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PFAS Update: European Chemicals Agency Publishes Proposal That Would Ban or Severely Restrict the Manufacture, Use and Marketing of Thousands of Broadly Used Man-Made PFAS Chemicals

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In a move with potential significant future ramifications for companies conducting business in Europe, including U.S. and global businesses, authorities from Germany, Denmark, the Netherlands, Norway and Sweden have submitted a regulatory dossier to the European Chemicals Agency (ECHA) proposing new restrictions aimed at significantly reducing the introduction of per- and polyfluoroalkyl substances (PFAS) into the environment. The proposal was made by way of an Annex XV Restriction Report pursuant to the regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (EC) 1907/2006 (as amended from time to time).¹ While the five-nation submission to ECHA was formally announced in January 2023, the scope and nature of the proposal were an open question until February 7, 2023, when the 211-page proposal (the “Dossier”) was published to ECHA’s website.² This *Alert* summarizes the Dossier’s findings and proposed restrictions, including certain phase-in periods, and identifies key challenges raised by the chemicals industry, including arguments that ECHA’s “one size fits all” treatment of thousands of PFAS as a single class is scientifically inaccurate and could undermine the use of PFAS in low-carbon energy technologies. The proposed ban remains subject to a scientific review and six-month consultation period (similar to the U.S. Environmental Protection Agency (EPA) comment period for stakeholder input) to commence in March 2023. The proposed restrictions are not expected to become effective for at least three or four years.

Dossier Raises Concerns Regarding PFAS

Many of the findings of the February 2023 Dossier will be unsurprising to those familiar with the increasing publicity and regulatory attention to PFAS, a group of more than 10,000 chemical substances with multi-sectoral industrial applications ranging from use in textiles, food packaging, household surface coatings, cosmetics, medical devices, electronics, batteries and many other products.³

The Dossier concludes that these substances raise human health and environmental concerns, particularly due to their high persistence in the environment, tendencies for mobility and bioaccumulation (in animals and plants), long-range transport potential, global warming potential, and (eco)toxicological effects, including on humans.⁴ The Dossier acknowledges multiple sources of entry into the environment by PFAS, including from manufacturing and chemical mixing processes involving PFAS, use of PFAS products by consumers and other end users, and industrial and consumer waste streams. The Dossier also states that the amount of PFAS introduced to the EU market without regulation is expected to continue increasing under a baseline scenario.⁵

Form of Proposed Restrictions

In response to these concerns, the Dossier proposes a robust ban on the future manufacture, use, import and marketing of PFAS within the EU under one of two alternative regulatory approaches. The first regulatory option would include a total ban on PFAS above threshold amounts after a limited 18-month transition period (“Restriction Option 1”).⁶ The second regulatory option would include a similar ban and transition period but with limited additional exemptions or phase-ins (termed “derogations”) for certain categories of PFAS use, the vast majority of which would also be time-limited (“Restriction Option 2”).⁷

Either option would utilize a single chemical definition of PFAS rather than enumerating a list of specific banned substances.⁸ This single class approach is unlike several notable U.S. regulatory efforts related to PFAS that define PFAS with a finite list of identified chemistries, including the U.S. Toxic Substances Control Act (TSCA) reporting and recordkeeping rule targeting PFAS manufacturers, slated for finalization in March 2023;⁹ EPA’s proposed significant new use rule related to inactive PFAS under TSCA, issued in January 2023;¹⁰ proposed PFAS additions and reporting requirements under the U.S. Emergency Planning and Community Right-to-Know Act’s (EPCRA)

Toxic Release Inventory Program;¹¹ and the proposed designation of two types of PFAS (PFOS and PFOA) as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act issued in September 2022, [discussed in our prior Alert](#).¹² The Dossier contends that using a unitary, open-ended definition would be more likely to capture all of the more than 10,000 known and likely PFAS in existence, as well as to prevent users from evading restrictions by simply transitioning to other non-restricted and potentially problematic per- or polyfluorinated chemical substitutes, or by developing new PFAS chemistries.¹³ By contrast to what has been proposed to ECHA, EPA plans to request public input by an advance notice of public rulemaking in February 2023 regarding whether the agency should consider precursors to PFOA and PFOS as hazardous substances, as well as whether the agency should consider designating other PFAS as CERCLA hazardous substances and whether there is information that would allow the agency to designate PFAS as a class or subclass.

Both EU regulatory options would also include mixtures and articles containing PFAS above a certain concentration.¹⁴ Further, unlike certain regulatory approaches taken in the U.S. that target intentionally-added PFAS, such as the food packaging bans in New York¹⁵ and California¹⁶ or Maine's impending prohibition on all products containing PFAS not designated as an unavoidable use¹⁷, both of the Dossier's alternatives appear broad enough to include incidental or unintentional additions of PFAS into products as well as intentional ones.

Socio-Economic Analysis and Proportionality of Restrictions

After cataloguing 14 sectors of the EU economy with the largest uses and emissions of PFAS,¹⁸ the Dossier evaluates potential socio-economic effects of the proposed restrictions, including the overall public health costs from PFAS exposure in Europe, the potential for economic costs on stakeholders from the proposed ban (e.g., from the future unavailability of certain products), and the costs of regulation and enforcement for public authorities. The Dossier finds that the Restriction Option 1 has the potential to be proportionate in the medium- and long-term on the basis that societal costs associated with continued PFAS emissions without a ban under a baseline scenario would continue to increase and eventually outweigh societal costs of the stricter restriction option.¹⁹ Separately, the Dossier finds that Restriction Option 2 more appropriately balances short-term societal costs associated with the PFAS restriction (i.e. reducing severe economic disruption to society in the short-term compared to Restriction Option 1 and affording necessary time for development of

alternatives), with more long-term societal costs of continued PFAS emissions shifting the impacts of continued PFAS use on human health and the environment to future generations.²⁰ The Dossier ultimately concludes that the benefits of a total ban or a ban with limited restrictions would be proportional to the costs of regulation.²¹

Restriction Phase-In Periods of 5 or 12 Years

While Restriction Option 1 fails to provide derogations for any group or subset of PFAS users, the Dossier does provide information regarding potential derogations that could exist under Restriction Option 2. In particular, the Dossier notes that economic impacts from the general ban, including costs imposed through the need for businesses to transition to alternative chemistries, costs to consumers as a result of product price changes, welfare or quality losses, loss of surplus stock, job losses, and other factors, are to be considered in determining whether time-limited derogations are appropriate in each particular sector. Time-limited derogations of either five or 12 years (after the end of the 18-month transition period ends) are proposed for many groups of uses based on the strength of evidence that a ban would cause economic losses within the given sector. For instance, food contact materials for industrial and professional food and feed production are granted a five-year derogation, while certain implantable medical devices are granted a longer 12-year derogation due to the potential for public health complications and the lack of available alternative products.²² A small subset of PFAS (mainly in HVACR refrigerants required by national safety or health standards) are provided a time-unlimited derogation from restriction. Finally, the Dossier submitters identified several PFAS uses with weak evidence supporting derogation and for which additional information may be needed.²³

Also under Regulatory Outcome 2, manufacturers and importers of PFAS-containing articles and formulators of PFAS mixtures that wish to take advantage of derogations would be required to submit annual reports clarifying the basis of their derogations and identifying types and quantities of PFAS placed on the market in the previous year. Importers and downstream users of derogated substances would be required to prepare site-specific management plans detailing the identity of the substances and products they are used in, provide justification for the continued use of PFAS, and provide details on the conditions of use and safe disposal practices.

Industry Challenges and Next Steps

The proposed EU regulations provide for sweeping restrictions relevant to manufacturers, distributors and end users in the EU and beyond, including for those with known or potential involvement with PFAS. Products containing PFAS may need to be reformulated or discontinued where replacement substances are unavailable. The American Chemistry Council has indicated that it will challenge to the proposal, including arguing that the proposal's broad approach disregards individual chemistries' unique properties and uses, including the role of PFAS in reducing climate change emissions due to the use of PFAS in low-carbon energy technologies. Notably, the REACH regulatory framework provides a lengthy formal review process before PFAS can be formally added to the REACH list of restricted substances in Annex XVII and the proposed restriction thus become binding law. Next steps for the proposal include a review of the Dossier by ECHA's scientific committees for Risk Assessment and Socio-Economic Analysis beginning in March 2023, an online information session scheduled for April 5, 2023, and a six-month period of open consultation with the public planned to start on March 22, 2023.²⁴ After that, ECHA's committees will form opinions regarding whether the proposed restriction is appropriate to reduce health and environmental risks and on socio-economic impacts. Once the opinions are adopted, the opinions and proposed restriction would be subject to review by the European Commission and the EU member states, who then will make a final decision regarding the inclusion of the restriction in Annex XVII.²⁵

1. A copy of the original announcement can be found here: ECHA, [ECHA receives PFASs restriction proposal from five national authorities](https://echa.europa.eu/-/echa-receives-pfass-restriction-proposal-from-five-national-authorities), available at <https://echa.europa.eu/-/echa-receives-pfass-restriction-proposal-from-five-national-authorities>. Pursuant to REACH, EU member states or the European Chemicals Agency shall prepare an Annex XV dossier to propose a restriction of the manufacturing, marketing and use of substances within the EU where it considers the substance to pose a risk that is not adequately controlled. See [REACH, Article 69\(4\)](#). After evaluation by the European Commission in accordance with REACH, adopted restrictions are added to Annex XVII of REACH and become part of the REACH regulation. See ECHA, [Guidance for the preparation of an Annex XV dossier for restrictions](https://echa.europa.eu/documents/10162/2324906/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6), available at https://echa.europa.eu/documents/10162/2324906/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6. Similar processes have been used to restrict intentionally added microplastics and perfluorooctanoic acid and its salts and related substances. ↩

2. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea), available at <https://echa.europa.eu/documents/10162/f605d4b5-7c17-7414-8823-b49b9fd43aea>. ↩

3. For general information regarding the presence and risks of PFAS, see EPA, [Per- and Polyfluoroalkyl Substances \(PFAS\)](https://www.epa.gov/pfas), available at <https://www.epa.gov/pfas>, and U.S. Food and Drug Administration, [PFAS](https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas), available at <https://www.fda.gov/food/environmental-contaminants-food/and-polyfluoroalkyl-substances-pfas>. ↩

4. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), page 22. ↩

5. The Dossier states that the expected mean PFAS tonnage in the EEA is 49 million tonnes, leading to emissions of about 4.4 million tonnes during the manufacture and use phase when no action is taken. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), page 2. ↩

6. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), page 75. The ban would apply to concentration limits in mixtures and articles above 25 parts per billion of any PFAS (based on targeted analysis), 250 parts per billion of any combination of PFAS substances (either based on targeted analysis of a sample, or after chemical degradation of a sample), and 50 parts per million of PFAS (inclusive of polymeric PFAS). The third standard applies where the first two standards are not applicable (e.g., for fluoropolymers). Exceedance of this standard may require additional analysis. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), page 9. ↩

7. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), page 75. ↩

8. Subject to limited exceptions, the proposal would generally restrict “[a]ny substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it).” Fully degradable PFAS subgroups are excluded from the scope of the proposed restriction. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), page 2. ↩

9. After initially proposing a similar open-ended definition for this upcoming regulation, see EPA, [Proposed Rule Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances](#), available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0001>, the U.S. EPA later received comments from industry regarding the complexity of applying such a rule, and indicated it would alter the rule to incorporate a finite list of known PFAS. See EPA, [Initial Regulatory Flexibility Analysis and Updated Economic Analysis for TSCA Section 8\(a\)\(7\) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances](#), available at https://www.epa.gov/system/files/documents/2022-11/2070-AK67_TSCA%208a7%20IRFA_11-25-22%20clean.pdf. ↩

10. See EPA, [Proposed Rule, Significant New Use Rule: Per- and Poly-fluoroalkyl Chemical Substances Designated as Inactive on the TSCA Inventory](#), available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0867-0001>. ↩

11. See EPA, [Proposed Rule, Changes to Reporting Requirements: Per- and Polyfluoroalkyl Substances and to Supplier Notifications for Chemicals of Special Concern; Community Right-to-Know Toxic Chemical Release Reporting](#), available at <https://www.regulations.gov/document/EPA-HQ-TRI-2022-0270-0001>. ↩

12. See EPA, [Proposed Rule, Comprehensive Environmental Response, Compensation, and Liability Act Hazardous Substances: Designation of Perfluorooctanoic Acid and Perfluorooctanesulfonic Acid](#), available at

<https://www.regulations.gov/document/EPA-HQ-OLEM-2019-0341-0001>. ↵

13. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), page 21. ↵

14. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), page 2. ↵

15. See [New York Environmental Conservation Chapter 43-B, Article 37, Title 2, Section 37-0209](#). ↵

16. See [California Assembly Bill No. 1200](#), available at

https://leginfo.ca.gov/faces/billCompareClient.xhtml?bill_id=20210220AB1200. ↵

17. See [Public Law c. 477, An Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution](#). ↵

18. The Dossier lists the following sectors: Textile, upholstery, leather, apparel and carpets (TULAC); food contact materials and packaging; metal plating and manufacture of metal products; consumer mixtures; cosmetics; ski wax; applications of fluorinated gases; medical devices; transport; electrics and semiconductors; energy sector; construction products; lubricants; and petroleum and mining. ↵

19. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), page 168. ↵

20. *Id.* ↵

21. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), page 3. ↵

22. Five-year derogations also cover textiles for use in filtration and separation media used in high performance air and liquid applications in industrial or professional settings that require a combination of water- and oil repellence, refrigerants in low temperature refrigeration below -50°C, insulating gases in high-voltage switchgear (above 145kV), refrigerants in mobile air conditioning-systems in combustion engine vehicles with mechanical compressors, and proton-exchange membrane fuel cells, among others. Twelve-year derogations cover certain personal protective equipment and related impregnation agents, refrigerants in laboratory test and measurement equipment, certain implantable medical devices, diagnostic laboratory testing, and lubricants where the use takes place under harsh conditions or use is for safe functioning and safety of equipment, among others. See ECHA, [Annex XV Restriction Report: Proposal for a Restriction](#), pages 151-167. ↵

23. These include hard chrome plating, foam blowing agents in expanding spray foam building insulation, industrial and professional solvent-based debinding systems in 3D printing, and others. ↵

24. See ECHA, [Guidance for the preparation of an Annex XV dossier for restrictions](#); see also ECHA, [ECHA publishes PFAS restriction proposal](#). ↵

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Suggested Reading

- 13 September 2022 Kirkland Alert EPA Makes the Next Move in Increasing Regulation of Certain Broadly Used Man-Made PFAS Chemicals Under CERCLA
- 25 October 2021 Kirkland Alert Biden Administration Announces Plans to Regulate “Forever Chemicals”
- 21 August 2020 Energy Blog Managing PFAS Liability Risk

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