

COMMISSION TAKES ACTION TO BOOST BIOTECHNOLOGY AND BIOMANUFACTURING IN THE EU

Today, the Commission has proposed a series of targeted actions to boost biotechnology and biomanufacturing in the EU. The Communication on Building the future with nature identifies the challenges and barriers and proposes to tackle them, in line with the Communication on the long-term competitiveness of the EU.

The advances in life sciences, supported by digitalisation and artificial intelligence (AI), and the potential of solutions based on biology to solve societal issues, make biotechnology and biomanufacturing one of the most promising technological areas of this century. They can help the EU to modernise its agriculture, forestry, energy, food and feed sectors and industry. In addition, these technologies can contribute to a more competitive and resilient EU, that provides better healthcare to its citizens, and succeeds in its green and digital transitions.

Reaping the benefits of the biotechnology and biomanufacturing sector

The EU biotechnology and biomanufacturing sector is facing several challenges: research and technology transfer to the market, regulatory complexity, access to finance, skills, value chain obstacles, intellectual property, public acceptance and economic security.

This is why the Commission is putting forward a set of actions:

- **Leveraging research and boosting innovation:** To help to identify drivers and bottlenecks of innovation and of technology adoption, the Commission has launched a study to investigate the EU's position compared to other global leaders in emerging biotechnology generation and transfer to the biomanufacturing industry. To facilitate a more productive use of Research Infrastructures, the Commission will explore ways to accelerate the development and use of the Industrial Biotechnology Innovation and Synthetic Biology Accelerator as a trusted digital repository and service network for the sector.
- **Stimulating market demand:** To succeed on the market, bio-based products need to prove their lower environmental impact when compared, for instance, to petrochemical products. The Commission will review the assessment of fossil-based and bio-based products to ensure equivalence of treatment and incorporate methodologies for carbon storage in construction materials. To accelerate the substitution of fossil feedstock and to stimulate the demand and market uptake of bio-manufactured products, the Commission will conduct an in-depth impact assessment of the feasibility of bio-based content requirements in specific product categories and in public procurement. Furthermore, the Commission will explore how bio-manufactured non-food products could profile themselves better through labelling of bio-based products.
- **Streamlining regulatory pathways:** The Commission will assess how EU legislation and its implementation could be further streamlined to reduce any fragmentation, explore potential simplification, and shorten the time to market for biotech innovations; as well as regulatory obstacles that arise at national or other governance levels which impede an effective single market. The study will lay the foundations for a possible EU Biotech Act. The Commission will also work towards establishing an EU Biotech Hub, an operational tool for biotech companies to navigate through the regulatory framework and identify support to scale up, by end of 2024. The Commission will further promote the establishment of regulatory

sandboxes that allow to test novel solutions in a controlled environment for a limited amount of time under the supervision of regulators, as a way of bringing more of them quickly to the market.

- **Fostering public and private investments:** The EU has a broad range of financing instruments to support biotechnology and biomanufacturing such as Horizon Europe, including the Circular Bio-based Europe Joint Undertaking and the Innovative Health Initiative Joint Undertaking; the Innovation Fund; and now also the Strategic Technologies for Europe Platform. To develop and scale up innovations with the potential to create new markets, the Commission will advocate the inclusion of specific challenges on biotech and biomanufacturing in the European Innovation Council Accelerator Work Programme 2025. In line with the recent Eurogroup statement on Capital Markets Union, the Commission will launch a study by the end of 2024 to identify barriers and ways to support the consolidation of investment funds, stock exchanges and post-trading infrastructure in order to enable the development of the necessary scale, enhance the knowledge base, create deeper pools of liquidity and help lower the cost of financing for high-growth companies.
- **Strengthening biotech-related skills:** Large-Scale and Regional Skills Partnerships can play a significant role in providing upskilling and reskilling opportunities on biotech and biomanufacturing. A specific large-scale partnership for the biotech and biomanufacturing could be explored, which can be co-financed through the Blueprint Alliances activity of the Erasmus+ programme. The expanding number of dynamic European Universities alliances and Erasmus+ partnerships and alliances for innovation can also strengthen the development of skills required by the biotech sector.
- **Elaborating and updating standards:** The Commission will continue to encourage the elaboration and updating of European standards for biotechnology and biomanufacturing to facilitate market access and innovation.
- **Supporting collaboration and synergies:** The Commission will encourage the deployment of technologies related to biotechnological processes and biomanufacturing across EU regions through relevant Regional Innovation Valleys.
- **Fostering engagement and international cooperation:** The Commission will explore the possibility of launching international biotech and biomanufacturing partnerships with key international partners, such as the US, India, Japan, and South Korea, to collaborate on research and technology transfer, and to explore possibilities for strategic cooperation on regulatory and market access-related topics. Through the Global Gateway and in line with its Global Health Strategy, the Commission will advance existing partnerships with Africa, Latin America and the Caribbean on manufacturing health products aiming to diversify global supply chains, overcome shortages of critical health products and reduce the global burden of disease.
- **Using AI and generative AI:** the Commission will support structured exchanges with stakeholders to accelerate the uptake of AI, and in particular Generative AI, in biotech and biomanufacturing. The Commission will also raise awareness of facilitated access to the EuroHPC supercomputers for AI startups and the science and innovation community, in the course of 2024.
- **Reviewing the Bioeconomy strategy:** The Commission will review the EU Bioeconomy Strategy by end 2025. The review will take into account the current societal, demographic and environmental challenges, reinforcing the bioeconomy's industrial dimension and its links to biotechnology and biomanufacturing to contribute to a stronger EU economy.