EuropaBio Position on the EU Biotech Act: Prosperity, resilience and leadership for the European Union

Biotechnologies play an essential role for the delivery of EU objectives for competitive, healthy, resilient and sustainable economies and societies. Future-proofing fundamental frameworks across all biotech applications including healthcare, agri-food supply chains, manufacturing processes, chemicals and consumer goods, is critical. **EuropaBio welcomes the Commission's commitment to an EU Biotech Act with a broad scope covering all biotech applications, and acknowledgement of the biotech industries as key competitiveness and security drivers.**

In the current challenging trade and geopolitical environment, the Biotech Act must serve to maximise Europe's global impact and strategic leadership in biotech and biomanufacturing, whilst enhancing competitiveness and economic security. Current regulatory barriers must be resolved urgently through a dedicated **Biotech Omnibus Package** followed by a **forward-looking EU Biotech Act** to build the next generation ecosystem. This should be further amplified through other initiatives, including the EU Life Sciences Strategy, Bioeconomy Strategy and Clean Industrial Deal, illustrated by the legislative cluster (Annex).

The EU Biotech Act should focus on three key objectives to pave the way for the future of biotech innovation in the EU:

1. **Faster Financing to power the next generation breakthrough biotech** by securing speed and scale of finance for the development and deployment of biotech innovation (**Pilar I**).
2. **Simpler EU to unlock biotech innovation at scale** by delivering a streamlined and predictable legislative environment to accelerate time to markets and patients (**Pilar II**).
3. **Stronger Together to build a resilient, competitive, and globally attractive Biotech Europe** by strengthening regional and global value chains that deliver tangible benefits to all Member States and their citizens (**Pilar III**).

This paper outlines EuropaBio recommendations for the EU Biotech Act to anchor and grow the European biotech and biomanufacturing ecosystem as a global leader of the biotech revolution.

Faster Financing to Power the Next Generation Breakthrough Biotech

The biotech sector is driven by fast-paced, high-risk innovation that demands substantial investment to scale. Access to finance remains a persistent barrier in the EU, where fragmented and risk-averse capital markets create an investment gap. Many biotech companies currently turn to non-EU markets to raise capital and scale up, leading to a loss of strategic value and economic return on its innovation for the EU. Both the Letta and Draghi reports underlined the urgent need to deeper and integrate EU capital markets to secure long-term competitiveness. Bridging the investment gap will require a supportive EU environment to mobilise private finance and channel public investment into biotech innovation.

To secure faster financing, EuropaBio recommends:

Horizontal	• **Establish a Biotech for Europe Initiative** to support the acceleration of R&D and development of biotech and biomanufacturing in Europe. Similar to Horizon Europe or ReArm Europe Plan/ Readiness 2030, the Initiative should be opened to countries with which the EU has a strategic partnership. • **Establish a Biotech and Life Sciences Index** (EU biotech NASDAQ) to allow biotech companies to raise sufficient capital for development and scale up in the EU. • **Complete and leverage the Savings and Investments Union** to unleash capital into innovative projects. • **Complete the Single Market** by harmonising market, product and services regulations to remove non-tariffs trade barriers within the EU and deliver innovation at European scale. • **Maintain strong intellectual property rights and accelerate the roll-out of the Unified Patent System** and encourage all Member States to rapidly ratify and implement the Agreement. • **Introduce time-limited regime for preferential VAT rates for biotech products**, including manufacturing inputs and intermediates, to accelerate and amplify the EU's competitive biomanufacturing revolution.
Industrial Biotech	• **Accelerate the deployment of the bioeconomy throughout the value chain with increased public-private partnerships** such as CBE-JU, and mechanisms from across programmes over the long term (e.g., Important Projects of Common European interest, centres of excellence hubs). • **Expand the scope of public procurement for bio-based products and biotech** applications outside of healthcare, to cover both sustainable public procurement and green public procurement.

	• **Remove barriers to financing for the bioeconomy** through eligibility criteria for sustainable financing mechanisms, allowing access to all sources of renewable and sustainable carbon feedstock, irrespective of their origin. The industry is currently exploring different pathways and solutions and should not be hindered in its innovation process by simplistic restrictions based on feedstock type.
Health Biotech	• **Create stronger intellectual property protections and regulatory incentives for innovative biotech** to de-risk long term investment at scale and ensure the EU remains attractive for biotech innovation. • **Support life sciences innovation by preserving "Framework Programme 10"** funding levels and continuing public-private partnerships (such as IHI and ERDERA) to accelerate discovery and translational research. **Enhance public-private collaboration** to fill research pipelines, optimise clinical trials, and develop infrastructure in line with the recommendations of the Rare Disease Moonshot. • **Modernise procurement rules** to increase efficiency, move away from price-only and prioritise forward-thinking criteria by establishing **"Buy Innovative" principles** fit for the procurement of innovative biotech therapies.

A **Simpler EU** to Unlock Biotech Innovation at Scale

Biotech companies face a complex and often fragmented regulatory environment at global, EU and national levels. Many existing frameworks were not designed with biotech in mind, leading to inconsistencies and contradictions that slow down innovation and decrease EU attractiveness. Fragmentation across Member States further undermines innovation and commercialisation at scale. EU global leadership requires the modernisation of EU regulatory frameworks through a dedicated "Biotech Omnibus" to create coherent, innovation-friendly regulatory pathways without compromising high EU standards. The EU Biotech Act can then pave the way for a future-proof regulatory environment that positions the EU as a destination of choice for homegrown and global biotech innovation.

To make the EU simpler, EuropaBio recommends:

Horizontal	• **Accelerating academic discovery into commercial development** by earmarking additional EU funding for universities with excellence in academic research and track record in technology transfer and spin-offs; introducing metrics to assess maturity and impact of translational research; and creating targeted incentives to achieve higher technology readiness level (TRLs). • **Accelerate the digital transformation of biotech research and innovation**, including use of AI, to reduce administrative burden, accelerate discovery and translational outcomes and facilitate cross-border collaboration. • **Establish a fast-track framework for permitting** of new R&D and manufacturing sites to significantly shorten time to operation and boost manufacturing capacity in the EU, similar to the frameworks proposed in the Net Zero Industry and Critical Medicines Act. • **Conduct a comprehensive mapping and assessment of all legislations** (global, EU, and national) applicable to biotechnologies to ensure consistency and avoid conflict. Review all relevant EU legislations and include a mandatory review clause in all legislations to future-proof it to science and innovation. • **Modernise the regulatory framework for genomic techniques** to simplify and accelerate authorisation pathways for biotech products. • **Create an EU-level one-stop-shop to streamline and harmonise access and benefit-sharing** (ABS) procedures under the Nagoya Protocol.
Industrial Biotech	• **Improve product authorisation process of biotech products-related legislations** to accelerate market access, including

	through innovative regulatory tools, such as regulatory sandboxes for product authorisation. • **Adopt a risk based regulatory framework for microorganisms focusing on the strain itself rather than its development or improvement process (whether it contains genetic modifications or not).** The objective is to move away from the current authorisation pathway where the emphasis is on the process of how a strain has been developed or improved. • **Remove current barriers (taxonomy restriction and EIB funding) to feedstock access and establish sustainability criteria** to accelerate the sustainable development of biomanufacturing. • **Establish a level playing field with fossil-based products** by developing sustainability criteria for feedstocks, unbiased accounting mechanism for bio-based products and potential inclusion of bio-based targets in product legislation. • **Agree meaningful language** for consumer uptake and acceptance of biotech products. • **Distinguish between biotech and conventional processes** in the EU Taxonomy framework.
Health Biotech	• **Modernise the EMA centralised procedure approval pathway** to introduce greater flexibility and regulatory modernisation that can accommodate the growing number of biotech therapies in the pipeline, including fit-for-purpose requirements, quality controls, and standards. Consider establishing a **biotech scientific advisory panel within the EMA** to provide consistent, expert guidance, and to be involved in the scientific advice process. • **Establish an early partner framework for rare diseases and breakthrough biotech** to accelerate time to patients by providing early-access to health data space, clinical trial infrastructure, EMA approval, HTA, and pricing & reimbursement. • **Address the capacity gaps of the European regulatory network** (EMA/HMA), including through appropriate resources, use of digital tools, to ensure it can sustainably assess innovation throughout the value chain, supporting faster access to innovation for patients. • **Encourage the HMA to build and coordinate biotech-specific pool of trained regulators** accessible for all Member States, leveraging the EU Network Training Centre, in areas critical to biotech innovation, including R&D, biomanufacturing, scale up, regulatory science, and drug-device combination products. • **Review the Clinical Trials Regulation (CTR)** to create an EU environment capable of supporting large-scale and multi-country CTs, including by improving the coordination between ethic

	committees and streamlining approval timelines for CTs to reduce burden on authorities and sponsors. • **Review the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR)** to remove regulatory burden on biotech innovators by improving the interplay of the Regulations with the CTR and other EU legislations, enabling the parallel assessment of medicines and IVDs, ultimately creating a dedicated EU procedure for combined medicine-device clinical trials. • **Modernise the EU Variation Framework** to reduce burden on regulatory and innovators by streamlining the variation submission processes and to make it easier for companies to adopt bio-based alternative manufacturing and quality control methods, supporting the sustainability of the sector. • **Review the Cross-border Healthcare Directive**, together with the Social Security Coordination Regulation to ensure their proper functioning and support for wider patient access to healthcare, including for highly innovative treatments such as ATMPs and rare disease therapies. Improve collaboration opportunities between ERNs and industry. • **Scaleup genomic sequencing capacity** to improve early diagnosis and screening to support better healthcare delivery. Improve the funding and coordination of national genetic testing programmes, including through EU guidelines to harmonise newborn screening programmes and others.

Stronger Together to Build a Resilient, Competitive and Globally Attractive Biotech Europe

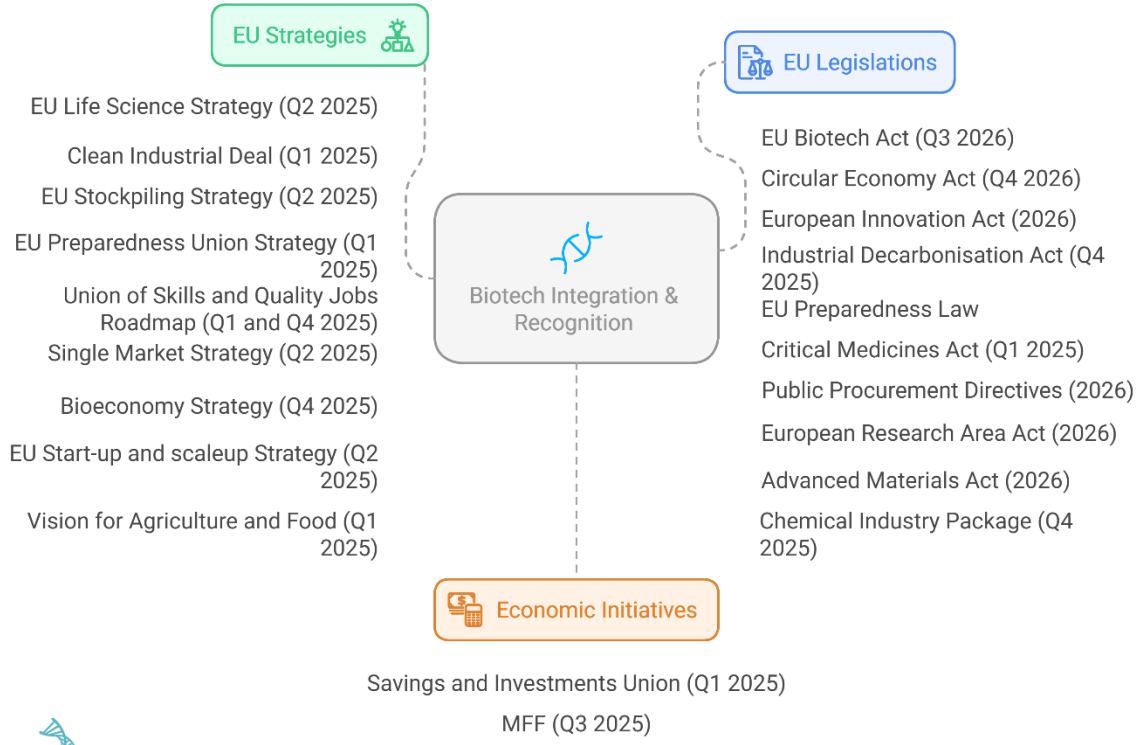
The biotech sector operates in an increasingly competitive global environment, where the EU must strengthen its position to remain a leader in innovation, production, and value creation. The EU Biotech Act offers a strategic opportunity to reinforce Europe's advantages in R&D and manufacturing, while addressing critical gaps, including in policy fragmentation, skilled workforce availability, and supply chain resilience. To succeed, the EU must also deepen cooperation with like-minded countries to secure resilient, high-value supply chains. including EEA, Switzerland and the United Kingdom, and promote Europe as a global hub for biotechnology.

To secure a resilient, competitive, and attractive EU, EuropaBio recommends:

Horizontal	• **Create an EU Biotech & Life Science Office**, headed by a **Chief Biotech Officer**, within the Commission Secretariat General responsible to improve coordination and collaboration across all Commission directorates to ensure coherence. • Designate **National Biotech Offices** to foster policy coherence and the creation and scale up of biotech innovators in our regions. • **Create a EU Biotech Board** to bring together representatives of Member States, EU institutions, relevant agencies, academia, and industry to foster policy coherence across legislations and governance levels. • **Introduce "Competitiveness" and "Fit for SME and mid-cap" criterion within the Better Regulation** guidelines and revise the "coherence" criteria to include impact across legislations beyond the immediate policy area, in particular with horizontal legislation. • **Improve the implementation of existing EU legislations** to address fragmentation across Member States and introduce faster mechanisms to update legislations. • **Improve the coordination and collaboration between EMA, EFSA, and ECHA** to foster coherence across regulatory frameworks and address inconsistencies. **Improve collaboration with regulatory agencies of partner countries**, including standards, to promote global harmonisation and accelerate time to market. • **Establish strategic partnerships with partner countries** to remove trade barriers, enable regulatory cooperation, and safeguard innovation to improve the resilience of supply chains for biotech, including raw materials, feedstock, and intermediates for biotechnology use.

	• **Establish**, **pan-European education, re-skilling, and upskilling programmes for biotech and biomanufacturing** to improve skilled workforce availability and support scale-up, including non-EU partners, such as EEA, Switzerland and the United Kingdom • **Support the mutual recognition of professional qualifications** relevant to biotech & biomanufacturing within the EU and with like-minded countries, including the EEA and countries with which the EU has strategic partnerships.

Annex – Biotech Legislative Cluster, 2024-2029



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