



STATEMENT

Brussels, 29 September 2025

Orgalim's reaction to PFAS restriction evaluation process

Need for a targeted, proportionate and differentiated approach that ensures in-depth assessment of uses in all relevant sectors

In August 2025, the European Chemicals Agency (ECHA) published an update on the ongoing PFAS restriction evaluation process under REACH. This update includes the release of a revised Background Document and timeline, which now incorporates additional sectors that were not considered in the original restriction proposal such as: sealing applications, machinery applications, other medical applications, technical textiles, and broader industrial uses.

Orgalim is fully committed to engaging constructively in the process and to supporting evidence-based, proportionate measures that effectively protect human health and the environment, while safeguarding Europe's capacity to innovate, manufacture, and deliver essential cleantech solutions.

The inclusion of additional sectors appears to be the direct result of the consultation process and a thorough evaluation by the dossier submitters of the nearly 6,000 comments received, showcasing the breadth of PFAS real-life applications across the European economy and the importance of consulting with relevant stakeholders in the process – which we support.

However, Orgalim is greatly concerned to learn that, despite their enormous significance, the additional sectors will not be subject to sector-specific evaluations by ECHA's scientific committees (RAC and SEAC) in the current process. While we understand the desire to conclude the process swiftly for the sake of regulatory predictability and to provide planning and investment certainty for industry, such a step must not exclude, or come at the expense of, rigorous, science-based assessments of all relevant evidence in all relevant applications.

A consistent and pragmatic approach is essential. Grouping thousands of PFAS substances and diverse uses under one single "horizontal" assessment raises questions about the scientific integrity and accuracy of the approach and makes it doubtful whether the resulting regulation will be workable in practice. Without sector-specific analysis, there is a risk that important technical, socio-economic, and environmental considerations could be overlooked – which could lead to partially un-evidenced, disproportionate or practically unimplementable measures.

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The decision to stop assessing individual sectors in detail indicates that the procedure is already too complex for ECHA committees to deal with it in the usual way. Therefore, Orgalim requests a targeted, differentiated approach to the PFAS restriction proposal, focusing on specific uses of PFAS where risk is not adequately controlled and which have been analysed by ECHA in depth.

The absence of a full evaluation for these additional sectors could send a strong and unintended message to the European Commission in the next steps of the process: namely, that certain uses should be seen as less relevant or as not requiring careful scrutiny. As the process continues, it is crucial to maintain confidence in a scientific, evidence-based, and proportionate REACH restriction process.

We believe that sectors and applications that have not undergone a thorough scientific evaluation as foreseen in the REACH restriction process must <u>not</u> be included in the restriction scope. In other words, the restriction should address only specific PFAS applications that have been fully evaluated. Accordingly, the eight additional sectors must undergo specific and individualised assessments by RAC and SEAC committees. before being included in the scope of the restriction.

Imposing a broad PFAS restriction without a complete scientific assessment risk overlooking important and currently irreplaceable uses of PFAS. In addition, imposing a broad PFAS ban with a large and ever-growing number of derogations ('regulation by derogation') will make implementation difficult for both industry and authorities.

In terms of the general regulatory approach, rather than pursuing a universal PFAS ban with a complex list of application-specific derogations, we need targeted restrictions that address only specific uses of PFAS. This would prevent currently irreplaceable uses from being overlooked simply because they have not yet been identified or assessed as part of the evaluation process.

We therefore call on ECHA and the European Commission to ensure that the final proposal reflects a balanced, risk-based and differentiated approach which recognises the continued relevance of PFAS uses, particularly in areas where no suitable alternatives exist to date, as outlined in the Orgalim PFAS position.

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