i) vehicle systems, components or separate technical units [(excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and	{6.o - applications affecting the proper functioning related to the safety of transport vehicles, and affecting the	Potential derogation confirmed based on information from the consultation on the Annex XV report.	13.5 years after EiF

Sector/topic	Paragraph in Draft entry text[13] Background Document (2025)	Annex XV report (2023)	Remark	Proposed transition period
	electrical systems, HVACR, technical textiles*)] that are subject to EU vehicle type approval, where the type approval was obtained within 13.5 years after EiF OR ii) systems, components or separate technical units [(excluding 'sealing applications', batteries and fuel cells, lubricants, electronic and electrical systems, HVACR, technical textiles*)] in vehicles that are not within the scope of paragraph i, where the use of fluoropolymers or perfluoropolyethers are strictly necessary for safety or environmental performance of those vehicles	safety of operators, passengers or goods].	Scope broadened and further specified.	
Electronics and Semiconductors	6.g - Heat transfer fluids for industrial and professional use of vapor phase soldering for electronics	N.A.	Newly added	13.5 years after EIF
Electronics and Semiconductors	6.h - Wires and cables (incl. connectors)	N.A.	Newly added	13.5 years after EiF
Electronics and Semiconductors	6.i - Insulation material of electronic components (excluding wires, cables and connectors)	N.A.	Newly added	13.5 years after EiF
Electronics and Semiconductors	6.j - Anti-drip agent in plastics of electronic components	N.A.	Newly added	13.5 years after EiF
Energy	6.k - Fuel cells and electrolysers	6.e - Proton-exchange membrane (PEM) fuel cells	Scope broadened to all fuel cells and electrolysers.	13.5 years after EIF
Energy	6.l - Separator coatings for batteries	N.A.	Newly added	6.5 years after EiF
Energy	6.m - PTFE nozzles in high voltage (>145 kV) switchgears and circuit breakers	N.A.	Newly added	6.5 years after EiF

Sector/topic	Paragraph in Draft entry text[13] Background Document (2025)	Annex XV report (2023)	Remark	Proposed transition period
Energy	6.n - Front- and backsheets in photovoltaic cells	N.A.	Newly added	6.5 years after EiF
Construction	6.o - Bridge and building bearings	N.A.	Newly added	13.5 years after EiF
Sealing applications	6.p - Sealing applications in industrial uses	N.A.	Newly added	13.5 years after EiF
Machinery Applications	6.q - Machinery applications in industrial uses	N.A.	Newly added	13.5 years after EiF
Other Medical Applications	6.r - Coatings in release liners and backing film in transdermal patches	N.A.	Newly added	13.5 years after EiF
Other Medical Applications	6.s - Blisters for solid oral dose formulations	N.A.	Newly added	6.5 years after EiF
Other Medical Applications	6.t - Coated rubber stoppers in vials/flasks for injectable medicinal products	N.A.	Newly added	13.5 years after EiF
Other Medical Applications	6.u - Coated canisters in pressurized metered-dose inhalers (pMDIs)	N.A.	Newly added	13.5 years after EiF
Other Medical Applications	6.v - Coated plungers in pre-filled syringes	N.A.	Newly added	13.5 years after EiF
Other Medical Applications	6.w - Pre-filled injection pens & autoinjectors	N.A.	Newly added	13.5 years after EiF
Explosives	6.x - Explosives in military applications	N.A.	Newly added	13.5 years after EiF
Technical textiles	6.y - Industrial use in filtration and separation media for water treatment and purification	N.A.	Newly added	6.5 years after EiF