

Xylem is a downstream user of PFASs and a global provider of high technology products and systems designed to effectively meet the demands and challenges of treating water and wastewater and of premium field, portable, online and laboratory analytical instrumentation serving water, wastewater, ocean/coastal, food & beverage, environmental, chemical and pharmaceutical markets. Xylem recognizes the concerns raised by the Dossier Submitters on the safe use of some PFAS and is aware of the increased scrutiny on PFAS substances in line with the EU's chemical strategy for sustainability and goals of the Green Deal for a toxic-free environment.

Per- and polyfluoroalkyl substances (PFASs) are a broad class of different, but structurally related, chemical substances that have diverse and special properties. For instance, fluoropolymers, a sub-group within the large PFAS family, are high molecular weight polymers that have, not only specific toxicological and environmental profiles but also unique physicochemical properties. These properties have led to fluoropolymers, being used in applications where they enable high levels of product performance.

In 2020, the European Commission published the Chemical Strategy for Sustainability (CSS)¹ and announced an intention to ban non-essential uses of PFASs in the EU. In 2023, five European Countries² proposed a far-reaching ban on the entire PFAS class across industrial, professional and consumer uses and/or subsequent article service life under the EU REACH regulation. This proposal is known as the 'universal' PFAS restriction³. To avoid significant (i.e., disproportionate) negative impacts on EU society, the proposed PFAS restriction acknowledges that it will be necessary to continue to use PFASs in specific (derogated) uses, at least for the time needed until safer alternative substances or technologies become available.

Under REACH, a restriction is any measure on the manufacture, placing on the market or use of a substance (on its own, in a mixture or in an article) used to address an 'unacceptable' risk. REACH restrictions, therefore, are not limited to bans but can comprise, for example, requirements for use of risk management measures, training or certification. Before a restriction can be implemented, the European Commission and the EU member states must have concluded that it is the most appropriate way to address the identified risk. To inform this decision, restriction proposals (also called Annex XV restriction reports) should include a comprehensive restriction and regulatory management option analysis (RMOA).

The European Chemicals Agency (ECHA) is currently considering the Annex XIV report for the universal PFAS restriction, including the restriction and regulatory management option analysis performed. Specifically, ECHA's scientific committees for risk assessment (RAC) and socio-economic analysis (SEAC) are developing 'opinions' on the proposal for the European Commission, who will then decide on whether to implement the proposal after discussions with EU member states. The RAC and SEAC opinions will be informed by the public consultation on the proposal, which is open until the 25th of September 2023. The RAC and SEAC opinions are expected in 2024.

Xylem, as an expert stakeholder on the applications of PFASs in water, wastewater and analytical technologies for industrial and professional uses, intends to engage constructively in the public consultation on the proposal and would like to take this opportunity to inform ECHA that it is currently developing a detailed response to the public consultation with the aim of facilitating better, more proportionate, regulation of PFASs. Xylem will provide a more detailed submission in September and through this initial submission, Xylem will outline the approach it will take to contribute to the public consultation.

Xylem has over 30 specific brand companies that specialize in water products and services that move, treat, analyze, monitor and return water to the environment, in public utility, industrial, residential and commercial building services settings. Xylem's products cover every aspect of water, from pumping, piping, measuring, analyzing, cleaning, and pipe inspections. Fluoropolymers are used in these applications to provide essential functionality such as chemical and thermal resistance, elasticity, abrasion resistance, dirt- and hydrophobic functions, as well as excellent electrical resistance.

Xylem considers that because the Annex XV report does not assess a complete range of potential restriction or regulatory management options (it only assesses the appropriateness of a ban), it has **not been clearly demonstrated that the proposed restriction is the most appropriate means to regulate the potential risks of PFASs**. Specifically, the Annex XV report should include a comprehensive comparative restriction and regulatory management option analysis based on the criteria given in Annex XV of REACH of effectiveness, practicality and monitorability.

As currently proposed, a ban on all PFASs will have significant negative impacts on the water and wastewater industry and, as a result, European society. The impacts of a ban on many critical uses in the water and wastewater industry, as outlined above, have not yet been identified and assessed in the Annex XV report. This is a significant limitation of the Annex XV report and is not consistent with evidence-based decision-making and the principle of better regulation.

For example, Xylem's ultraviolet (UV) and ozone systems are used to sterilize and disinfect contaminated water to independently verified drinking water standards, internationally recognized certification and regulatory processes- and meet World Health Organization (WHO) standards and European (Drinking Water Directive) legislation. PFAS polymers are used in UV disinfection and ozone oxidation systems in articles such as seals and connectors to hold parts in place or provide low friction and anticorrosion properties. No viable alternative has been identified for these uses and failure to use PFAS polymers would result in these parts disintegrating from the UV rays. A ban on PFAS would, therefore, lead to potential substitution with lesser suitable materials, lowering the water quality and subsequently causing harm to many people's health and safety.

Xylem intends to demonstrate that an alternative restriction proposal, including a derogation for the continued use of PFASs, more specifically fluoropolymers and perfluoropolyethers, in industrial and professional applications where safe use for human health and the environment are assured over their complete lifecycle) would be a more appropriate regulatory measure than a ban.

Xylem is currently undertaking assessments that will address two main aspects:

- i) whether restriction options other than a ban, for example the mandatory use of specific risk management measures that control or minimize emissions and exposures would be a more appropriate approach to regulation; allowing essential uses to continue;
- ii) under what circumstances, a ban on the use of fluoropolymers and perfluoropolyethers could be designed to ensure that critical functions (and benefits) are not lost to society.

Specifically, the assessments will explore the scope (i.e., applications) and duration of any transitional periods needed to avoid disproportionate social impacts by using information on alternatives (technical and economic feasibility) and socio-economic analysis.

Following this high-level submission, Xylem will submit a detailed submission in September 2025.

Xylem's technologies enable a zero-pollution future and is committed to contributing to evidence-based chemical policy and regulation. Xylem is confident that a coherent, regulatory approach for PFASs that ensures their safe use whilst also ensuring that critical technologies remain available can be achieved.