

## Introduction

On February 7, 2023, Germany, Denmark, the Netherlands, Sweden and Norway<sup>1</sup> jointly proposed a [restriction proposal](#) to ban over 10,000 Per- and Polyfluoroalkyl Substances (PFAS),<sup>2</sup> commonly designated as “forever chemicals.”

The proposed restriction pertains to (i) the manufacturing, placing on the EU market<sup>3</sup> and use of PFAS as substances on their own and (ii) the placing on the EU market of PFAS (a) as a constituent of another substance, (b) in a mixture, or (c) in an article.<sup>4</sup>

The legal basis for the restriction proposal is Article 68 of Regulation (EC) No 1907/2006 (REACH). This provision enables the amendment of Annex XVII of REACH to include substances for which the aim is to prohibit their use, production and sale within the EU market, when there is “an unacceptable risk” to human health or the environment.

The proposal sets forth two options for restriction. Restriction Option 1 (RO1) entails a complete ban without any exemptions and incorporates an 18-month transition period following the entry into force of the restriction. Restriction Option 2 (RO2) proposes, in addition to the 18-month transition period after the restriction comes into effect, derogations of five or 12 years for specific uses identified in the proposal, alongside limited instances of time-unlimited derogations. Notably, the proposed restrictions would not be applicable to active substances in biocidal products (Regulation (EU) 528/2012), plant protection products (Regulation (EC) 1107/2009) or human and veterinary medicinal products (Regulation (EC) No 726/2004, Regulation (EU) 2019/6, and Directive 2001/83/EC).

The European Chemicals Agency (ECHA) following the publication of the restriction proposal initiated on March 22, 2023, a [public consultation](#) to allow stakeholders to voice concerns and submit derogation proposals for various PFAS uses. The consultation period concluded on September 25, 2023.

## Challenges and Concerns Raised by the Proposed PFAS Restriction

ECHA has received an unprecedented number of comments in response to the consultation, which primarily underscore that the industry did not yet have adequate time to identify the uses of PFAS across different industrial sectors.

The proposal for restriction has generated significant apprehensions, particularly as industries encounter difficulties in identifying all uses and sub-uses of PFAS in their applications. Furthermore, the lack of alternatives for numerous uses, especially in final product components, gives rise to concerns that certain goods may become unproducible. As a result, industries, such as electronics, automotive and aerospace, are grappling with evaluating the true impact of the proposed restriction at this juncture.

Another sensitive point of the restriction for industry pertains to its overall scope: many firms advocate for a more targeted restriction, concentrating on substances considered hazardous based on specific applications. The unprecedented grouping of such a large number of substances calls into questions their appropriate individual assessment. Concerns are also raised regarding the demonstrated risk of these individual substances across all affected uses, creating uncertainty about compliance with the requirement as outlined in Article 68(1) of the REACH regulation, which mandates justification for a restriction proposal based on an “unacceptable risk to human health or the environment.”

Critics argue that the current restriction proposal lacks a comprehensive risk assessment supporting the alleged unacceptable risk. They assert that the proposal, as it stands, relies solely on “environmental fate” – the fate of a chemical or organism once released into the environment – with risks and effects assumed rather than scientifically substantiated. Consequently, the adoption of the current restriction proposal as such could lead to a significant number of legal challenges.

Finally, it has been argued that the proposed restriction could hinder the EU’s efforts to reduce greenhouse gas emissions, as PFAS is used in the production of green technologies, potentially conflicting with major EU strategies such as the [EU Green Deal Industrial Plan](#).

<sup>1</sup> In accordance with Article 69(4) of Regulation (EC) No 1907/2006 (REACH), Member States can formulate a restriction proposal after notifying ECHA of their intention to work on it. Subsequently, if conditions apply, the restriction proposal may be incorporated by the European Commission into a draft amendment to Annex XVII of REACH. Therefore, this represents a specific case in which, at the initiative of Member States, a procedure can be initiated to amend an existing law.

<sup>2</sup> The proposal defines PFAS as any substance containing at least one fully fluorinated methyl (CF<sub>3</sub>-) or methylene (-CF<sub>2</sub>-) carbon atom, without any H/Cl/Br/I attached to it. Details regarding the exclusion of a substance from the scope of the restriction can be located on page 4, column 1, paragraph 3 of the [Annex XV](#) restriction report.

<sup>3</sup> REACH applies to legal entities established in the EU and the other Member States of the European Economic Area, namely Norway, Iceland and Liechtenstein. References to the EU or to the EU market should be construed to encompass these three countries as well.

<sup>4</sup> For the placing on the market of PFAS present in another substance, mixture or article, concentration thresholds are established and can be found at page 4, column 2, paragraph 2 of the [Annex XV](#) restriction report.

## Next Steps

In the upcoming procedural stages, the proposed restriction may undergo revisions based on feedback received during the public consultation. Potential outcomes include the member state proposers of the restriction deciding to alter the proposal substantially or even to withdraw it. Recent instances, such as Germany temporarily withdrawing the Bisphenol A restriction proposal<sup>5</sup> following a public consultation, indicate that such actions are not unprecedented.

Simultaneously, ECHA's two technical committees, the Socio-Economic Assessment Committee (SEAC) and the Risk Assessment Committee (RAC), are working on their opinions. According to information from ECHA sources, these committees will initially address specific topics, with opinions on consumer mixtures, cosmetics and ski waxes expected in March 2024. This selection is based on ECHA's belief that it already possesses the necessary information to form opinions on these topics, with substantial contributions from the public consultation not anticipated.

ECHA's committee opinions are subsequently transmitted to the European Commission. If the conditions outlined in Article 68 of REACH, which relate to an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of substances, are satisfied, the Commission proceeds to draft an amendment to Annex XVII. EU member countries, in a comitology procedure chaired by the European Commission, will then make the final decision regarding the proposed restrictions. In this final phase, scientific aspects will be considered alongside internal policy considerations of EU member states.

Given the considerable volume of comments received, along with the diverse interests and concerns associated with this proposal, predicting the overall timeline is challenging. While, according to the timelines outlined by REACH, the Commission's draft opinion should be prepared by 2024, adhering strictly to these timelines is improbable. This is due to the sensitivity of the issue, which is raising various concerns in the industry and beyond, as well as the anticipated political changes (executive roles within the European Commission are expected to change in 2024). We may also see the proposal being substantially changed, or even split up into multiple restrictions. Therefore, if some form of restriction is approved, its implementation is more likely to occur around 2026.

## How We Can Help

We actively support clients from a legal and policy perspective in professionally engaging in the ongoing policymaking process, as well as in preparing for the evolving regulatory landscape.

This notably will include preparing robust responses to the next round of public consultation. As the PFAS restriction process unfolds, stakeholders will be called upon to respond to ECHA's SEAC Opinion. This will allow responders to address the socioeconomic rationale of the proposal. These responses need to be meticulously justified, as per ECHA's requirements, by providing evidence of the absence of viable alternatives and the potential socioeconomic impact arising from the lack of alternatives once the ban is in force. Our firm will assist clients in preparing robust responses and providing compelling evidence to support derogation proposals. We also devise appropriate policy engagement strategies with relevant decision-makers, to ensure our clients are heard at the right time and by the right people. For example, the absence of a dedicated consultation on the RAC Opinion is no reason to remain inactive on the scientific soundness of the restriction proposal if concerns are present. Additionally, we will keep our clients informed about any changes in the restriction proposal that may occur after the initial consultation and provide guidance on influencing the proposal during the later stages of the comitology procedure at the political level.

The policymaking process is at an early stage, but the restriction proposal – sometimes even referred to as a ban – is already starting to impact supply chains. Some major organizations have announced that they are phasing out their uses of PFAS. For others, the restriction proposal is already an incentive to seek substitution. In some instances, the EU initiative is even already being used to support litigation threats or actions worldwide. Our firm can assist in addressing all those challenges.

Moreover, as European Commission regulations often set the stage for regulations in other jurisdictions and internationally, we believe it is important for potentially impacted clients to actively engage in this EU process regardless of their current exposure to the EU market.

<sup>5</sup> Proposal for a Restriction of 4,4'-isopropylidenediphenol (Bisphenol A) and bisphenols of similar concern for the environment. Accessible at: <https://echa.europa.eu/documents/10162/6b2321cf-5334-9354-cbcd-57a9345ae0fb>.

## About Us

As a full-service global law firm, we provide insight at the point where law, business and government meet, giving our clients a voice, supporting their ambitions and achieving successful outcomes. Our multidisciplinary team of more than 1,500 lawyers and public policy experts in over 40 offices across four continents provides unrivaled access to expertise and invaluable connections on the ground. It is a seamless service that operates on any scale – locally or globally. It encompasses virtually every matter, jurisdiction and market. And we place our clients at the center. We combine sound legal counsel with a deep knowledge of our clients' businesses to resolve their legal, public policy and political challenges. We care about the quality of our services, the success of our clients and the relationships that are forged through those successes. Our client base spans every type of business, both private and public, worldwide.

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