baua:

Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

PFAS-Beschränkung unter REACH: aktueller Sachstand

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Einleitung

PFAS-Beschränkungsverfahren

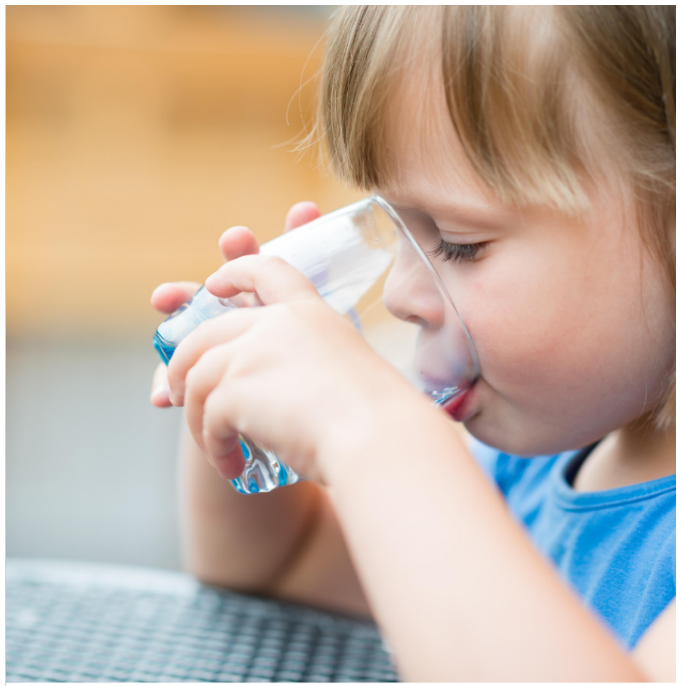
- Gemeinsame Aktivität von Behörden aus 5 MS (DE, DK, NL, NO, SE)
- Gruppenansatz (alle PFAS einschl. Fluorpolymere (FP))
- Risiko aufgrund
  - Extremer Persistenz in Verbindung mit anderen gefährl. Eigenschaften
  - Fluorpolymere: Freisetzung von PFAS während Herstellung und Abfallphase
- Ziel: Minimierung der Emissionen / Vermeidung “Regrettable substitution”
- Beschränkung der Herstellung, des Inverkehrbringens und der Verwendung mit verwendungsspezifischen Ausnahmen

Arbeiten der Dossier-Submitter

- Konsultation zum Annex XV Dossier (März – September 2023)
- Mehr als 5600 Kommentare von mehr als 4400 Stakeholdern
- Sektor-basierter Ansatz in Abstimmung mit Arbeitsplanung ECHA-Ausschüsse (RAC/SEAC)
- Alle Kommentare geprüft und in 12 gezielten Updates des Hintergrunddokuments berücksichtigt (September 2023 – Juni 2025)
- Finales Hintergrunddokument (BD) im August 2025 von ECHA veröffentlicht: Link zum Registry of Restriction Intentions until outcome
- Weitere Begleitung RAC/SEAC-Verfahren, Beantworten von Fragen der ECHA

Das Hintergrunddokument: Eckpunkte

Zusammenfassung der wichtigsten Änderungen im BD



What you need to know about the updated PFAS restriction dossier

- Das Dokument finden Sie hier
- Erstellt von den Dossier Submittern
- Derzeit nur auf Englisch verfügbar

Chemischer Scope / PFAS-Definition

OECD (2021):

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

Ausnahmen:

A substance that only contains the following structural elements is **excluded from the scope** of the restriction: **CF_3-X or X-CF_2-X'**,

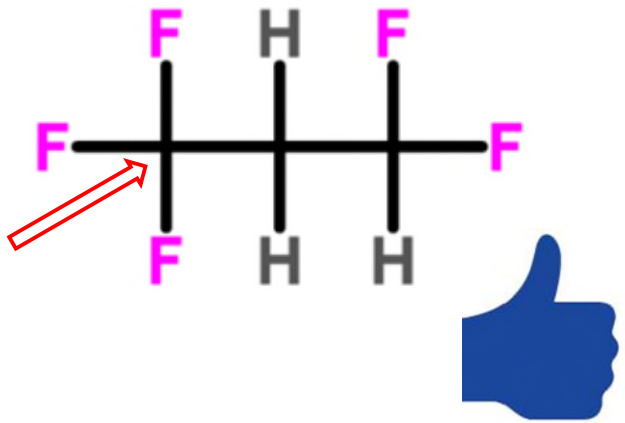
where X = -OR or -NRR' and X' = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or –NR''R'''; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).

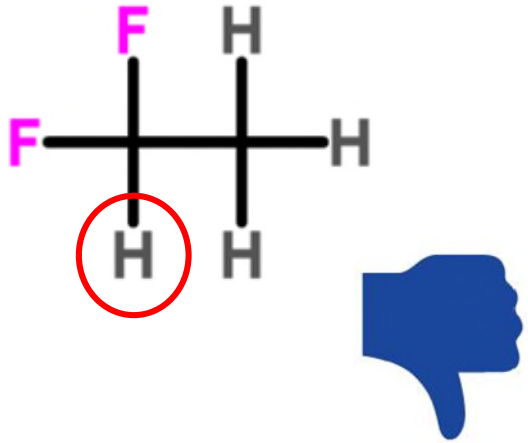
=> Keine Änderungen

PFAS - Definition

PFAS = **P**er- und Poly**F**luorierte **A**lkyl**S**ubstanzen

OECD (2021): Jeder Stoff, der mindestens ein **vollständig fluoriertes Methyl (CF_3-) oder Methylene (-CF_2-) Kohlenstoffatom** enthält (ohne ein daran gebundenes H/Cl/Br/I-Atom).

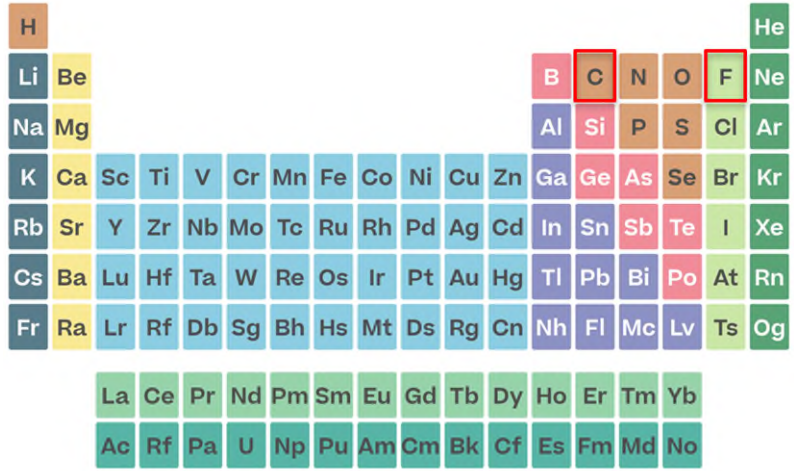




PFAS: technische Eigenschaften

Die C-F-Bindung verleiht Stoffen/Materialien eine Reihe vorteilhafter technischer Eigenschaften:

- Zugleich fett-/wasser-/schmutzabweisend
- Stabilität unter extremen Bedingungen
  - Temperatur, Druck, Strahlung, Chemikalien
- Elektrische und thermische Isolierung
- Oberflächeneigenschaften
- Effiziente Kältemittel



Einzelbindungsstärke (kJ/mol)

C–H	413
C–C	347
C–N	305
C–O	358
C–F	**485**
C–Cl	339
C–Br	276
C–I	240
C–S	259

Gefahreneigenschaften und Risiko

Hohe Persistenz

+

- Bioakkumulation
- Mobilität
- Ferntransport-Potenzial
- Anreicherung in Pflanzen
- (Öko)Toxizität
- Hormonelle Effekte
- Kombinationswirkungen

- Einmal freigesetzt verbleiben PFAS über lange Zeit (Jahrzehnte bis –Jahrhunderte) in der Umwelt und reichern sich an
  - Eine Entfernung aus der Umwelt mit technischen Mitteln ist schwierig und mit hohen Kosten und hohem Aufwand verbunden
- Ableiten eines sicheren Grenzwerts für die Umwelt ist nicht möglich („non-threshold“)
- Emissionen als Maß für das Risiko

=> Keine größeren Änderungen, Stärkung der Argumentation bezüglich Fluorpolymeren

Fluorpolymere/Perfluorpolyether

Betrachtung des gesamten Lebenszyklus der PFAS einschließlich Herstellung und Abfallphase

Emissionen bei Herstellung und Entsorgung nicht vernachlässigbar:

- Herstellung: Einsatz von monomeren PFAS und PFAS-Hilfsstoffen
- Entsorgung: Deponierung (Mikroplastik) oder Verbrennung (Bildung von kurzkettigen PFAS, z.B. TFA)

Betrachtete Sektoren

- Textiles (TULAC)
- Food contact materials and packaging
- Metal plating and manufacture of metal products
- Consumer mixtures and miscellaneous consumer articles
- Cosmetic
- Ski-wax
- Applications of fluorinated gases
- Medical devices
- Transport
- Electronics and semiconductors
- Energy
- Construction products
- Lubricants
- Petroleum and mining

NEU im Hintergrunddokument:

- **Printing applications**
- **Sealing applications**
- **Machinery applications**
- **Other medical applications**
- **Military applications**
- **Explosives**
- **Technical textiles**
- **Broader industrial uses**

Betrachtete Beschränkungsoptionen (Restriction Options, RO)

- RO1: Vollständiges Verbot mit 18-monatiger Übergangsfrist
  - Für viele Sektoren nicht verhältnismäßig
- RO2: Verbot mit verwendungsspezifischen und zeitl. befristeten Ausnahmen (6,5 oder 13,5 Jahre) für Verwendungen mit niedrigem Substitutionspotenzial

⇒ **Zusätzliche Beschränkungsoption für bestimmte Sektoren:**

- **RO3:** Weitere Verwendung von PFAS unter streng kontrollierten Bedingungen (z.B. Einhalten von Emissionsgrenzwerten) oder zusätzliche Emissionsminderungsmaßnahmen zur Steigerung der Effektivität von RO2
- Sektoren: Transport, Elektronik und Halbleiter, Energie, Dichtungsanwendungen, Maschinenanwendungen, technische Textilien

PFAS-Herstellung

⇒ **Neu im Hintergrunddokument: Vorschlag RO3**

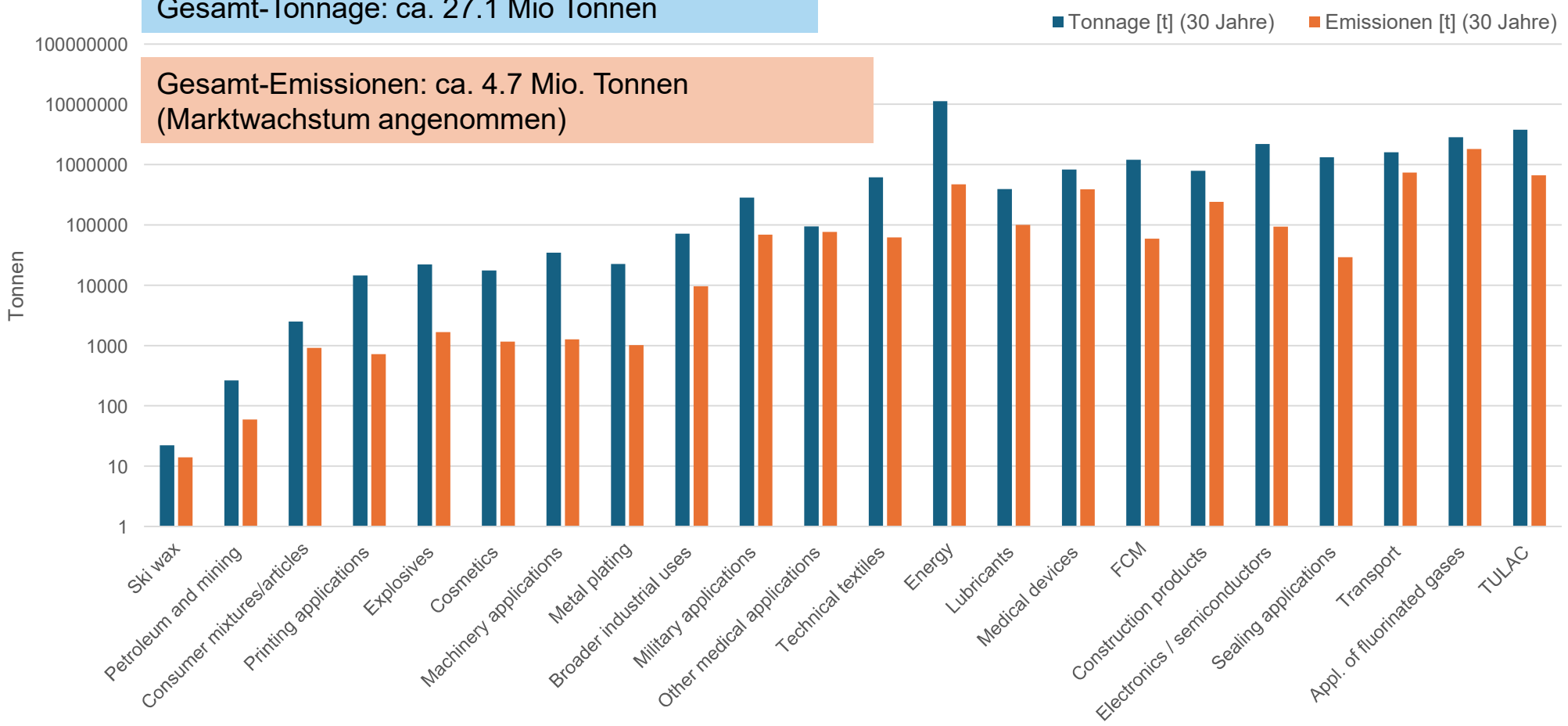
- **Unbefristete Ausnahme für Herstellung von PFAS**
- **Einhaltung von Emissionsgrenzwerten**
  - Entsprechend freiwilliger Selbstverpflichtung der Fluorpolymer-Hersteller:
  - Emissionen ≤ 0.01% der an einem Standort hergestellten Menge an PFAS; Übergangsfrist: 6,5 Jahre
  - Emissionen ≤ 0.0036% der an einem Standort hergestellten Menge an PFAS bei Verwendung von Polymerisationshilfen; Übergangsfrist: Ende 2030
  - Bestehende strengere EU-weite oder nationale Maßnahmen behalten Gültigkeit

Tonnagen und Emissionen je Sektor

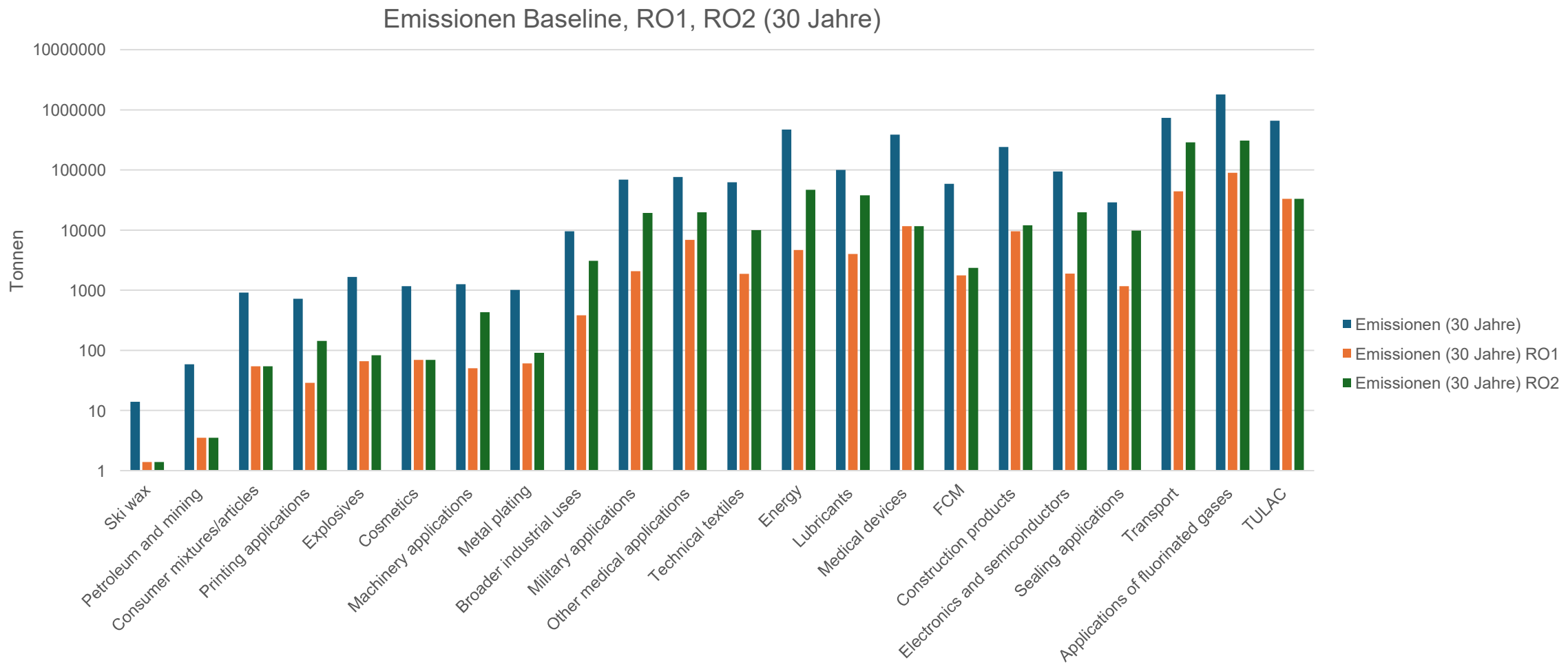
=> Baseline aktualisiert mit Informationen aus Konsultation

Gesamt-Tonnage: ca. 27.1 Mio Tonnen

Gesamt-Emissionen: ca. 4.7 Mio. Tonnen (Marktwachstum angenommen)



Emissionsminderung je Sektor



Sozio-ökonomische Betrachtungen - Methodologie

- Kosten/Nutzen
- Betrachtung je Sektor
- Quantitative Betrachtung wo möglich, sonst semi-quantitative Kategorisierung in fünf Kategorien: sehr niedrig, niedrig, moderat, hoch, sehr hoch
  - Kosten: u.a. Substitutionskosten, Kosten aufgrund von Firmenschließungen, Veränderungen der Produkte etc.
  - Nutzen: Vermiedene Emissionen bzw. Effektivität der Emissionsreduktion

⇒ Gegenüberstellung RO1/RO2/RO3 in Matrix

⇒ Auswahl der geeigneten Beschränkungsoption für jeden Sektor

=> Verfeinerung der Herangehensweise

Verhältnismäßigkeitsmatrix (Beispiel techn. Textilien)

Effectiveness: emission reduction [%]	Economic costs or other impacts of a restriction option				
	Very low	Low	Moderate	High	Very high
Very Low (<70%)					
Low (70 – 79%)		RO3 (76%)			
Moderate (80 –89%)			RO2 (84%)		
High (90 - 98%)					RO1 (97%)
Very high (≥99%)					

RO nicht effektiv genug	Wahrscheinlich verhältnismäßig	Nicht verhältnismäßig
Verhältnismäßig	Wahrscheinlich nicht verhältnismäßig	Zu hohe Kosten

Weitere Auswirkungen der Beschränkung

⇒ **Neu ins Hintergrunddokument aufgenommen**

⇒ **Bewertung der Auswirkungen auf:**

- Zweitmarkt (“Second-hand market”)
- Ersatzteile
- Recycling von Kunststoffen, Papier und Karton, Textilien, Metallen

⇒ **Ausnahmen** vorgeschlagen (außer für Metallrecycling)

Weitere Themen

⇒ **Neu ins Hintergrunddokument aufgenommen**

- Überprüfungsklausel: Empfehlung
- Vorgeschaltete Lieferkette: Ausgenommen für ausgenommene Verwendungen
- Forschung
  - Produkt- und Prozessorientiert (PPORD): Ausnahme
  - Wissenschaftl. Forschung und Entwicklung (SR&D): Verweis auf Artikel 67(1) Ausnahme

Praktikabilität und Überwachbarkeit

Konzentrationsgrenzen

- **25 ppb für einzelne PFAS**
- **250 ppb für die Summe einzelner PFAS**
  - Messung **spezifischer Stoffe** mit gezielter Analyse
- **50 ppm für PFAS (einschl. polymerer PFAS)**
  - Gesamtfluorgehalt
  - Fluorgehalt oberhalb 50 ppm => Möglichkeit, nachzuweisen, dass Teil des Fluorgehalts von Nicht-PFAS-Verbindungen stammt, z.B. durch weitere Messungen, Lieferketteninformation, etc.

=> Keine Änderungen, Informationen aktualisiert

Das Hintergrunddokument: Orientierungshilfe

Aufbau

- **Hauptteil (Background Document)**
  - Vorschlag für **Rechtstext** einschl. **Erläuterungen (explanatory note)**
  - Zusammenfassung der Informationen aus den Anhängen
- **Anhänge** A bis G (Annexes to Background Document)

A: Stoffidentität, **Verwendungen und Tonnagen nach Sektoren**

B: Gefahreneigenschaften, Risiko, **Emissionen nach Sektoren**

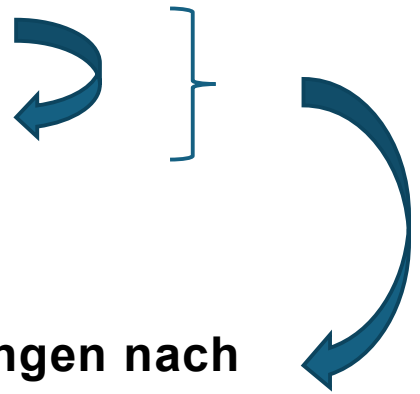
C: Begründung für EU-weite Maßnahme

D: Baseline

E: Analyse der Alternativen und **sozio-ökonomische Betrachtungen nach Sektoren**, Praktikabilität und Überwachbarkeit

F: Unsicherheiten

G: Stakeholder-Informationen



Identifizierung relevanter Sektoren – Abschnitt „Scope“ (Anhänge A, B, E)

A.3.20. Other medical applications

A.3.20.1. Scope

The use sector ‘other medical applications’ was not included in the Annex XV report.

This new use sector covers excipients, immediate packaging and drug delivery devices. Drug delivery devices are included here since the principal intended action comes from the active substance. Therefore it is considered a medicinal product that includes a medical device. Some of the uses assessed as part of this sector were included originally in the medical devices sector (e.g. propellants in pMDIs, PFAS-coating of pMDIs and fluoropolymers in blisters), but have been moved here since being part of the medicines other than API so therefore it seems more appropriate to be included in this new sector. These are the uses that are part of an EU medicinal product authorisation (both human and veterinary medicinal products), other than the active pharmaceutical ingredients (APIs) that are proposed to be derogated time unlimited from the scope of the restriction (see section 2.2.4 of the main report). Some of the identified uses are covered by other sectors:

- The use of fluoropolymer-coated electronics in pre-filled on-body delivery systems is covered in the electronics sector, section A.3.12.
- The use of lubricants in drug delivery devices is covered by the use lubricants, section A.3.15.
- Process chemicals are covered in the sector broader industrial uses, section A.3.24.

Identifizierung relevanter Sektoren – Zusammenfassung BD

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)	• Industrial equipment with fluoropolymers (e.g., sealings, gaskets, piping, conveyor belts) in food/feed production, except non-stick

Tonnagen und Emissionen

Betrachtung/Extrapolation auf gesamten europäischen Wirtschaftsraum (EEA) für das Jahr 2020 (Baseline)

Tonnagen (Anhang A)

- **Sektorspezifische** Bewertung in Anhang A.3.X
- Ermittelte Werte in tabellarischer Form i.d.R. am Ende der Abschnitte
- Übersicht über alle Sektoren: Hauptdokument Tabelle 3 / Tabelle A.11

Emissionen (Anhang B)

- **Sektorspezifische** Bewertung in Anhang B.9.X
- Anwendung spezifischer Emissionsfaktoren sofern vorhanden, ansonsten nach ECHA-Guidance R.16 (Übersicht siehe Tabelle B.18)
- Ermittelte Werte in tabellarischer Form i.d.R. am Ende der Abschnitte
- Übersicht über alle Sektoren: Hauptdokument Tabelle 1 / Tabelle B.121

Analyse der Alternativen (Anhang E)

Sektor-/verwendungsspezifische Betrachtung folgender Aspekte

- Technische Machbarkeit
- Wirtschaftliche Machbarkeit
- Verfügbarkeit
- Gefahren/Risiko
- Benötigte Zeit für die Umstellung auf Alternativen
- Schlussfolgerung zum Substitutionspotenzial

Table E.28. Summary of assessment of alternatives to PFAS in home fabric treatment (sprays).

Technical feasibility	The desktop research identified one use-specific alternative for home fabric treatments. Only silicone-based alternatives are identified as technically feasible alternatives in treatment products but specific cleaners or the use of inherently stain-resistant fibres are also mentioned as options in the context of carpet care products. No information specific to this application was provided during the CfE and the 2nd stakeholder consultation. The conclusion that technically feasible alternatives exist was corroborated in the consultation on the Annex XV report. Among others, a supplier reported that a PFAS-free alternative is available and a Danish NGO communicated that 9 of 16 investigated waterproofing sprays do not contain PFAS. Two stakeholders however expressed concerns regarding water repellence (e.g. in more demanding applications), and one stakeholder mentioned a lack of oil and soil repellence as disadvantages of sprays using alternatives.
Economic feasibility	Limited 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 and that silicone-based carpet care products are available on the market, the Dossier Submitters consider that alternatives are also economically feasible.
Availability	Information on whether the alternatives are available in the quantities required for use in home fabric treatments is 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.
Hazards/Risks	There is an indication of potential hazards in relation to the identified alternative substance group, i.e. silicones, due to the potential presence of residues of cyclic siloxanes, such as D4, D5 and D6 (which are SVHCs), in some but not all silicone polymers. The Dossier Submitters however consider, based on the reasons detailed in section E.2.2.2.2, and the fact that other alternatives such as the use of inherently-stain resistant fibres exist that technically and economically feasible alternatives that are safer are available.
Time required for transitioning to alternative	No information on the timeframe required for substitution of PFAS in relation to home fabric treatments is available to the Dossier Submitters.
Conclusion on substitution potential	The Dossier Submitters consider that there is sufficiently strong evidence to conclude that the substitution potential is high. No derogation is therefore proposed and further assessed for home fabric treatments.

Schlussfolgerungen Verwendungen/Ausnahmen (Anhang E)

Abschnitt E.2.X.X „Summary of cost and benefit assessment“

- Tabellarischer Überblick über die Schlussfolgerungen zu Alternativen, Nutzen und Kosten
- Letzte Zeile: Zusammenfassung bzgl. Ausnahmen

Conclusion	A ban with a transition period of 18 months and a 12-year derogation is proposed for: • Sealing applications in industrial uses Based on the absence of information on professional and consumer uses of sealing applications containing PFASs, a ban of PFASs with a transition period of 18 months is currently proposed for: • Consumer uses of PFASs in sealing applications • Professional uses of PFASs in sealing applications The Dossier Submitters note that there may be professional or consumer uses of fluoropolymers or perfluoropolyethers in sealing applications where technically or economically feasible alternatives are not available at EiF (i.e., having similar requirements to sealing applications as applications in industrial settings) and, consequently, have a low substitution potential. However, insufficient information was provided in the consultation on the Annex XV report to conclude on the need for a use-specific derogation. Therefore, under RO2, they are proposed to be subject to a ban on placing on the market and use 18 months after EiF.

Übersicht Ausnahmen

Annex 2 Zusammenfassung des Hintergrunddokuments (Tabelle)

Sector/topic	Paragraph in Draft entry text[13] Background Document (2025)	Annex XV report (2023)	Remark	Proposed transition period
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,

Relevante Informationen hinsichtl. Dichtungsanwendungen

Überblick Dichtungsanwendungen (Anhang A.3.18, B.9.18, E.2.17)

Verwendungen im Sektor bewertet	Verwendungen nicht im Sektor bewertet
• Fluorpolymere (FPs) und Perfluorpolyether (PFPEs) zur Verhinderung von Leckagen, zur Druckbegrenzung und zum Ausschluss von Verunreinigungen (z. B. Rohre, O-Ringe, Dichtungen). • Anwendungen in der Lebensmittelproduktion/-verarbeitung, Metallbeschichtung, Kosmetikproduktion, HLK-Anlagen, medizinischen Geräten, Transportfahrzeugen, Elektronik/Halbleiter, einschließlich Produktionsanlagen, Energie, Bauwesen, Erdöl/Bergbau.	• Endoskope, ePTFE-Geräte; (Medizinprodukte, A.3.10). • Transportschläuche in Verbrennungsmotoren, Schlauchauskleidungen in der Luft- und Raumfahrt (Transport, A.3.11). • Beschichtungen für elektronische Bauteile, Kabelummantelungen, Belüftungsöffnungen für Elektronik/Halbleiter (Elektronik und Halbleiter, A.3.12; technische Textilien, A.3.23). • Spezifische Anwendungen im Bereich Energie (Energie, A.3.13). • Dichtstoffe für Verbraucher, Schwellenabdichtungen, spezielle Bauklebebänder (Bauprodukte, A.3.14). • Schmierung von dynamischen Dichtungen (Schmierstoffe, A.3.15). • Ersatzteile (Ersatzteile, E.3.3).

Dichtungsanwendungen – Tonnagen und Emissionen

Tonnagen:

- Anhang A, Tabelle A.76

Emissionen

- Anhang B, Tabelle B.99

Table A.76. Volumes of different polymeric PFAS used in sealing applications estimated for EEA.

	Polymeric PFASs [t/y]		
	Low	Mid	High
Production of articlesa	3 000	3 409	3 818
Use phase	20 000	22 725	25 450
Total volume	**20 000**	**22 725**	**25 450**

[a]Used for the calculations of emissions but not included in total summary, because the volumes in the use phase are considered to already include the volumes used for the production of articles.

Table B.99. Emissions of polymeric PFASs from sealing applications estimated for the EEA.

	Polymeric PFASs [t/y]		
	Low	Mid	High
Production of articles used in service life	45	51	57
Use phase	300	341	382
End of life	7.40	110	212
Total emissions	**352**	**502**	**651**

Dichtungsanwendungen – Analyse der Alternativen (Anhang E, Tabelle E.366)

Table E.366. Summary of assessment of alternatives to fluoropolymers and perfluoropolyethers in sealing applications.

Technical feasibility	On the basis of the available information, the Dossier Submitters conclude that there is **sufficiently strong evidence** that alternatives do not have the same combination of properties as fluoropolymers and perfluoropolyethers and that where a combination of all or many of the properties of fluoropolymers or perfluoropolyethers are required in a sealing application in an industrial use to ensure compliance with applicable performance and safety standards then alternatives are not currently technically feasible. It is furthermore concluded that there are indications that alternatives are technical feasible for sealing applications in industrial uses where a combination of only some of the properties provided by fluoropolymers and perfluoropolyethers are required to ensure compliance with applicable performance standards **[weak evidence]**. However, the Dossier Submitters cannot distinguish with sufficient confidence between specific sealing applications in industrial uses where alternatives are currently technically feasible from industrial uses where they currently are not. Performance losses associated with the use of a alternatives do not necessarily mean that they are concluded to not be technically feasible. However, the Dossier Submitters cannot identify with sufficient confidence those specific applications where alternatives are considered technically feasible despite certain performance losses. There is insufficient information **[no evidence]** to conclude on the technical feasibility of alternatives in professional and consumer uses of sealing applications.
Economic feasibility	Alternatives are typically reported to be cheaper than fluoropolymers **[sufficiently strong evidence]**. Therefore, in general, such alternatives are deemed to be economically feasible when technically feasible.
Availability	The Dossier Submitters conclude that all alternatives listed in Table E.364, except HNBR and AEM, are available on the market and that there are no indications of insufficient supply of these alternatives to meet increased demands in the future after entry-into-force of the restriction **[sufficiently strong evidence]**.
Hazards/Risks	The Dossier Submitters conclude based on a screening of REACH registration dossiers for 22 alternative substances with unique CAS numbers that none of these alternatives are known to fulfil the PBT or vPvB criteria and no other hazard properties were identified. For 4 alternative substances without unique CAS numbers no information on classification or PBT and vPvB assessments is available. Therefore, it is not possible to conclude on their hazard and risk. Silicone-based materials may contain hydrocarbyl siloxanes (including D4, D5 and/or D6) which have been identified for risk management based on suspected PBT/vPvB properties. However, until the risk management process is concluded it would be premature to conclude that use of silicone polymers that contain hydrocarbyl siloxanes as impurities would be regrettable substitution relative to the use of PFASs. Metal based alternatives are considered, in general, to have a lower risk compared to PFASs. The Dossier Submitters conclude, based on the available information, that alternatives are likely to pose a lower risk to human health or the environment compared to fluoropolymers and perfluoropolyethers.
Time required for transitioning to alternative	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. Stakeholders report that the time required for transitioning to alternatives is in the range of 2 – 20 years starting from when suitable alternatives are identified, although the majority of comments to the consultation on the Annex XV report indicate that around 10 years would be required.
Conclusion on substitution potential	The Dossier Submitters conclude that there is a **low substitution potential at EiF** [sufficiently strong evidence] for industrial uses of fluoropolymers and perfluoropolyethers in sealing applications which require a combination of all or many of the properties currently provided by these substances. It is furthermore concluded that there is a **high substitution potential at EiF** [weak evidence] for industrial uses of fluoropolymers and perfluoropolyethers in sealing applications which require a combination of only some of the properties currently provided by fluoropolymers and perfluoropolyethers. However, due to the limited information available on specific industrial uses of fluoropolymers and perfluoropolyethers in sealing applications, the Dossier Submitters cannot distinguish with sufficient confidence between specific industrial uses where alternatives are currently suitable from those where they currently are not. In addition, there is insufficient information **[no evidence]** to conclude on the substitution potential of professional and consumer uses of fluoropolymer and perfluoropolyethers in sealing applications. As a result, the following derogations are further assessed: • Industrial use in sealing applications until 13.5 years after EIF (RO2); • Industrial use in sealing applications where provisions are in place to minimise emissions during the production of articles and to ensure proper collection and disposal, including adequate waste treatment (RO3).

Dichtungsanwendungen – Schlussfolgerungen (Anhang E, Tabelle E.374)

RO2

Beschränkung mit **Übergangsfrist 13,5 Jahre** für

- Dichtungsanwendungen in industriellen Verwendungen

Beschränkung mit **Übergangsfrist 18 Monate** für

- Dichtungsanwendungen in Verbraucherverwendungen
- Dichtungsanwendungen in berufsmäßigen Verwendungen

RO3: Weitere unbefristete Verwendung bei Minimierung von Emissionen bei der Herstellung und am Ende des Lebenszyklus

=> Geringere Effektivität als RO2, da weiterhin Emissionen während der Verwendung

Dichtungsanwendungen – Verhältnismäßigkeit

Table E.376. Proportionality assessment for sealing applications.

Effectiveness: emission reduction [%]	Economic costs or other impacts of a restriction option				
	Very low	Low	Moderate	High	Very high
Very Low (<70%)		RO3	RO2		
Low (70 – 79%)					
Moderate (80 – 89%)					
High (90 - 98%)					RO1
Very high (≥99%)					

Stand des Verfahrens

Wissenschaftliche Bewertung RAC/SEAC

Background Dokument  &  Kommentare aus Konsultation

RAC:
Gefahren/Risiko,
Emissionen, Alternativen

SEAC:
Alternativen, Auswirkungen
(Kosten/Nutzen),
Vollziehbarkeit

RAC/SEAC
Stellungnahme

Wissenschaftliche Bewertung RAC/SEAC

Vorläufige Schlussfolgerungen RAC/SEAC

- EU-weite Beschränkung zur Minimierung der Emissionen gerechtfertigt
- EU-weite Beschränkung ist am besten geeignete Maßnahme
- Bestätigung Gefahr/Risiko, Unterstützung Gruppenansatz
- Emissionen als Proxy für Risiko
- Bewertungsmaßstäbe Emissionen, Alternativen, Kosten
  - Teilweise abweichend von Dossier Submitter
- Vorläufige sektor-basierte Bewertung weitestgehend abgeschlossen

Wissenschaftliche Bewertung RAC/SEAC

ECHA announces timeline for PFAS restriction evaluation

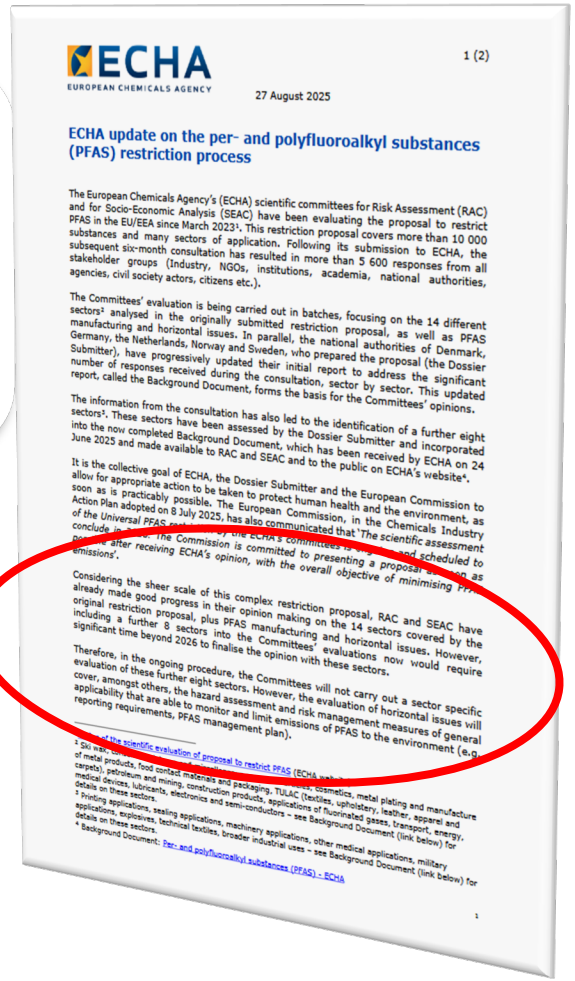
ECHA/NR/25/25

The European Chemicals Agency (ECHA) aims to complete its scientific evaluation of the proposed EU-wide restriction on per- and polyfluo[illegible]l substances (PFAS) by the end of 2026.

Helsinki, 27 August 2025 – In a note, published today, ECHA provides an update on its assessment of the proposal and clarifies the expected timeline. This follows the publication of the updated restriction proposal, which took place on 20 August 2025.

Considering the sheer scale of this complex restriction proposal, RAC and SEAC have already made good progress in their opinion making on the 14 sectors covered by the original restriction proposal, plus PFAS manufacturing and horizontal issues. However, including a further 8 sectors into the Committees' evaluations now would require significant time beyond 2026 to finalise the opinion with these sectors.

Therefore, in the ongoing procedure, the Committees will not carry out a sector specific evaluation of these further eight sectors. However, the evaluation of horizontal issues will cover, amongst others, the hazard assessment and risk management measures of general applicability that are able to monitor and limit emissions of PFAS to the environment (e.g. reporting requirements, PFAS management plan).



ECHA
EUROPEAN CHEMICALS AGENCY

1 (2)

27 August 2025

ECHA update on the per- and polyfluoroalkyl substances (PFAS) restriction process

The European Chemicals Agency's (ECHA) scientific committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) have been evaluating the proposal to restrict PFAS in the EU/EEA since March 2023[1]. This restriction proposal covers more than 10 000 substances and many sectors of application. Following its submission to ECHA, the subsequent six-month consultation has resulted in more than 5 600 responses from all stakeholder groups (Industry, NGOs, institutions, academia, national authorities, agencies, civil society actors, citizens etc.).

The Committees' evaluation is being carried out in batches, focusing on the 14 different sectors[2] analysed in the originally submitted restriction proposal, as well as PFAS manufacturing and horizontal issues. In parallel, the national authorities of Denmark, Germany, the Netherlands, Norway and Sweden, who prepared the proposal (the Dossier Submitter), have progressively updated their initial report to address the significant number of responses received during the consultation, sector by sector. This updated report, called the Background Document, forms the basis for the Committees' opinions.

The information from the consultation has also led to the identification of a further eight sectors[3]. These sectors have been assessed by the Dossier Submitter and incorporated into the now completed Background Document, which has been received by ECHA on 24 June 2025 and made available to RAC and SEAC and to the public on ECHA's website[4].

It is the collective goal of ECHA, the Dossier Submitter and the European Commission to allow for appropriate action to be taken to protect human health and the environment, as soon as is practicably possible. The European Commission, in the Chemicals Industry Action Plan adopted on 8 July 2025, has also communicated that '*The scientific assessment of the Universal PFAS [illegible] the Commission is committed to presenting a proposal [illegible] scheduled to conclude in [illegible] the ECHA's committees [illegible] after receiving ECHA's opinion, with the overall objective of minimising PFAS emissions*'.

Considering the sheer scale of this complex restriction proposal, RAC and SEAC have already made good progress in their opinion making on the 14 sectors covered by the original restriction proposal, plus PFAS manufacturing and horizontal issues. However, including a further 8 sectors into the Committees' evaluations now would require significant time beyond 2026 to finalise the opinion with these sectors.

Therefore, in the ongoing procedure, the Committees will not carry out a sector specific evaluation of these further eight sectors. However, the evaluation of horizontal issues will cover, amongst others, the hazard assessment and risk management measures of general applicability that are able to monitor and limit emissions of PFAS to the environment (e.g. reporting requirements, PFAS management plan).

[illegible] of the scientific evaluation of proposal to restrict PFAS (ECHA web[illegible]

[1] Ski wax, cosmetics, metal plating and manufacture of metal products, food contact materials and packaging, TULAC (textiles, upholstery, leather, apparel and carpets), petroleum and mining, construction products, applications of fluorinated gases, transport, energy, medical devices, lubricants, electronics and semi-conductors – see Background Document (link below) for details on these sectors.

[2] Printing applications, sealing applications, machinery applications, other medical applications, military applications, explosives, technical textiles, broader industrial uses – see Background Document (link below) for details on these sectors.

[3] Background Document: Per- and polyfluoroalkyl substances (PFAS) - ECHA

Wissenschaftliche Bewertung RAC/SEAC

Nächste Schritte

- Dezember 2025:
  - Elektronik/Halbleiter, PFAS-Herstellung und übergreifende Themen
- März 2026:
  - Finalisierung RAC-Stellungnahme sowie Entwurf SEAC-Stellungnahme
- Anschließend («kurz darauf»):
  - Beginn öffentliche Konsultation SEAC-Stellungnahme (60 Tage)

SEAC-Konsultation – Was ist zu beachten?

SEAC-Konsultation - Überblick

- Beginn: Kurz nach Abstimmung Entwurf SEAC-Stellungnahme
- Dauer: 60 Tage (Vorgabe REACH Rechtstext)
- Struktur:
  - Fragebogen
  - Zwei Arten von Fragen:
    - Allgemeine Fragen zu Abschnitten des Entwurfs der Stellungnahme
    - Spezifische Fragen zur Bewertung der Sektoren (14 Sektoren und PFAS-Herstellung)
  - Vorgegebenes Eingabeformat (keine Anlagen)

=> ECHA-Webinar 30. Oktober

SEAC-Konsultation - Überblick

	Allgemeine Fragen	Spezifische Fragen
Art der Fragen	Freitext (Zeichenbegrenzung)	• Numerische Fragen • Auswahl aus vorgegebenen Antworten • Freitext (Zeichenbegrenzung)
Beispiele	• Begründung EU-weites Risiko • Sozio-ökonomische Analyse • Umsetzbarkeit • …	• Verfügbarkeit von Alternativen • Nicht-Verwendungsszenario • Kostenabschätzung • …
Umfang	Abschnitte des Entwurfs der Stellungnahme	Sektor-/Verwendungsspezifisch (14 Sektoren + PFAS-Herstellung)

Hilfestellungen der ECHA

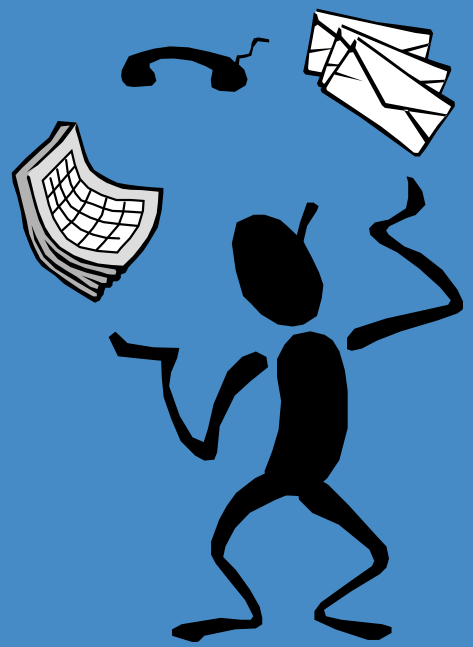
„Use-mapping“

- ECHA erstellt Übersicht über Verwendungen innerhalb des Scopes der 14 Sektoren (sowie PFAS-Herstellung)
- Orientierung für Konsultationsteilnehmer zur Auswahl des korrekten Sektors
- Granularität entsprechend SEACs Schlussfolgerungen im Entwurf der Stellungnahme

Vorbereitung auf die Konsultation

- Webinar am 30. Oktober 2025
  - Veröffentlichung vorläufiges „Use-mapping“: 13 Sektoren
- Mitte Dezember 2025
  - Veröffentlichung Anleitung zur Einreichung von Kommentaren
  - Vervollständigung „Use-mapping“: 14 Sektoren und PFAS-Herstellung
  - Nachfragen an ECHA, lebendes Dokument
- Beginn der Konsultation:
  - Finales „Use-mapping“

Vielen Dank für Ihre Aufmerksamkeit



Kontakt

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PFAS manufacturing

- Manufacture of PFASs in the EU from raw materials like monomers or starting compounds
- Does not include formulation of PFAS containing mixtures or production of articles

Cross-cutting assessments

- Second-hand market.
- Spare parts for complex objects already in end use.
- Secondary (recycled) materials (e.g., paper, plastics and textiles).
- Scientific research & development (SR&D).
- Product & process-oriented research & development (PPORD).

PFAS uses outside of assessment scope

- Active substances in medicinal products for human & veterinary use.
- Active substances in PPP & biocides.

Overarching (generic) applications of PFASs

- **Electronics and semiconductors** – *wires/cables; electrical and photonic components (inc. data storage); semiconductor manufacturing processes; heat transfer/management fluids.*
- **Lubricants** – *mixtures for low-viscosity lubrication, greases, solid/dry films (e.g., piston-rings) and slip/release agents – including in sealed articles/objects*
- **Sealing applications*** – *fluoropolymers and perfluoropolyethers used (i) to prevent leakage (ii) to contain pressures (iii) to exclude contamination (e.g., o-rings, gaskets, pipes & tubing)*
- **Machinery applications*** – *fluoropolymers and perfluoropolyethers used (i) for self-lubricating (low friction) parts (ii) as structural elements (iii) as coatings for protection/durability*

Sector-specific applications of PFASs (overarching applications of PFASs and PFAS manufacturing are not within the scope of sector-specific assessments)

Consumer mixtures & miscellaneous consumer articles

- ***Uses in scope***: eyewear anti-fog; musical strings; fishing lines; synthetic turf
- ***Related uses in other sectors***: home textile treatments; razor blade coatings.

Cosmetics

- ***Uses in scope***: PFAS ingredients in cosmetic products; PFASs used to manufacture cosmetic ingredients (e.g., peptide synthesis).
- ***Related uses in other sectors***: manufacturing equipment; product packaging.

Ski wax

- ***Uses in scope***: formulation & use of ski waxes.

Medical devices

- ***Uses in scope***: implantable, invasive & other medical devices (e.g., wound treatment, sterilisation gases); sterile & non-sterile medical device packaging.
- ***Related uses in other sectors***: excipients, immediate packaging, medicinal product packaging, drug delivery devices, medical textiles & venting, PPE, IVDs.

Other medical applications*

- ***Uses in scope***: excipients, immediate packaging, drug delivery devices e.g., metered-dose inhalers (MDIs), pre-filled syringes, injection pens.

TULAC (textiles, leather, upholstery, apparel, carpets)

- ***Uses in scope***: home textiles and treatment agents (e.g., carpets/upholstery); consumer and professional apparel; PPE; leather.
- ***Related uses in other sectors***: packaging, optical fibres, printing inks, technical textiles, dry cleaning of textiles,

Petroleum & mining

- ***Uses in scope***: anti-foaming agents, tracers, wetting agents, foam stabilisers.
- ***Related uses in other sectors***: Industrial automation/monitoring/control (IAMC).

Energy

- ***Uses in scope***: wind turbines, solar panels, batteries, switchgear, hydrogen fuel cells & electrolysers.
- ***Related uses in other sectors***: oil & gas, hydropower, battery vents, hydrogen storage, solid-oxide fuel cells, IAMC.

Construction products

- ***Uses in scope***: Architectural coatings, paints & adhesives, greenhouse roofing, coil coated materials, anti-drip polymer additives, polymer processing aids, window frames, plumbing, bridge & building bearings.
- ***Related uses in other sectors***: architectural & weatherproofing membranes, foam blowing agents (foam insulation), plain bearings for non-building applications, cable/wire insultation, metal plating & coil coating processes.

Metal plating & manufacture of metal products

- ***Uses in scope***: wetting agents & mist-suppressants, production of coated metal articles/objects, razor blade coatings.
- ***Related uses in other sectors***: downstream use of coated metal products.

Transport

- ***Uses in scope***: automotive, aerospace, watercraft, rail, agricultural, forestry, construction and industrial vehicles; mobile air conditioning (MAC) & heat pumps; transport refrigeration; reflective signage.
- ***Related uses in other sectors***: batteries & fuel cells, textiles in vehicles, PPE, aircraft fire-extinguishers, pyrotechnic charges (e.g., airbags).

Technical textiles*

- ***Uses in scope***: Outdoor textiles (e.g., tents, furniture), architectural & weatherproofing membranes (tensile & non-tensile), filtration & separation media, medical textiles, textiles in transport vehicles (excluding interior).
- ***Related uses in other sectors***: greenhouse roofing, medical devices, fuel cells, TULAC, printing inks, solvents for dry cleaning.

Broader industrial uses*

- ***In scope***: catalysts and processing aids (e.g., ionic liquids), solvents (for cleaning or extraction), hydraulic fluids
- ***Related uses in other sectors***: metal plating; anti-acid coatings; hydraulic fluids in vehicles.

Fluorinated gases

- ***In scope***: heating, ventilation, air-conditioning & refrigeration (HVACR); foam blowing agents (foam insultation); propellants; clean-fire suppression; cover gases, insulating gases in electrical equipment, paper preservation.
- ***Related uses in other sectors***: metered dose inhalers (MDIs), MAC, transport refrigeration, immersion cooling of electronic equipment.

Food contact materials (FCMs) & packaging

- ***In scope***: consumer and industrial cookware, packaging for oil/grease resistance & water repellence (baking paper/vehicle wraps), polymer processing aids for plastic film production, printing inks & lacquers for FCMs.
- ***Related uses in other sectors***: medicine/medical device packaging, water treatment membranes.

Printing*

- ***In scope***: consumables (e.g., toners, latex printing inks, PTFE wax/powder), photosensitive materials, surfactants, permanent parts (e.g., plates and rollers)
- ***Related uses in other sectors***: printing inks & lacquers for FCMs

Explosives*

- ***In scope***: military and civil applications - mining, pyrotechnics for vehicle safety (e.g., airbags & seatbelts), flares, fireworks, ammunition.

Military*

- ***In scope***: Military vehicles, military equipment
- ***Related uses in other sectors***: military explosives, non-military HVACR, military textiles, military PPE, uniforms and protective apparel.