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Client Alert

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EU Aims for Ban of PFAS. Now is the Time to Act.

Earlier this year, the European Chemicals Agency (ECHA) published a proposal for a ban on the production, use and placing on the market (including import) of at least 10,000 per- and polyfluoroalkyl substances (PFAS). Companies in the life sciences industries will be severely affected by a ban on these chemicals.

Companies should review the use and extent of PFAS in their own businesses and production processes to assess the impact of the proposed ban on their individual operations. Companies should further consider submitting comments to ECHA on the proposed PFAS ban to convey its significant impact on the supply of medicines, medical devices, and foodstuffs to the public. Stakeholders from both within and outside the European Union (EU) are invited to submit comments on the proposed PFAS ban until September 25, 2023.

IMPACTS JUST ABOUT EVERYONE

The proposed ban affects almost every company in the life sciences, food, and many other industries. PFAS are used in a variety of applications because they have a grease-, dirt- and water-repellent effect. As such, they are used as ingredients in pharmaceuticals and medical products, found in foods, used in research and product development, used in packaging material, and found in production lines in the form of coatings for seals, hoses, filters, membranes, and other components.

In many cases, alternatives to PFAS are currently unavailable, and eliminating these substances would have a major impact on the manufacturing and distribution of the products at issue. Recertification and application for new authorizations may become necessary under the PFAS ban.

A decision by the European Commission on this proposal is expected in 2025. If the PFAS restriction proposal is adopted, this would be one of the most extensive bans on chemical substances since the REACH Regulation came into force in 2007.

PROHIBITS JUST ABOUT EVERYTHING

ECHA is considering the adoption of a **full PFAS ban with a few use-specific time-limited derogations** (18-month transition period plus either a five- or 12-year derogation period) **and very few time-unlimited, more general derogations**, including for PFAS used as an active substance in human and veterinary medicinal products.

In particular, the proposed restriction not only prohibits PFAS from being manufactured, used, or placed on the market as substance on its own, but it also prohibits PFAS from being placed on the market as a component of another article, such as a medicinal product or medical device, in a concentration at or above the following:

i. 25 ppb for any PFAS;

ii. 250 ppb for the sum of PFASs (polymeric PFASs excluded); and

iii. 50 ppm for PFASs (polymeric PFASs included).

Under the proposed PFAS ban, only **active** pharmaceutical ingredients (API) in human and veterinary pharmaceuticals, biocidal products and plant protection products are exempt. The exemption applies only to APIs, not to excipients or other parts of the medicinal product, such as packaging material.

The proposed ban foresees a temporary derogation only for, amongst others:

- diagnostic laboratory testing,
- fluoropolymers and perfluoropolyethers for use in food contact materials for the purpose of industrial and professional food and feed production,
- fluoropolymers and perfluoropolyethers for use in implantable medical devices (not including meshes, wound treatment products, tubes and catheters),
- fluoropolymers and perfluoropolyethers for use in tubes and catheters in medical devices, and
- fluoropolymers and perfluoropolyethers for use in coatings of metered dose inhalers.

The derogation for these categories will last for 13.5 years after the ban takes effect, except for fluoropolymers and perfluoropolyethers for use in food contact materials, which will last for 6.5 years after the ban takes effect.

ECHA is considering additional potential temporary derogations, which would last for 13.5 years after the ban takes effect, for, amongst others:

- engineered fluids for medical devices,
- membranes used for venting of medical devices,
- fluoropolymers and perfluoropolyethers for use in hernia meshes,
- fluoropolymers and perfluoropolyethers for use in wound treatment products,
- fluoropolymers and perfluoropolyethers for use in coating applications for medical devices other than metered dose inhalers,
- fluoropolymers and perfluoropolyethers for use in rigid gas permeable contact lenses and ophthalmic lenses,
- fluoropolymers and perfluoropolyethers for use in PCTFE-based packaging for medicinal preparations, medical devices, and medical molecular diagnostics,
- fluoropolymers and perfluoropolyethers for use in PTFE in ophthalmic solutions, and

- fluoropolymers and perfluoropolyethers for use in packaging or terminally sterilized medical devices.

For these potential temporary derogations, ECHA requires additional evidence to be able to include the derogations in the final version of the proposed ban. If the evidence remains weak, then the above potential temporary derogations will not be included in the final version of the PFAS ban.

Alternatively, ECHA is considering an even more severe PFAS restriction with a full ban with no derogations and a transition period of 18 months. Although both restriction options are deemed proportionate, the adoption of a full ban with use-specific, time-limited derogations is considered the most likely option.

TAKEAWAYS: NOW IS THE TIME TO ACT

Considering the significant impact of the proposed PFAS ban on the production and distribution of medicines, medical devices, foods and other products in the EU, we encourage businesses to consider the following next steps:

1. **Raising stakeholder voices**

   March 22, 2023 marked the beginning of the official six-month consultation period, which ends on September 25, 2023. The consultation period aims to give anyone with information on PFAS the opportunity to have their say. Stakeholders can submit additional information to justify, for example, the inclusion of further exemptions in the restriction proposal. Of particular interest for ECHA is information relevant to the risks, socio-economic aspects, and alternative substances. ECHA will use the consultation input to evaluate the proposed restriction and to form a final opinion. Stakeholders from both within and outside the EU are invited to submit comments.

   We encourage firms to carefully review the proposed PFAS ban, taking note of the limited derogations and proposed potential derogations to assess the impact of the proposed ban on the business. We further encourage firms to submit comments to ECHA on the impact of the proposed PFAS ban on the supply of medicines, medical devices, and foodstuffs to the public before the comment period expires on September 25, 2023. This will ensure that ECHA hears from a wide variety of voices and addresses key issues before adopting the final PFAS ban.

2. **Preparing for use of PFAS alternatives**

   We further encourage businesses to evaluate potential alternatives and substitutes for PFAS substances. We note that regulatory authorities and Notified Bodies would need to evaluate any alternative materials used in the production and distribution of medical devices, medicinal products, and certain other products. Given the length of the drug approval and medical device certification procedures, and the already heavy workload of Notified Bodies, the proposed ban's implementation timelines may be difficult and/or unreasonable.

King & Spalding's team of life sciences lawyers can advise stakeholders on how best to address the legal issues involved in a proposed PFAS ban.

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