The EU Biotech Act

Prosperity, resilience and leadership for the European Union

Biotechnology plays an essential and significant role for the delivery of EU goals for competitive, healthy, resilient and sustainable economies and societies. Applications are integrated throughout our industrial and social ecosystems, including the medicines that create and sustain a healthy society, agri-food supply chains, manufacturing processes, plus biomanufacturing of chemicals and consumer goods. It is a hallmark of success, demonstrating EU growth and benefit through innovation.

The EU Biotech Act must maximise Europe's global impact and position this strategic technology, with an ambitious, cross-sectoral approach. It must be bold, addressing the fundamental frameworks through which biotechnology innovation is anchored, grown and delivered in the EU from its rich heritage of research and invention. It must also enable the innovators who lead societal and industrial transformations in Europe and beyond. A strong EU Biotech Act will further amplify the effectiveness and impact of initiatives including the EU Life Sciences Strategy, Bioeconomy Strategy and Clean Industrial Deal, illustrated by the legislative cluster in Figure 1.

The EU Biotech Act provides a pathway to:

- **Strengthen value chains**, **from R&D to end-users:** so that disruptive advances from European research mature at the speed and scale needed to reinforce Europe as a global hub for citizen and economic benefit.
- **Create coherent regulatory pathways:** so that Europe is a priority destination for homegrown and global innovation, bringing with it early adoption and access for citizens, investment, employment and resilience within Europe's vision for a healthy, secure and sustainable society.
- **Build a next generation ecosystem:** with skilled and high-quality employment, globally resilient value chains, and integration and benefit within all Member States.

A Biotech Act for Europe: An ecosystem for the future

The EU Biotech Act should address **3 pillars** that reflect EU ambition for competitiveness, sustainability, health and strategic autonomy:

Faster Financing (Pillar 1) Establishing a 'Biotech for Europe Initiative' to secure speed and scale of finance through public and private pathways for the development and deployment of next generation of biotechnology innovation towards EU growth and global performance.

Simpler EU (Pillar 2) Creating a streamlined and predictable legislative environment for biotechnology and biomanufacturing, including regulatory frameworks and protection of IP, that enables the full strength of the Single Market and unlocks benefits for all citizens.

Stronger together (Pillar 3) Enabling the delivery of biotechnology within strong regional and global value chains, through a skilled and diverse workforce across all EU Member States, accessible capacity and capability, and connectedness for the anchoring and growth of innovation into process and products.

Biotechnology across the 2025-2029 EU legislative ecosystem
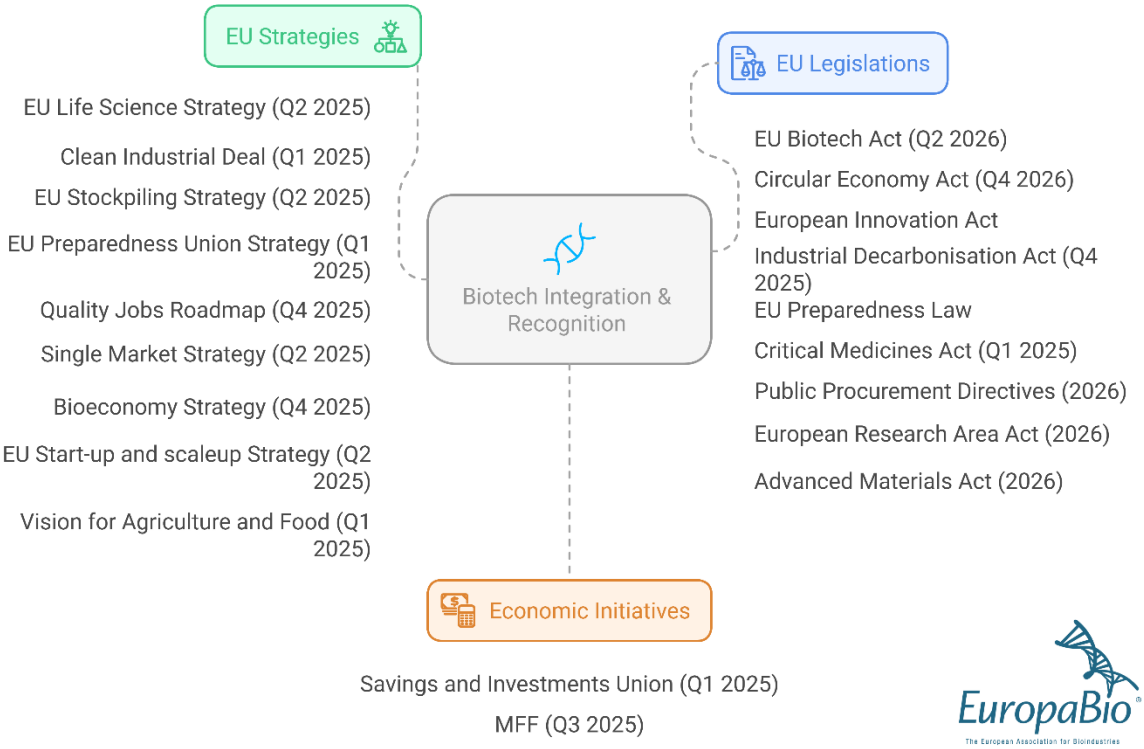
Figure 1: Legislative Cluster supporting integration and impact of biotechnology