SPECTARIS e. V.
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Position Paper

Position Paper on the universal PFAS restriction proposal in Europe

“How to avoid an unintended high-tech ban”

» An unintended high-tech ban is on the horizon

In January 2023, authorities responsible for REACH in Germany, the Netherlands, Denmark, Sweden and Norway submitted a proposed restriction of around 10.000 per- and polyfluoroalkyl substances (PFAS) to the European Chemicals Agency (ECHA) and thus gave way for a restriction procedure under REACH. The reasoning being that some PFAS accumulate in the environment and in organisms and are also harmful to health. They are often referred to as "forever chemicals". Fluorochemicals are exclusively produced artificially. According to the dossier submitted to ECHA, around 300,000 tons of these industrial chemicals are produced and processed each year in the EU alone. PFAS have outstanding technical properties: Among other things, they are resistant to temperature, pressure, corrosion and radiation, are inert and flexible and have therefore been tried and tested chemicals for a long time. High performance materials containing PFAS are politically doomed for exactly the technical property for which they are needed and predominantly irreplaceable: their durability and resistance even in essential applications, industrial high-tech products and production processes. Large areas of analysis, biotechnology and laboratory technology, optics, photonics and medical technology are directly threatened by the PFAS ban. This would not only affect the products themselves, but also the production processes required to manufacture them.

The industry is to be granted staggered transitional periods of 18 months to a maximum of 13.5 years - depending on whether alternatives to PFAS already exist, whether they still need to be developed or whether lengthy approval procedures or certifications are required. Any alternative would have to have the same properties as the banned substances, i.e. be extremely resistant and legally permitted for its applications. SPECTARIS, as a representative of various high-tech industries in Germany, is therefore very concerned about the proposal for a universal PFAS restriction in Europe. In order to avert potential damage to the entire high-tech sector, the industry urgently needs clear signals and measures from political decision-makers to restore planning certainty and to pursue a fundamentally different approach. We believe that the current approach, characterized by far-reaching bans and limited exemptions, is not practicable and requires an immediate reassessment.

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» **Effects of a PFAS ban using the example of the medical technology industry:**
PFAS are often used in medical devices due to their durability and resistance on and in the human body. Medical devices such as incubators for newborns, heart-lung machines or implants such as pacemakers, stents or joints, but also products with blood contact or packaging for medical devices placed on the market under sterile conditions can no longer be manufactured and used following a blanket ban on the PFAS substance group.

Endoscopy and minimally invasive surgery are also important areas of diagnostic and interventional medicine. Fluoropolymers or fluoroelastomers from the large PFAS group are predominantly used there. Only due to these materials this medical field has become as successful as it is today. Gall bladder, appendix, hernia, uterus or prostate, to name just a few examples, could no longer be treated minimally invasively using endoscopic surgery without PFAS. There are no suitable replacement materials. As a result, such medical devices will disappear from the market and patients will have to undergo maximally invasive surgery through the opening of the abdominal cavity, as was the case in the last century.

Medical technology is just one example. No aircraft, no car, no lithium or fuel cell can function without these high-performance materials, and no semiconductor chip can be manufactured without PFAS; the green transformation is dependent on these high-performance materials. Central European projects such as the Green Deal or the EU Chips Act are inconceivable without PFAS.

» **SPECTARIS Key Asks:**

1. **Return to Risk-Based Approach:**
   - We advocate for a return to a risk-based approach in line with the existing REACH Regulation. The current proposal goes beyond reasonable measures and raises legal uncertainties. Persistence alone does not constitute a risk.
2. **Exemptions for Fluoropolymers:**
   - Fluoropolymers, such as Teflon (PTFE), classified as "Polymers of Low Concern" by the OECD, should be exempted. Unlike PFOS and PFOA, these fluoropolymers have distinct risk profiles and do not accumulate in groundwater or the human body. Pursuing a risk-based approach inevitably means defining substance-specific exemptions and not just product- or application-specific ones.
3. **Broad Exemptions Considering Supply Chains:**
   - The proposed product-specific exemptions with predefined transition periods overlook crucial aspects of production facilities, supply chains, and spare parts availability. We urge for broader exemptions that consider these complexities. In addition, an obligation to provide information on PFAS in the supply chain is initially an important prerequisite for being able to identify relevant PFAS applications and the associated risks in the complex supply chains in the first place.
4. **Ensuring Practicality:**
   - The current proposal risks over-bureaucratization, leading to regulatory ambiguities and enforcement challenges. A clear framework for exemptions and robust enforcement mechanisms are essential for practical implementation. Effective enforceability is not considered or addressed at all in the current restriction proposal. Market surveillance and customs would be faced with a gigantic and unsolvable task of checking small-scale product exemptions and proving the non-existence of PFAS in low concentrations. As the selected group of substances is extremely large and is only defined by its molecular structure, it is often not even clear what exactly to look for.
5. **Feasible Transition Periods:**
   - Transition periods should only be implemented once viable substitution options are actually available. However, in many industrial sectors, like for example medical technology, alternatives are not

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foreseeable, in particular with regard to fluoropolymers. Transition periods are useless, if there are no viable alternatives available to work on a transition.

6. **Focus on Emission Control and Waste Management:**
   - Manufacturers of fluoropolymers must assume environmental responsibility, including adhering to stringent emission limits. Some fluoropolymer manufacturers are aware of their responsibility for the environment and have already signed a voluntary commitment and taken steps to comply with strict emission limits. Efforts towards emission control and responsible waste disposal should be encouraged.

» **Additional Points:**

- The distinction between fluoropolymers and other PFAS compounds is vital. Fluoropolymers have demonstrated long-term safety in medical applications.
- The proposed "differentiated approach" obscures the impracticality of hundreds of product-specific exemptions and transition periods.
- Alternative approaches in regions like the USA and UK demonstrate more balanced and risk-based strategies.
- The Gendorf Chemical Triangle is crucial for Europe's industrial ecosystem. Political support is urgently needed to prevent adverse impacts from Dyneon's closure in 2025. After all, this plant alone supplies 40% of the fluoropolymers required in Europe. Dyneon is even the only European producer of some of the specialty materials required by the semiconductor industry.

» **Conclusion:**

A blanket ban on PFAS makes the use of indispensable high-performance materials impossible in many cases and massively jeopardizes technological sovereignty and security of supply in the EU. Therefore, SPECTARIS urges policymakers to reconsider the universal PFAS restriction proposal in Europe. We emphasize the **need for a balanced, risk-based approach** that safeguards both public health and industrial interests. High-level political support is essential to address these concerns effectively. A wait-and-see approach along the lines of the official procedure that has been adopted is already causing massive planning uncertainty in the short term and encouraging a creeping exodus of important European high-tech industries. We therefore need political engagement in the process and clear, rapid signals from political decision-makers now, even if not part of the current process.

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