

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

20 November 2024

1. General aim of the regulatory initiative on PFAS

In January 2023, authorities from Denmark, Germany, the Netherlands, Norway and Sweden (the Dossier Submitters) submitted a REACH dossier for a restriction proposal for per- and polyfluoroalkyl substances (PFAS) in the EU to the European Chemicals Agency (ECHA). PFAS are a group of thousands of mainly man-made substances that are used in numerous applications in the EU.

The basis for the proposed restriction is the fact that PFAS and their degradation products may persist in the environment for a very long period, longer than any other man-made chemical. Further concerns are their bioaccumulation, mobility, long range transport potential (LRTP), accumulation in plants, global warming potential and (eco)toxicological effects. The EU-wide risk arises from the continued emissions of PFAS into the environment during manufacture, the use phase, and the waste stage.

This restriction dossier is built on the principle that PFAS are to be substituted where already feasible today, or to become feasible in the foreseeable future. At the same time, it provides the possibility for allowing the continued use of PFAS in certain circumstances e.g. where there are no suitable alternative substances or technologies available, while still ensuring that emissions into the environment are minimised.

Like for all restriction dossiers under REACH, the PFAS dossier includes an assessment of the risk reduction capacity and proportionality to the risk of any proposed restriction option while taking into account the availability of alternatives and their practicability and monitorability. These elements are key considerations in the evaluation of ECHA's scientific committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) respectively and will thereby be reflected in the final consolidated opinion sent to the European Commission.

2. What is currently being done?

General process

RAC and SEAC are carrying out an evidence-based scientific evaluation of the REACH restriction dossier for PFAS. The aim is to deliver transparent, independent, and high-quality opinions as soon as possible, while ensuring a thorough scientific review by the committees as well as the opportunity for third parties to provide input.

Given the broad scope of the restriction dossier (covering >10,000 substances used in 14+ sectors), the committees have decided to take a sector-based approach in their evaluation. This allows for proper attention to the specificities and different nature of the uses, risks and respective restriction options.

To date, the RAC has reached a provisional conclusion on the hazard assessment of PFAS. In addition, provisional conclusions have been reached by the RAC and SEAC on five sectors: consumer mixtures and miscellaneous consumer articles, cosmetics, ski wax, metal plating and manufacture of metal products and petroleum and mining. These have a provisional status, because it is only when all sectors are discussed by both committees that final conclusions will be possible across the entire proposal. These conclusions will be documented in the final consolidated opinion from both RAC and SEAC, sent by ECHA to the European Commission.

Third-party consultation

More than 5 600 scientific and technical comments were received from interested third parties submitted during the six-month consultation on the restriction dossier held in 2023. These comments contain extensive information on the hazards and risks of PFAS, the uses of PFAS across the EU and European Economic Area (EEA) as well as information on the availability and suitability of alternatives and the socio-economic impacts of the proposed restriction and are being considered and evaluated in detail.

The input from the consultation helps the Dossier Submitters to progressively update and improve the information on PFAS in the form of a *Background Document*. It also helps to **identify uses that were not yet specifically named in the initial restriction dossier**, incorporating these into existing sector assessments or creating additional sectors, as necessary. This further information feeds into the committees' evaluation of the restriction dossier.

Examples of **newly identified uses** are:

- Sealing applications: a broad range of fluoropolymer uses in consumer, professional and industrial applications, including seals, pipe lining, gaskets, valve parts, etc.
- Technical textiles: uses of PFAS in for example high-performance membranes, medical applications that are not covered in medical devices, outdoor technical textiles (like tarps).
- Printing applications: permanent parts and consumables for printing applications.
- Other medical applications (e.g., packaging and excipients for pharmaceuticals).

Fluoropolymers are one example of a group of PFAS with high interest for stakeholders and the consultation has brought further insight into the availability of alternatives for certain uses of these polymers, technical and organisational measures to minimise their emissions in the environment and potential socio-economic impacts of a ban of their manufacture, placing on the market and use. Specific attention is being given to this group by all actors in the opinion development process.

3. Further restriction options being considered

It is important to note that the intention of the Dossier Submitters is to minimise emissions of PFAS to avoid further build-up of PFAS in the environment and subsequent exposure to humans and the environment. The initial PFAS restriction dossier contains two restriction options: a full ban or a ban with time limited derogations (where alternatives are not yet available). The Dossier Submitters propose the latter option to allow for an orderly substitution process when alternatives have become available, without jeopardising the availability of the uses, e.g. for achieving the green energy transition.

The additional information brought forward in the 2023 consultation is also resulting in consideration being given to whether **restriction options other than a ban** may achieve the regulatory aim to significantly reduce the PFAS emissions throughout their life cycle, in addition to the need for appropriate derogations. This assessment is particularly relevant for those uses and sectors for which information was provided to demonstrate that the socio-economic impacts of a ban are likely to be disproportionate (for example because technical substitution is currently not foreseeable). It also helps to improve the practicality of the restriction proposal for specific applications.

Possible additional restriction options will be compared to the already proposed two restriction options where for some uses an alternative to a ban may be suggested. These could be conditions to be met to allow for the continued manufacture, placing on the market or use of PFAS instead of a ban, or conditions that must be met for the manufacture, placing on the market or use of PFAS until alternatives are available.

This assessment is currently underway for the use of PFAS in certain industrial applications e.g. batteries, fuel cells and electrolyzers. The same assessment will also be carried out for other sectors, for example medical devices and semiconductors, provided that such information has been brought forward in the consultation. In addition, information has been submitted in the consultation that may form a basis for alternative restriction options for e.g. fluoropolymers in manufacturing, service life and end of life, while still adhering to the purpose of the proposal to minimise emissions to the environment.

All considerations are still subject to scrutiny by the RAC and SEAC and subsequently during the decision-making phase by the European Commission, with Member States.

4. Concluding remarks

The opinion development work will further progress during 2025 and will lead to an opinion of the RAC and a draft opinion of the SEAC. A consultation will be held afterwards on the draft opinion of the SEAC. This will provide an opportunity for all interested third parties to provide relevant information regarding socio economic aspects to be considered in the final SEAC opinion.

The progress on the PFAS restriction so far has been possible through the combined and committed efforts of ECHA and the Dossier Submitters, who are focussed on supporting the development of a consolidated opinion from RAC and SEAC. As an additional result of this process, more has become known about the use of PFAS, which has resulted in all parties becoming more aware of the associated concern.

Working together with the Dossier Submitters, ECHA aims to provide the European Commission with a transparent, independent, and high-quality RAC and SEAC opinion as soon as possible. The European Commission will ultimately decide on the restriction in consultation with EU Member States. Further information and progress updates:

<https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas>.