



OVERVIEW OF THE PROPOSED EUROPEAN 'UNIVERSAL' RESTRICTION FOR PFAS

BACKGROUND

The much-anticipated proposal for restriction of PFAS (per- and polyfluoroalkylated substances) under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation has now been published by the European Chemicals Agency (ECHA). The Annex XV restriction report has been prepared by Member State authorities in Denmark, Germany, the Netherlands, Sweden and Norway. The concern for PFAS arises because of widespread environmental contamination and their extreme persistence, which leads to increased environmental concentrations over time. PFAS are also mobile, meaning they can move long distances from their source, bioaccumulate in wildlife and humans, and some are known to have harmful impacts on human health and wildlife.

In a report published in 2019 by the Nordic Council, annual health costs associated with exposure to PFAS in Europe were estimated between €52 billion and €84 billion.

The proposed restriction will have important implications on industry, with millions of products likely to need reformulating, substances needing to be substituted and involve a significant time and cost investment to reduce the use of PFAS within product portfolios.

The large number of substances in this group and the desire to avoid further instances of regrettable substitution, as occurred following the restriction of individual PFAS in the past, has led to the development of this landmark restriction proposal. **The authorities estimate that without action, around 4.4 million tonnes of PFAS will enter the environment over the next 30 years.**

SCOPE

The restriction proposal uses the widely adopted definition of PFAS developed by the OECD/UNEP global working party on PFAS published in 2021 and covers both polymeric and non-polymeric PFAS. The definition encompasses more than 10,000 substances. In defining the scope of the restriction, the restriction report acknowledges that the OECD definition includes some fully degradable PFAS subgroups.

As these fully degradable subgroups are not persistent, they are of less concern and are excluded from the scope of the restriction proposal.

PFAS are defined as “any substances that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/I attached to it).”

– OECD 2021



THE PROPOSED RESTRICTION

The proposed restriction prohibits the manufacture, use or placing on the EU market of PFAS substances on their own or as another constituent in a mixture or article in a concentration above:

- i. 25 ppb for any PFAS (polymeric PFAS excluded from quantification);
- ii. 250 ppb for sum of PFAS (polymeric PFASs excluded from quantification);
- iii. 50 ppm for PFASs (polymeric PFAS included).

PFAS used as active substances in plant protection products, biocidal products and medicinal products (human and veterinary) have time unlimited derogations and are not included in the proposed restrictions. The proposal also includes several time limited derogations of either five or 12 years, for specific uses where sufficiently strong evidence is available that technically and economically feasible alternatives are not available on the market or possible alternatives are still in development.

Other potential derogations are proposed, referred to as 'bracketed derogations'. These are instances where the evidence base is currently too weak to propose a derogation, but the dossier submitters recognise that a derogation could be warranted. These potential derogations have been marked for reconsideration following the Annex XV consultation period. The restriction report sets out clear expectations on the strength of evidence required to support a derogation in these instances. If inconclusive evidence, or no evidence, is submitted for a specific use then the derogation will not be supported.

A six-month consultation period for submitting comments on the proposal and evidence to support potential derogations started on 22 March 2023.

Two restriction options (RO) were assessed:

RO1 – full ban with no derogations and a transition period of 18 months.

RO2 – full ban with specific time limited derogations and a transition period of 18 months.

The dossier submitters deemed both restriction options appropriate since the societal cost of inaction would surpass the costs of a ban on the use of PFAS.

Dossier submitters have proposed RO2 as the most balanced option as it leaves room to mitigate unwanted impacts on society because of the sudden unavailability of products. However, they note that a delay in banning PFAS as per RO2 simply shifts the cost burden arising from health and environmental impacts to future generations.

The proposal also outlines reporting obligations for manufacturers, formulators and importers of PFAS, mixtures and articles containing PFAS, and making use of any of the derogations. Except for formulators, downstream users are not included in these reporting obligations.

TIMELINE

ECHA's scientific committees will check that the proposal meets the legal requirements of the REACH Regulation. If it does, they will begin their scientific evaluation to form an opinion on whether it is appropriate for reducing the risks to people's health versus the costs to society.

They will also consider the enforceability of the proposal. The adopted opinions will then be sent to the European Commission who, together with Member States, will conclude on the proposed restriction.

ECHA have set out the following timeline for the next steps (as published [here](#)).



ADDITIONAL POINTS TO NOTE

- A regulatory management options analysis (RMOA) for PFAS under UK REACH has been published by the Environment Agency and Health & Safety Executive and is available [here](#).
- 15 individual PFAS and their related precursor compounds and salts are already designated as substances of very high concern (SVHCs) and subject to restrictions or restrictions proposed between 2006 and 2023.
- An EU-wide restriction on the use of PFAS in firefighting foams has already been developed by ECHA at the request of the European Commission. Following consideration of five options, the proposed option would ban the placing on the market, use and formulation of all PFAS in firefighting foams. **This restriction proposal is further advanced than the universal restriction described above.**

WHAT SHOULD YOU BE DOING NEXT

We expect that producers and users of PFAS will need to reformulate products and modify processes in response to tighter regulation and customer demand for safer, more sustainable chemistries.

If you manufacture, supply or use PFAS or are unsure if you have any in your portfolio, our immediate suggestions would be to:

- Use our horizon scanning tool to identify if you have any PFAS in your portfolio.
- Participate in consultation regarding the universal restriction proposal which began on 22 March. We can help you build an evidence base to contribute to the consultation.
- Engage with your trade association as appropriate.

These are important steps to address the challenges the chemical industry will soon find themselves in, but more importantly, these steps will help you make future business decisions around investment, reformulation, and substitutions in your product portfolio.

HOW CAN NCEC SUPPORT

NCEC, the environmental chemistry and toxicology experts at Ricardo, have extensive experience of dealing with the identification and management of hazardous substances. **We can support you to understand the impact of PFAS on your business operations and within your portfolio, and implement processes and policies to help you transition away from PFAS.**

Our trusted experts provide PFAS training and consultancy services to support you to:

- **Identify** PFAS use in your supply chain and product portfolio;
- **Understand** the implications of the changing regulatory landscape and environmental policy;
- **Transition away** from PFAS in your portfolio;
- **Communicate** your use of non-PFAS substances with customers, shareholders, and other stakeholders.

Additionally, we have experts that can support clients within the food, airport, agriculture and water industries. Together, we understand the environmental risk and public health challenges that PFAS pose across the value chain and can offer bespoke guidance across industries to help you manage your risks from PFAS and move towards a more sustainable future.



MEET OUR ENVIRONMENTAL CHEMISTRY AND TOXICOLOGY EXPERTS

At Ricardo, we have 50 years of expertise in providing regulatory support to the chemical industry. Our specialists have a deep knowledge of environmental chemistry and toxicology gained through their work in multinational chemical companies, the public sector, and within industry associations and consortia. They have gained a wealth of experience of placing, monitoring and evaluating regulatory tests, as well as specialist expertise in developing alternative approaches to standard testing requirements.

Our lead PFAS expert, Dr Emma Pemberton, has over 23 years' experience of dealing with persistent chemicals. She is currently working across a variety of projects, including evaluation of risks to drinking water from persistent, mobile and toxic chemicals and organo-phosphate flame retardants; gap analysis of pesticide legislation; and evaluation of data used for persistent, bioaccumulative and toxic/very persistent very bioaccumulative substance assessment under REACH.

Our team works closely with our customers and would be happy to have a discussion with you to understand your regulatory challenges and highlight how we have been supporting organisations like yourself.



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