LSMA
Position for the Public Consultation for the Biotech Act
November 2025

Introduction

The Life Science Manufacturers Association (LSMA) is a coalition of industry leaders in bioscience innovation and manufacturing. Our members supply the tools, equipment, and know-how that enable Europe's biotech and biomanufacturing ecosystem from discovery through production. We are committed to advancing and accelerating life science innovation, ensuring access to critical technologies, and empowering the biotechnology sector to deliver transformative solutions for healthcare, sustainability and the economy.

The forthcoming Biotech Act presents an opportunity to reinforce this ecosystem. By aligning regulation, incentives, and industrial strategy with the realities and needs of biomanufacturing, the Act can ensure that Europe remains a global leader in translating science into scalable innovation.

To achieve this, LSMA urges policymakers to focus on two priorities where targeted action will have the greatest impact:

- **Make regulation work for, not against, the needs of the biotech industry** by improving speed, predictability, and coherence horizontally across frameworks as well as EU and national levels to enable faster technology adoption and facility build-out. This is critical as Europe's complex regulatory landscape, while aiming for high standards, currently lags behind the speed and efficiency of systems in the US, Japan, and Canada.
- **Strengthen incentives for biotech R&D and commit to an ecosystem approach** with suppliers of key inputs recognised as essential to the research, development and large-scale production-readiness of life-saving treatments for patients in the EU.

These priorities can be addressed through:

- **Simplifying and streamlining the regulatory environment:** Europe's complex regulatory framework creates significant burdens that hinder innovation and delay market access for life-changing products. A key priority must be to simplify and accelerate regulatory pathways. We believe new solutions to regulatory inconsistencies can be found with close collaboration between authorities and industry. Specifically, there needs to be a unified effort to overcome the issue of authorities not talking to each other (often called the 'one-stop-shop-approach'), alongside the establishment of regulatory sandboxes to demonstrate solutions that work in practice. For further information, please read the LSMA's Regulatory Bottleneck paper.
- **Science-based and proportionate Regulation:** We urge the Commission to develop a regulatory landscape that is proportionate, science-based, and that minimises unnecessary burdens. The Act must ensure that horizontal regulations, such as the planned revision of the REACH chemicals regulation, do not inadvertently create new barriers for the biotechnology and biomanufacturing sectors. For example, exempt sectoral uses in health and life science sectors from REACH Restriction and Authorisation requirements; the whole manufacturing chain is already covered by other authority assessments or EU OSHA regulations.
- **Transparent and simplified procedures:** The Act should establish clear and transparent rules for essential uses and risk assessments. This will facilitate and speed up the development and approval of biotech products, enabling shorter pathways to market without compromising safety or biosecurity standards or redirecting critical resources from "re-innovation" of established products.

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- **Regulatory efficiency:** Modernise clinical trials and marketing authorisation procedures, e.g. by simplifying, streamlining, shortening or introducing greater flexibility to adapt them to the needs of future therapies as well as decarbonisation efforts.
- **Accelerating manufacturing innovation:** The Act must specifically address the cautious, risk-averse culture and regulatory complexity that act as significant hurdles to integrating innovation into established manufacturing processes (change management). We urge the establishment of clear, risk-based, and specific regulatory pathways for manufacturing changes, similar to the US FDA's Advanced Manufacturing Technologies Designation Program (AMT designation). Establishing clear mechanisms, requirements, and timelines for such pathways would unlock a competitive advantage, enabling faster integration of innovation, reducing costs, increasing efficiency, and accelerating time to market.
- **Addressing capacity:** Ensure the European regulatory network is sufficiently resourced to enhance capacity for timely authorisation and biotech-specific know-how, including addressing the limited availability of inspectors and the resulting lengthy scheduling queues for facility audits.
- **Efficient permitting for manufacturing**: The Act must ensure a competitiveness-driven approach by introducing flexible, streamlined permitting procedures and clear time limits for all new and scaling up of existing biotech manufacturing facilities. It should recognise the essential nature of biotech manufacturing on par with other critical sectoral considerations to accelerate local production, enhance preparedness, and reduce supply chain dependencies. To overcome the current issues that extend processes from months to years, the Act must harmonise and simplify national procedures, timelines, and documentation requirements, resolving fragmentation caused by overlapping rules from various sectors (e.g., health, environment, industrial safety).

Strengthening incentives and committing to an ecosystem approach

The Biotech Act should create a clear and competitive incentive framework that takes an ecosystem approach, integrating innovation, manufacturability, and scale-up from the start.

- Link European innovation funding to downstream industrialisation. Considerations of process design, scalability, and manufacturability must be built in from the earliest research stage.
- Establish a dedicated Life Sciences Fund and streamline and better coordinate funding mechanisms between the EU and national levels. Funding should support early-stage, high-risk proof-of-concept research with simple and streamlined access to funding to facilitate industrial demonstration at scale and readiness of promising academic technologies; both help drive innovation that improves process design, scalability and manufacturability (e.g. increased efficiency or reduced costs).
- Explore and implement measures to attract private and corporate investment into the biotech sector.
- LSMA supports exploring options to facilitate the development, operation, governance, and coordination of pan-European biotech clusters. Such clusters should specifically support the collaboration of public and private sectors and should aim at integrating a “lab-to-pilot-to-manufacturing” pipeline with shared pilot-scale and GMP-compliant facilities, advanced analytical tools, and process development expertise, supporting start-ups or academic researchers to test and scale technologies without needing to build their own plants while providing access to training, regulatory guidance and sustainability support.

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- The Act should encourage secure data-sharing partnerships and strong IP protection mechanisms between academic, private, and non-profit organisations to foster collaboration and accelerate innovation.
- Launch EU-supported training and reskilling programmes focused on bioprocessing, automation, and regulatory compliance. It is also crucial to equip academic developers with the necessary entrepreneurial skills to create and grow new companies.

Conclusion

LSMA is committed to working with policymakers and stakeholders to secure Europe's position as a global leader in biotechnology. By addressing the challenges facing the EU biotech sector, namely streamlining regulations to enable faster technology adoption and strengthening incentives for R&D within a cohesive ecosystem approach, the EU can drive economic growth, improve public health, and enhance societal well-being. We stand ready to provide further insights and constructive input as the legislative process for the Biotech Act moves forward.

About LSMA

The Life Science Manufacturers Association (LSMA) is the unified voice of diverse companies powering the life science industry, dedicated to fostering a thriving ecosystem where innovation flourishes and critical technologies are accessible globally. As the industry's advocate, LSMA engages with policymakers to shape supportive policies that contribute to healthcare, sustainability, and the European economy. Uniquely positioned to address regulatory challenges, particularly concerning substitution, LSMA advocates for a proportionate approach, recognising the unique characteristics of life science applications, often involving highly sophisticated products critical to essential uses. By fostering collaboration, supporting innovation, and ensuring regulations are tailored to the industry's specific needs, LSMA aims to drive sustainable progress and maintain Europe's leadership in life sciences.

For further information and inquiries, please get in touch with the LSMA at info@lsma.org or visit their website at www.lsma.org

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