

The EU Biotech Act II

A vital Act for biomanufacturing in Europe

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The EU is positioned as a global competitor in biomanufacturing, at the heart of the €3 trillion+ contribution from bioeconomy and biopharma sectors in 2022/3.^{[1],[2]}

Such advanced manufacturing defines a knowledge-driven economy, creating competitive future supply chains that are resilient and sustainable, and which drive growth of high-quality employment across European regions.

Despite this significance, the EU remains the only major global region without a dedicated biomanufacturing initiative. An EU Biomanufacturing Act across sectors is thus a necessity and has been championed at the highest political level within the European Commission and Member States.

Legislative and simplification initiatives, including the EU Biotech Act I (primarily within health) are increasing momentum for biotech innovation, however a critical gap remains in the transition from innovation to industrial scale across all sectors. The EU continues to experience regulatory fragmentation and duplication across sectors and Member States. This slows deployment and scaling of modern biomanufacturing, weakens the single market and limits regional and export performance.

Biomanufacturing initiatives are priorities in regions such as the US, India and China. China's 5-year plan for example, places biomanufacturing alongside 6G and quantum computing, with ambitious production targets for pharmaceuticals, food and nutrition (including microbial protein), and industrial biotechnology for chemicals, materials, enzymes and cosmetics.

These sectors are all important industrial champions for the EU. To maintain and strengthen their globally competitive position, it is essential to incentivise expansion and value creation through biomanufacturing and ensure that scale up investment will be prioritised by companies. Commitment into biomanufacturing capacity supports multiple sectors within high impact applications.

The EU Biotech Act II must create an ambitious growth and market-facing framework, providing coordination, innovation, market entry and scale. This supports the heart of the Bioeconomy Strategy and aligns with EU Competitiveness Compass ambition.

This Act represents the necessary market completion step to strengthen industrial confidence, unlock private investment, and support biomanufacturing solutions across the EU. It can ensure that the region's scientific excellence is translated into industrial leadership, resilient supply chains, and long term growth for the European bioeconomy.

The signatory organisations within this statement represent industries that use and enable biomanufacturing processes, biosolutions and biomanufactured products. They represent employment and economic activity scale essential to Europe's success.

Signatories





[1] Measuring the Economic Footprint of the Biotechnology Industry in the European Union. [Read](#)

[2] Bioeconomy: Council backs moving bio-based innovations from lab to production. [Read](#)

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