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PFAS Update: Scrapping Prior Broader Proposal, EU Publishes Updated Narrower Proposal to Restrict the Manufacture, Use and Marketing of PFAS Chemicals

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In 2023, the European Chemicals Agency (ECHA) proposed broad restrictions on the manufacture, import and use of all per- and polyfluoroalkyl substances (PFAS). After review of over 5,600 comments from stakeholders in response to its 2023 proposal, ECHA recently released an updated proposal under the EU's chemical regulation. While the original 2023 proposal included two potential regulatory approaches (both generally involving broad PFAS bans subject to a short phase-in period or time-limited exemptions for certain uses), the updated proposal introduces a third potential avenue that would allow for the continued manufacture, import and use of certain PFAS under conditions where the associated risks are considered to be controlled. In addition, the new proposal provides separate treatment for certain PFAS chemicals known as fluoropolymers. As discussed in our prior *Alert*, the initial proposal to restrict PFAS in the EU (the dossier) was submitted in January 2023 through 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) by authorities in Denmark, Germany, the Netherlands, Norway and Sweden. Since January 2023, the initial proposal has been subject to a six-month public consultation period and is currently undergoing a scientific review process.

The five European authorities who authored the 2023 proposal, collectively referred to as the dossier submitter, evaluated the extensive public feedback and updated the PFAS restrictions proposal. On August 20, 2025, the dossier submitter published their joint evaluation, and shortly afterwards, on August 27, ECHA published an updated timeline for its scientific evaluation of the proposed restrictions.

This *Alert* summarizes the updates to the dossier (including a new alternative that may allow for the continued use of certain PFAS under controlled conditions), discusses the potential implications of the updated proposal and previews ECHA's next steps prior to implementation.

Initial Broader Proposal and Response

The 2023 dossier proposed two alternative regulatory schemes to achieve its goal of reducing the emission of PFAS to the environment by restricting the manufacture, use, import and marketing of PFAS above certain threshold levels. The first regulatory approach, called Restriction Option 1 (RO1), would implement a total ban on PFAS above a threshold level after an 18-month transition period. The proposal included three different threshold levels of PFAS concentration based on different analytical methods: (1) 25 parts per billion for individual PFAS using a targeted analysis; (2) 250 parts per billion for the sum of PFAS using a targeted analysis either analyzed directly as a sample or after chemical degradation of the sample material; and (3) 50 parts per million when a targeted analysis is not applicable, as in the case of fluoropolymers.

The second regulatory approach, called Restriction Option 2 (RO2), would implement a similar ban and transition period while allowing for time-limited exemptions, called "derogations," for certain categories of PFAS use. Derogations of either five or 12 years were proposed to begin after the initial transition period of 18 months for different sectors depending on the availability of alternatives to PFAS in the relevant sectors.

The six-month public consultation period for the dossier opened in March 2023 and ended in September 2023. During that time, ECHA received over 5,600 comments from more than 4,400 organizations, companies and individuals. The comments generally addressed specific sectors, including electronics and semiconductors, transport, energy, and medical devices. Nearly 70% of comments were submitted by companies and industry or trade associations, with the remainder comprising individuals, academia, national authorities, international organizations, nongovernmental organizations, regional or local authorities, and other stakeholders. The country with the highest number of constituent comments was Sweden (which ECHA notes was in part due to individual comments submitted as part of a national campaign), followed by Germany, Japan, Belgium, China, Italy, the U.S., France, the UK and the Netherlands.

Stakeholder comments covered a range of topics, notably including fluoropolymers. Industry groups pushed back on restrictions targeting fluoropolymers, calling for a

differentiation between fluoropolymers and other PFAS based on their relatively less significant environmental and human health impacts and highlighting the critical application of fluoropolymers for use in energy technologies, including batteries, fuel cells, wind turbines and solar photovoltaics. Comments also covered specific recommendations for revisions to the mechanisms of the restriction, as well as more general concerns regarding the economic impacts of the proposal. For example, several commenters suggested the inclusion of "review clauses" that would require derogations to be reviewed prior to their expiration, particularly for applications of PFAS for which suitable alternatives do not exist, including batteries, semiconductor manufacturing and certain fluorinated gas applications. Additionally, stakeholders raised concerns about impacts on trade and competitiveness, including concerns about increased costs, reduced product performance and shorter product lifespan, which could make it challenging for European Economic Area companies to compete on the global market. Comments also addressed the impacts of a PFAS restriction on the supply chain, product- and process-oriented research and development, and scientific research and development.

Public comments were then evaluated by two groups: (1) ECHA's scientific committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) and (2) the national authorities from the five countries who submitted the original proposal.

Based on the evidence received via the consultation, the dossier submitter updated the initial proposal. On August 20, 2025, ECHA published the updated proposal, which is called the background document.

Updated Narrower Proposal

More Flexibility for Restriction Options

Under the updated proposal, the basic premise of the regulation remains the same — all PFAS captured in the dossier's definition are restricted unless there is a specific exemption or derogation that applies. However, in addition to RO1 and RO2 included in the original dossier, the background document expands the potential regulatory framework to include a new Restriction Option 3 (RO3). The dossier submitter outlines that RO3 would involve conditions allowing for the continued manufacture, sale, placing on the market or use of PFAS where risks can be controlled. RO3 thereby represents a sector-specific, risk-based approach in comparison to an outright ban.

However, the dossier submitter only assessed RO3 for PFAS specific sectors, including manufacturing, transport, electronics and semi-conductors, energy, sealing applications, machinery applications, and technical textiles — namely, many of the sectors or applications not included or treated differently in the official proposal. According to the dossier submitter, RO3 is deemed to be "proportionate" (i.e., balanced and not excessive in relation to the regulatory objective) for electronics and semiconductors, likely proportionate for energy, manufacturing, and technical textiles, but not sufficiently effective for the other considered applications. Proportionality is legally significant as, according to the European Parliament, infringing on any rule of law relating to the application of the EU treaties, such as the principle of proportionality, can serve as the basis for a challenge to a final regulation.

Scope of "PFAS" and Separate Treatment of Fluoropolymers

The background document maintains the same chemical scope of the initial restriction proposal, defining PFAS as any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it). The focus of the restriction is proven highly persistent forms of PFAS. All forms of PFAS included in the proposal have strong bioaccumulation, mobility and long-range transport potential. Notoriously, longer-chain forms of PFAS, including PFOA and its salts, are believed to cause reproductive, developmental and immunological effects in animals. Accordingly, fully degradable subgroups are excluded from the scope of the proposal.

While the definition of PFAS remains the same, the background document proposes new derogations for the manufacture, import and downstream use of fluoropolymers — such as wires and cables, insulation material of electronic components, and separator coatings for batteries — provided operations are under controlled conditions consistent with the initial restriction proposal. Such uses would be subject to a site-specific management plan outlining the identity of the substances, products containing the substances, a justification of the use, and details on the conditions of use and safe disposal, which must be updated annually and maintained for regulatory inspection upon request. This approach appears responsive to comments regarding the original dossier's indiscriminate restriction of fluoropolymers, which are a polymeric form of PFAS generally considered non-toxic in solid form, less likely to bioaccumulate and not soluble in water (i.e., such that they are easier to separate and extract from water as compared to other forms of non-polymeric PFAS); these materials find broad use in energy technologies, plastics, medical devices and many other sectors. The background document further expands the scope of exemptions via

derogations from the ban, reflecting the recognition of sector-specific concerns. Additionally, the document references a requirement to justify the use of PFAS by proving that there remain no suitable alternatives in a specific use during an applicable derogation period.

The proposed restriction outlined in the background document prohibits the manufacture, use or placement on the market of PFAS as substances, mixtures or in articles above specified concentrations (described above).

Additional Sectors Considered

The updated restriction proposal also goes beyond the originally contemplated applications/uses of PFAS in at least one respect. The dossier submitter identified and carried out assessments for eight sectors not included in the official proposal: printing applications, sealing applications, military applications, technical textiles, other medical applications, explosives and broader industrial uses. However, in its note published on August 27, 2025, ECHA announced that these additional eight sectors introduced by the background document will not undergo a sector-specific evaluation as was applied to the 14 sectors in the initial proposal. This change is meant to avoid delays during the scientific review process, which ECHA states would require significant time beyond 2026. While those additional sectors will not be specifically analyzed, the ECHA announcement notes that the evaluation of "horizontal issues" (i.e., general cross-cutting aspects of the opinion, such as hazard assessment, risk of alternatives and enforcement) will cover topics that are generally applicable to the monitoring and limitation of emissions of PFAS from all sectors.

Market Implications for Regulated Industry Groups

The proposed EU PFAS regulations provide for sweeping restrictions that could impact manufacturers, distributors and consumers in the EU and beyond. The background document analyzes the potential economic impacts of RO1 (a total ban) and RO2 (derogations). RO3 (the alternative proposal) is still under review, so ECHA has not yet released an evaluation of the economic impacts of that proposal. However, ECHA includes an updated evaluation of the economic impacts associated with RO1 and RO2 in its recent update. While RO3 is more lenient than ROs 1 and 2, the cost analysis for ROs 1 and 2 is a useful baseline for assessing the possible impact of PFAS regulation in the EU.

According to the dossier submitter, the costs associated with any restriction option include producer surpluses of directly affected companies, as well as companies in the upstream supply chain, consumer surplus losses as a result of changing product prices and other costs associated with a change in the characteristics of goods that contain PFAS. The types of costs incurred by affected companies will turn on each company's response to the regulation, which will in turn depend on a variety of factors, including the availability and feasibility of adopting PFAS alternatives. A company that can substitute PFAS in its products or operations may face research and development costs, capital costs required to purchase or install new equipment, or operating costs such as changes in raw material expenditures. Alternatively, some companies may be forced to cease product production altogether and face costs associated with dismantling plants. If many companies are forced to stop production as a result of any restriction option, the whole EU market could be impacted.

As discussed, the fluoropolymer industry is one of the many that will be impacted by a PFAS restriction. According to Plastics Europe's Fluoropolymers Product Group (FPG), fluoropolymers are used in a broad range of applications and alternatives are not able to display the same characteristics that make fluoropolymers useful, such as heat resistance. The trade group states that any restriction forcing companies to adopt alternatives to fluoropolymers could result in the regression of advanced technologies and challenges to Europe's ability to secure investment in high- and medium technology manufacturing. According to the FPG, the consequences could include efficiency losses, higher capital costs, higher maintenance costs and lower product quality.

The dossier submitter noted that some regulated industry groups will be more affected than others because of cumulative impacts, including multiple uses or products incorporating PFAS, and identified two situations where cumulative impacts are particularly concerning. The first situation involves a company or sector that uses different PFASs across a range of products that are then used downstream in multiple sectors and for multiple uses. The second situation involves a company or sector that uses multiple PFAS simultaneously for multiple applications to the same complex product or multiple complex products. For example, 15% to 20% of the 5,000 to 7,000 components in an automotive vehicle would be affected by a restriction of PFAS. The dossier submitter has requested that cumulative impacts are taken into consideration when the 12-year derogations are reviewed.

The background document features a sector-by-sector evaluation of the economic impacts of RO1 and RO2, discussing the impacts of both a five-year and 12-year derogation period for each sector. The background document analysis builds on the

dossier submitter's initial proposal, which includes a similar analysis, by assessing the economic impacts of a PFAS restriction for the eight sectors that were not named in the original proposal.

The full list of analyzed sectors includes: (1) Textiles, Upholstery, Leather, Apparel and Carpets; (2) Food contact materials and packaging; (3) Metal plating and manufacture of metal products; (4) Consumer mixtures, including cleaners, dishwashing products and strings for musical instruments; (5) Cosmetics; (6) Ski wax; (7) Applications of fluorinated gases, including refrigeration and heat pump systems; (8) Medical devices; (9) Transport; (10) Electronics and semiconductors; (11) Energy; (12) Construction productions; (13) Lubricants; (14) Petroleum and mining; (15) Printing applications; (16) Sealing applications; (17) Machinery applications; (18) Other medical applications; (19) Military applications; (20) Explosives; and (21) Technical textiles. Based on the dossier submitter's full socioeconomic analysis, it considers RO2 and RO3 to be enforceable, implementable and manageable. The analysis states that the new RO3 alternatives are proportionate for electronics and semiconductors and likely to be proportionate for energy, manufacturing, and textiles, but likely not effective for transport, sealing applications and machinery applications.

Update on Process/Timing

The REACH regulatory framework provides a lengthy formal review process before PFAS can be formally added to the REACH list of restricted substances and the proposed restriction can become binding law. At this point, ECHA committees are continuing to assess the dossier. ECHA's RAC and SEAC are carrying out their assessments in batches, focusing on the 14 different sectors, plus PFAS manufacturing and horizontal issues. Both committees plan to conclude their discussions in early 2026. RAC will provide an opinion on whether the suggested restriction is appropriate in reducing the risk to human health or the environment based on the dossier and comments received during the consultation period. RAC's final and SEAC's draft opinions will be published on ECHA's website, with stakeholders given 60 days to submit comments on SEAC's draft. The SEAC must consider feedback from industry, NGOs and member states, and amendments to the scope or derogations are still possible.

ECHA has signaled a firm objective to deliver the final RAC and SEAC opinions to the European Commission and EU Member States for consideration in 2026. On September 15, 2025, ECHA announced that the agency plans to launch a consultation on SEAC's draft opinion on the proposed restriction after the committee's meeting in March 2026.

The consultation period will be open for 60 days, allowing stakeholders to provide feedback. On September 24, 2025, ECHA reaffirmed in an announcement that the committees plan to come to an agreement concerning SEAC's draft opinion after the March 2026 meeting. After reviewing consultation feedback, SEAC is expected to adopt its final opinion by the end of 2026. The final opinion will include ECHA's committees' scientific evaluation of the proposed restriction. Within three months of receiving the assessment, the European Commission will draft an amendment to the list of restrictions in Annex XVII to REACH. After publication of the final RAC and SEAC opinions, the final decision will be made through the European Union's comitology procedure, which involves scrutiny by member states and the European Parliament.

If the restriction is adopted, it will be binding on all member states, and member states will be responsible for enforcing the restriction. However, once finalized, an action for annulment may be brought before the European Court of Justice to challenge the restriction.

Entry Into Force

The background document includes a general transition period of 18 months from the restriction's entry into force for RO1 and RO2. The 18-month transition period is targeted at uses where alternatives are expected to be viable in the short term (i.e., where substitution potential is high). A derogation of 13.5 years is generally proposed when research and development efforts have yet to identify PFAS-free alternatives or where certification processes of known alternatives require more than 6.5 years. The transition period also applies in addition to any specific derogation periods (added on top of the transition period), including unlimited derogations. Many derogations are included for applications where a use-specific substitution is not yet feasible. General derogations also apply to products regardless of specific use, with time limits and labeling requirements varying on a case-by-case basis. These derogations cover a variety of applications and end uses, including PFAS manufacturing for exempted uses or export (under strict emission limits), placing on the market of articles which were already in end-use in the EU, textile articles containing recovered materials, and research and development applications. As mentioned above, RO3 would allow continued use under strict conditions.

Conclusion

Manufacturers, distributors and end users should closely monitor updates on the restriction proposal over the next year. With scientific assessments likely to be issued no sooner than the end of 2026, it is likely that a European Commission decision will be released in 2027. The 18-month entry-into-force provision further indicates that implementation of the selected restriction option could occur as early as late 2028 or 2029.

As developments continue to unfold, Kirkland's environmental team can assist clients in addressing potential changes to compliance requirements for their businesses.

Natalie Lara and Brynn Furey also contributed to this Kirkland Alert.

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