

A Proportionate Approach to PFAS for Life Sciences Manufacturing

LSMA Position on the Universal PFAS Restriction – October 2026

LSMA is the unified voice of companies that develop and supply the materials, consumables, equipment, and specialised services on which global pharmaceutical, biotechnology, and diagnostic production depend.

LSMA supports regulatory action on PFAS, given that such substances can pose risks to human and environmental health if used outside a controlled environment. However, LSMA's key concern is that life sciences manufacturing has not been assessed in the restriction process, creating regulatory uncertainty for PFAS uses that are essential to the production of medicines and diagnostics in Europe.

Life sciences manufacturers use small quantities of PFAS in highly controlled and regulated industrial environments, with limited potential for release into the environment. Viable alternatives are not always available and, even where they exist, substituting PFAS requires extensive revalidation and recertification, with timelines that may extend beyond the derogation periods currently under consideration. To avoid disruption to Europe's supply of medicines and diagnostics, it is therefore essential that PFAS uses in life sciences manufacturing, including the materials, equipment and upstream processes on which production depends, are specifically considered alongside uses in active pharmaceutical ingredients (APIs), medicines and diagnostics.

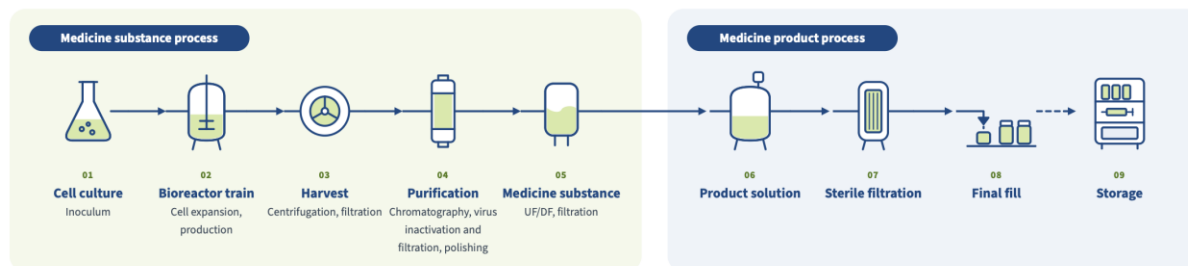
This paper therefore calls for a proportionate approach that recognises the specific risk profile and societal importance of life sciences manufacturing: a dedicated derogation covering essential uses across the full manufacturing value chain, legal certainty for scientific research and development, and a formal review mechanism to prevent disruption where qualified alternatives remain unavailable.

PFAS in life sciences manufacturing

In life sciences, PFAS are used in small quantities, in closed and controlled environments, with precise controls from production through to end of life. These are not dispersive consumer applications but professional and industrial uses, governed by Good Manufacturing Practice, with established disposal procedures such as high-temperature incineration.



The contribution of life science manufacturers to medicines production



LSMA estimates the sector accounts for less than 0.5% of the polymeric PFAS placed on the EEA market, so the environmental benefit of restricting these contained, low-volume uses would be marginal, while the cost to a critical value chain would be substantial. A full ban would impose that cost for little or no environmental gain.

For many of our applications, viable alternatives are not available, or do not yet meet the performance levels required for safe and effective use. Hence, substitution requires redesign, supplier qualification, testing, regulatory assessment, and full revalidation of the manufacturing process, a cycle that routinely runs to several years and often cannot be completed within the proposed derogation timeframes.

Forcing it prematurely would divert research and development capacity away from new medicines, diagnostics, and biomanufacturing technologies, slowing innovation in the bioeconomy and biotech sectors central to EU competitiveness at a time of intensifying competition from the United States and China.

Treating every substance within the broad PFAS definition as equivalent compounds the problem. Many fluoropolymers that our sector relies on, such as PVDF and PTFE, are already made without the small-molecule PFAS processing aids, following investment our members made years ago. Grouping these processing aids would penalise the industry and is not proportionate to the risks identified. Where persistence is the only shared property, the proportionate response is to control emissions, not to prohibit use.

A proportionate alternative exists

A full ban is not the only option. LSMA asks the Commission to recognise life sciences manufacturing as a sector warranting a dedicated derogation, or an interim derogation pending assessment, as was granted to the sectors added to the dossier in 2025.

That recognition must extend across the full value chain, so that a derogation for a finished medical or pharmaceutical use is not undermined by restricting the upstream materials and equipment needed to produce it. The current asymmetry, where the end product is protected but the manufacturing input that makes it possible is not, should be corrected, including by broadening the existing pharmaceutical and medical derogations to cover those inputs and the equipment used to monitor their quality.

LSMA also asks the Commission to provide legal certainty on the scope of the scientific research and development (SR&D) exemption, covering both substances and the equipment needed to conduct research, and to establish a formal review mechanism, with a socio-economic component, so that derogations can be extended where alternatives cannot yet be qualified, avoiding a regulatory cliff edge.



Any obligations on reporting, communication, or labelling should run through the frameworks that already govern this sector, such as CLP, the Digital Product Passport, and environmental permits, rather than as standalone PFAS requirements that duplicate existing controls and microplastics reporting. This approach, pairing targeted derogations and risk-differentiated treatment with existing controls and support for alternatives, would meet the objectives of the restriction while keeping a critical European value chain intact. This approach is consistent with the recommendations of a study requested by the European Parliament's ITRE Committee and published in December 2025.

Conclusion

LSMA shares the Commission's commitment to reducing the risks posed by PFAS and to developing alternatives as they become available. A restriction that is proportionate, science-based, and coherent with existing regulation can achieve that while safeguarding the supply of medicines and diagnostics on which European patients rely. LSMA would welcome the opportunity to provide further evidence and to engage directly with the Commission's services as the restriction is developed.

About LSMA

The Life Science Manufacturers Association (LSMA) is the trade association representing companies that develop and supply the materials, consumables, equipment, technologies, and specialised services that enable the research, development, and industrial production of medicines, vaccines, diagnostics, and advanced therapies. LSMA advocates at the EU level to ensure that life sciences manufacturers are recognised as the innovation actors and strategic enablers they are. For further information, please visit www.lsma.org.