

The Universal PFAS restriction pre-publication

On 13 January 2023, the Competent Authorities of The Netherlands, Germany, Norway, Denmark and Sweden introduced a restriction dossier with ECHA on **per- and polyfluoroalkyl substances (PFAS)**. ECHA issued a [pre-publication](#) of the proposal on 7 February, including the Annex XV Report, 7 Annexes and 3 Appendices (\pm 2000 pages in total). The final version of the restriction proposal is expected on 22 March.

Two restriction options have been assessed :

- 1) A full ban with no derogations and a transition period of 18 months.
- 2) A full ban with use-specific time-limited derogations (18-month transition period plus either a 5 or 12 year derogation period) and few time-unlimited, more general derogations (**preferred option**).

The restriction in short

Definition of PFAS and why they are grouped together in this restriction

PFAS stands for per- and polyfluoroalkyl substances. The Dossier Submitters propose the following definition for PFAS:

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

A substance that only contains the following structural elements is excluded from the scope of the restriction:

CF_3 -X or X- CF_2 -X', where

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

The proposal mentions that PFAS form a broad group of substances, including volatile as well as non-volatile PFASs, anionic, cationic, zwitterionic and non-ionic substances, polymers of different kinds as well as non-polymers, amphoteric liquids (surfactants), etc., with various chain-lengths and degree of fluorination. The group of PFASs therefore cannot be characterised by (a) specific (range of) physicochemical properties.

All PFAS have been grouped together, because they (and/or their degradation products) are considered to have the characteristic of 'very high persistence' in common.



Which PFAS and PFAS uses are proposed to be restricted by when

The universal PFAS restriction imposes a manufacturing, sale, use and import ban on all PFAS, and PFAS containing products, materials and finished goods¹. These bans are foreseen to apply 18 months from entry into force of the restriction.

Three types of derogations to the above-ban are mentioned:

- An exclusion (time-unlimited derogation) for active substances in plant protection, biocidal, and human & veterinary medicinal products (with a reporting obligation).
- Time-limited derogations where there is sufficiently strong evidence that today there are no viable alternatives available. Depending on the current state of development of alternatives, uptake of alternatives etc., the derogation is granted for 6.5 or 13.5 years² from the entry into force³. These derogations cover specific uses in food contact materials, medical devices, membranes in fuel cells, refrigerants, insulating materials, textiles, etc.
- Potential time-limited derogations where the current evidence on (non)availability of alternatives is inconclusive. These are mentioned between square brackets⁴ and cover *inter alia* certain uses of PFAS in textiles (incl. personal protective equipment (PPE)), very specific industrial uses, engineered fluids for medical devices, transport applications, etc. Stakeholders are expected to feed data into the upcoming public consultation to strengthen the evidence-based justification for a derogation.

The restriction process

The entire process, from introduction of the proposal to the final publication in Annex XVII of REACH, takes at least 18 months. Annex 1 depicts an indicative timeline, assuming all steps go through the streamlined process. A brief overview of the next steps:

10-15 March 2023	Conformity check assessment by the Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC)
22 March 2023:	Expected publication of the final proposal; start of a 6-month public consultation
5 Apr 2023:	ECHA will hold an online information session to explain the restriction process and to help those interested in participating in the consultation.
Mar 2023 - Dec 2023:	Risk Assessment Committee (RAC) opinion development: RAC will form an opinion on whether the proposed restriction is appropriate in reducing the risks to people's health and the environment.
Mar 2023 - Mar 2024:	Committee for Socio-Economic Analysis (SEAC) opinion development: SEAC will look into the socio-economic impacts, i.e. proportionality of the measure, benefits and costs to society; the ECHA's Enforcement Forum will also issue its advice.

¹ Except for the import of PFAS containing product, materials and finished goods that only contains very low levels of PFAS:

- 25 ppb for one non-polymer PFAS
- 250 ppb for the sum of non-polymer PFAS
- 50 ppm for all polymeric PFAS

² These 6.5 years and 13.5 years include the 18-month (1.5-year) transitional period.

³ Time-limited derogations are specified for 1) PFAS except for fluoropolymers and perfluoropolyethers and 2) fluoropolymers/perfluoropolyethers

⁴ 'Square brackets' are indicated in a way [*hernia meshes until 13.5 years after EoF*] for instance, as on page 7 of the restriction dossier.

- Dec 2023 - Feb 2024: **60-day consultation on the draft opinion by Committee for Socio-Economic Analysis (SEAC)**
- Mar 2024 - Q1 2025: European Commission drafts the legal text of the restriction⁵; and REACH Committee (Member States) discusses and adopts the text.
- Q2 - Q3 2025: Scrutiny by EU Parliament and Council
- Q4 2025 - Q1 2026: Publication in Official Journal

The above dates are all indicative and the process is expected to be delayed, as for complex files, the ECHA and Commission assessment periods are usually extended.

Important to note is that the **durations of public consultations are fixed**. The page set up for public consultations can be found here:

<https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term>

It contains:

- The pre-publication of the restriction proposal, its annexes and appendices
- All submitted comments

This page will continuously be updated. Please note that Helsinki time applies to all deadlines.

About FPP4EU

FluoroProducts and PFAS for Europe (FPP4EU) is a sector group of Cefic (the European Chemical Industry Association). The group represents producers, importers and users of the many potential substances that fall within the broad definition of PFAS.

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About Cefic

Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 16% of world chemicals production.

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⁵ The Commission submits it to the World Trade Organisation (WTO) to ensure that it does not create technical barriers to international trade.