

Biotech Act I

German Industry's Position on the European Commission's Proposal for a European Biotech Act I

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Executive Summary

The European Biotech Act I aims to strengthen Europe's biotechnology and biomanufacturing ecosystem by improving coordination, reducing regulatory fragmentation, and addressing financing gaps. German industry welcomes the initiative but stresses the need to avoid duplicative structures, extend the investment pilot beyond two years, and ensure SME-friendly procedures—especially for AI tools, sandboxes, and clinical trial timelines. Because biotechnology is cross-sectoral, the rapid publication of a so-called Biotech Act Part II is essential to unlock broader innovation potential. Overall, the Act moves in the right direction, but its impact will depend on practical implementation and coherent integration with existing EU frameworks.

Strengthening the Framework for Biotechnology in Europe

On 16 December 2025, the European Commission presented its proposal for a Regulation intended to strengthen the Union's biotechnology and biomanufacturing sectors, particularly in the field of health — the so-called *European Biotech Act (Part I)*. The proposal forms part of the Commission's broader Health Package, introduced under the leadership of Commissioner for Health and Animal Welfare, Olivér Várhelyi.

Biotechnology is a key driver of the European Union's competitiveness, strategic autonomy, and economic security. According to the Commission, the EU biotechnology sector has grown more than twice as fast as the overall EU economy over the past decade and is among the most productive industries in the Union. At the same time, Europe continues to face challenges in translating its strong research base into large-scale commercialization and industrial production.

German industry generally welcomes the initiative to establish a comprehensive framework to strengthen biotechnology and biomanufacturing. The proposal addresses several long-standing structural bottlenecks in the sector, including financing and scale-up gaps, regulatory fragmentation, and the need to integrate digital and AI-based tools more effectively into development and manufacturing.

A central element of the proposal is the creation of an **EU Health Biotechnology Support Network**. Designed as a coordination mechanism with national and regional “antennas,” the Network is intended to go beyond serving as a mere information platform. It aims to increase transparency and coherence across Member States, improve interactions between project promoters and public or private investors, facilitate access to pilot facilities and testing infrastructures, and offer guidance on intellectual property and responsible AI integration. This reflects the Commission’s understanding of biotechnology as a highly data- and knowledge-intensive sector.

If implemented effectively and aligned with existing structures, the Network could reduce regulatory fragmentation and accelerate the path to market for innovative biotechnology products. From an industry perspective, it is essential that no new authorities be created solely for this purpose. It should therefore be assessed whether an existing structure could assume this role. Concerns regarding duplication apply equally to the proposed Steering Group, the Foresight Panel, and other governance bodies. Against this backdrop, German industry would prefer a **single point of contact**, such as an EU-wide biotech hub for knowledge, expertise, and guidance.

The proposal also introduces an **EU Health Biotechnology Investment Pilot** to be implemented with the European Investment Bank Group (EIB). This initiative aims to mobilize private capital and use risk-sharing instruments to address the well-known financing gap for start-ups, SMEs, and mid-caps — particularly in late-stage development and scale-up phases. The mix of equity instruments, guarantees, and venture debt reflects the capital-intensive and high-risk nature of biotechnology. From an industry perspective, anchoring growth and manufacturing activities within the EU is strategically important for competitiveness, resilience, and value creation. German industry therefore calls for the duration of this pilot to be extended. The currently foreseen timeframe of only two years is far too short for biotech development cycles and will not generate meaningful results.

Recognizing privately led projects that contribute to a late-stage capital booster as high-impact, strategic health biotechnology projects may help strengthen Europe’s fragmented equity markets. Europe’s comparatively lower liquidity for biotech R&D has long hindered company growth. Facilitating cross-border investment and increasing visibility for strategic projects could improve financing conditions for growth-stage companies. However, the instruments outlined in Articles 22 and 23 of the proposed Act can only be fully effective if supported by an innovation-friendly state aid framework and functioning European capital markets. Without these reforms, any investment push will remain incomplete.

The proposal also highlights the rising importance of **artificial intelligence throughout the biotechnology lifecycle**. Planned measures include developing guidance, establishing testing environments, and improving data access. Ensuring legal clarity and coherence with existing horizontal legislation will be essential for practical implementation. For start-ups and SMEs, however, these instruments must be low-threshold and financially accessible. Regulatory sandboxes should not create additional testing or documentation requirements; rather, they must provide genuine spaces for innovation. Participation should not involve high fees or heavy administrative burdens that would exclude smaller companies.

Clinical trials are another crucial element addressed by the Biotech Act. The Act proposes significantly shorter approval timelines for multinational trials, reducing the overall process from 106 to 75 days, including validation and ethical review. Initial approvals are to drop from 75 to 47 days if no additional information is needed. The previous 50-day extension for ATMP trials is removed. Substantial amendments could now be processed within 47 days, and parallel submissions for different parts of the dossier will be allowed. These measures could strengthen the EU’s global competitiveness

and create a more efficient framework under the EU Clinical Trials Regulation (EU CTR, Regulation (EU) No. 536/2014).

However, shorter evaluation periods often result in shorter response windows for applicants. This can pose additional challenges, particularly for small and medium-sized biotech companies. To avoid delays or even termination of application procedures due to untimely responses, procedures must be designed to remain workable for SMEs and start-ups. Excluding novel foods, certain GMO applications, or innovative recycling technologies from sandboxes weakens their innovation potential and sends the wrong signal to research-based companies. Sandboxes are designed to support emerging technologies under controlled conditions and to generate evidence-based regulatory insights. Limiting them unnecessarily risks creating new fragmentation.

Biotechnology is a cross-sectoral technology platform. Although this proposal focuses on health biotechnology, many underlying technologies are used across medical, agricultural, and industrial applications. The horizontal nature of biotechnology makes coherence across regulatory frameworks vital. The Commission should therefore not delay publication of **Biotech Act Part II**, which is expected to address non-health-related biotechnology. A purely health-focused approach is insufficient to drive Europe's broader biotechnological transformation and bioeconomy.

Overall, the European Biotech Act I is a comprehensive step toward strengthening Europe's biotechnology ecosystem. It addresses major financing, regulatory, and structural challenges. From the perspective of German industry, the initiative moves in a constructive direction. Its ultimate impact will depend on effective implementation, coordination with existing instruments, and its ability to reduce fragmentation and create better conditions for innovation and production within the Union. German industry is open to further dialogue on concrete measures and implementation. A truly effective Biotech Act will be achieved only when all stakeholders benefit fairly.

Imprint

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