The Universal PFAS restriction pre-publication

Issued 7 February 2023

Following the large public pressure and attention for the topic, on 13 January 2023, the Competent Authorities of The Netherlands, Germany, Norway, Denmark, and Sweden ('Dossier Submitters') submitted a restriction dossier to the European Chemicals Agency (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 (± 2000 pages in total).

The final version of the restriction proposal is expected to be published on 22 March.

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.

European Chemical Industry Council - Cefic aisbl
Rue Belliard 40 b.15 B-1040 Brussels Belgium
Tel. +32.2.436.93.00 mail@cefic.be www.cefic.org
EU Transparency Register n° 64879142323-90

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 goods[1]. 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 years[2] from the entry into force[3]. 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 brackets[4] 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 EiF]*' 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 restriction[5]; 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.

Where you are needed

Industry input needed/ highly recommended for already mentioned proposed derogations

For the derogations indicated between square brackets, the dossier submitters invite stakeholders to provide data. If no supportive data are made available during the consultation period to minimise uncertainties, the derogation might not be supported by the ECHA committees and not included in the final restriction.

Looking at the content summary tables for the regulatory options 1 and 2 (pages 80-139 of the pre-published restriction proposal), it becomes clear that the following data are highly relevant to feed into e ECHA's public consultation:

- Data on the (non-)availability of alternatives
- Data on cost impact:
  - producer surplus losses
  - employment losses
  - consumer surplus losses
  - welfare losses
- Detailed data on emission/release control are very useful, as the base assumption is that emissions are unavoidable and high.

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

Industry input requested for lacking derogations

If the use of a (group of) PFAS or PFAS-containing products is not included in any of the listed derogations in the proposal, it will be banned within18 months after entry into force of the restriction.

PFAS containing products already in use can continue to be used until end-of life. Problems may thus arise with replacement of equipment and/ or its PFAS-containing spare parts.

All stakeholders are therefore advised to:

- Carefully assess the list of derogations and identify those uses that are missing.
- Engage with other players in their value chains, in compliance with competition law[6].
- Respond to the public consultation with data on the (non-)availability of potential alternatives for the missed uses and the cost impact of the proposed restriction (see Annex 2 for details on consultation page).
- Give an indication to the authorities of the time frames for developing viable alternatives in sufficient quantities (including re-design of end products).

Final remark

Special attention should be given to the ***use of PFAS in industrial settings (coated pipes, gaskets, valves, membranes, etc.)***, as these are not sufficiently covered.

Also the use of PFAS as ***intermediates, precursors, etc. for the production of active substances for plant protection products, biocides and veterinary & human medicines*** is missing. The active substances may be mentioned with a time-unlimited derogation, but companies should also be able to produce them within the EU or import them into the EU, which means that intermediates, precursors, etc. would need also a derogation.

Since the pre-published restriction proposal will further be modified by the time when the 6-month public consultation is launched, Cefic members are advised to assess and cite the conformity-checked dossier (to be published on 22 March) for response to the public consultation.

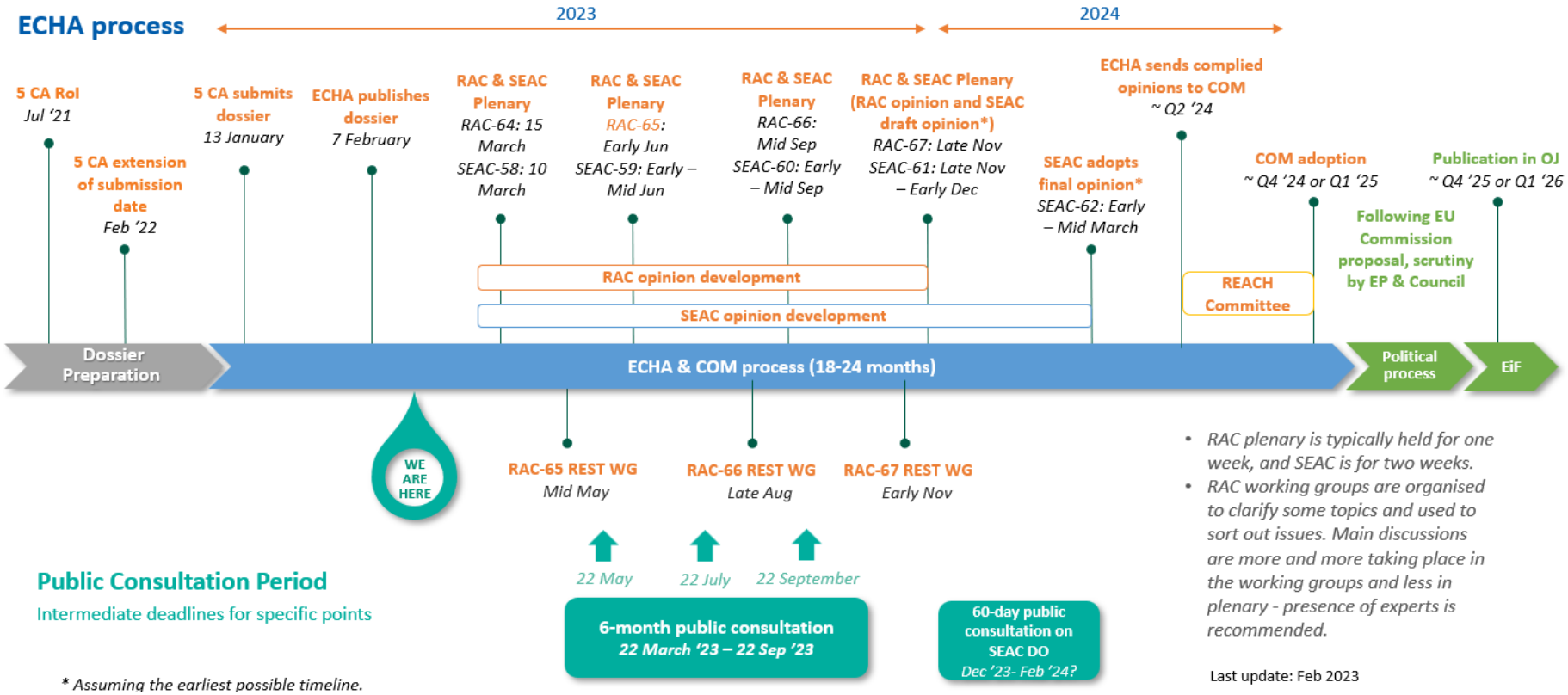
Key contact

Marleen Pauwels, Executive Director, Halogens Industry Sector (mpa@cefic.be).

[6] Information sensitive under competition law should not be exchanged. This includes any information that could reveal the commercial policy on one company to its (potential) competitor(s).

ANNEX 1: The universal PFAS restriction's indicative timeline

The restriction proposal – indicative timeline



- *RAC plenary is typically held for one week, and SEAC is for two weeks.*
- *RAC working groups are organised to clarify some topics and used to sort out issues. Main discussions are more and more taking place in the working groups and less in plenary - presence of experts is recommended.*

** Assuming the earliest possible timeline.*

Last update: Feb 2023

ANNEX 2: Public Consultation Page

Page set up for public consultations: 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

Please note that Helsinki time applies to all deadlines.