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Europe's Biotech Act: accelerating innovation without abandoning control ?

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Valentin Hammoudi is a molecular biologist and science communicator. After nearly fifteen years spanning academic research, entrepreneurship, science outreach, and scientific journalism, he now focuses on the intersections between biotechnology, public policy, and resilience strategies. He writes for the Institut Sapiens on emerging technologies and their societal implications.

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Introduction

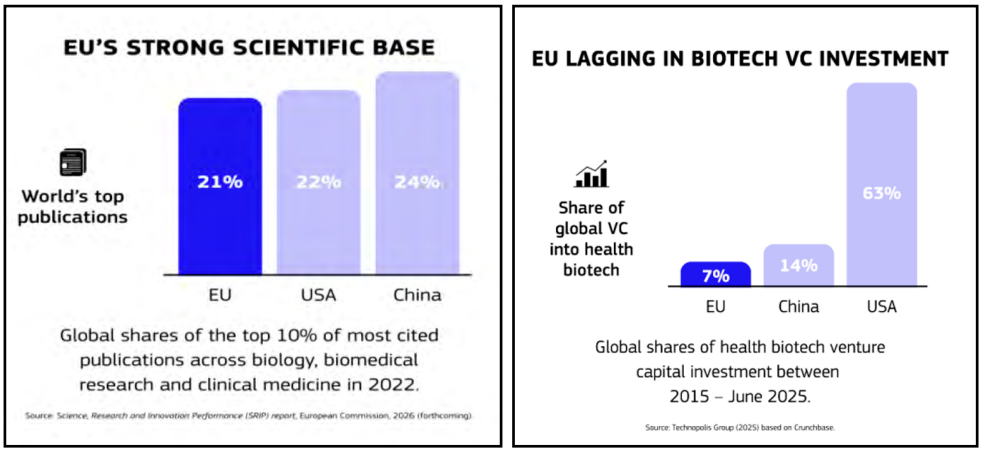
Biotechnology is quietly reshaping the world around us, from vaccines and personalized medicine to sustainable food and bio-based materials. But while Europe has world-class research, it has struggled to turn scientific breakthroughs into real-world solutions at scale. The European Union's new Biotech Act aims to change that. It promises to speed up innovation, attract investment, and strengthen Europe's global position, without compromising safety. Can Europe move faster while staying true to its values? This article explores what is at stake.

When the European Commission unveiled its proposed Biotech Act in December 2025, it did so against a backdrop of strategic unease. Over the past decade, biotechnology has moved from being a specialized research field to a cornerstone of economic competitiveness, public health preparedness, and geopolitical influence. Vaccines, advanced therapies, bio-manufacturing, and data-driven medicine are no longer peripheral innovations; they are infrastructure. Yet, Europe enters this phase from a position of relative weakness.

The Biotech Act is the Commission's explicit attempt to reverse this trajectory, as it aims to modernize the EU health ecosystem while strengthening industrial capacity. The ambition is clear: to shortening the distance between laboratory breakthroughs and real-world deployment, without compromising safety or public trust. Whether the Act can reconcile these objectives remains an open question.

A strategic sector, a structural lag

Biotechnology already represents a significant part of the European economy, employing close to one million people and contributing tens of billions of euros annually. But these figures mask a more troubling reality. Compared with the United States, and increasingly China, Europe struggles to scale biotech innovations. Promising start-ups often fail to secure late-stage financing, clinical trials remain fragmented across member states, and regulatory pathways are perceived as slow, complex, and unpredictable.



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This diagnosis is not new. It was articulated forcefully in recent competitiveness assessments, which pointed to chronic underinvestment, regulatory bottlenecks, and the absence of a truly integrated market for advanced health technologies. The Biotech Act is designed as a response to these constraints. Its central promise is not deregulation, but coordination: aligning funding, regulation, and industrial policy to create a more coherent innovation pipeline.

Global openness vs strategic autonomy

A central but often implicit tension in the Biotech Act is the balance between strategic autonomy and global openness. While the EU increasingly frames biotechnology as a domain of sovereignty (linked to health security, industrial resilience, and critical infrastructure) the sector itself remains deeply embedded in global value chains. Research collaborations, cross-border investment, and international supply networks are not optional but structurally embedded in how biotechnology develops and scales. This creates a persistent trade-off: strengthening Europe's autonomy may require tighter control over strategic assets and production capacity, yet excessive inward orientation risks reducing access to capital, talent, and technological exchange. The challenge for the Biotech Act is therefore not only regulatory coherence, but also managing interdependence in a geopolitically fragmented innovation landscape.

From lab to market: what changes in practice?

At the heart of the Act lies a set of measures that aim to ease the transition from research to commercialization. The proposal includes new investment mechanisms, notably a Health Biotech Investment Pilot developed with the European Investment Bank, intended to address the persistent "scale-up gap" faced by European firms. Targeted support for bio-manufacturing seeks to anchor production capacity within the EU, reducing dependence on external suppliers for critical therapies and inputs.

Regulatory reform is another key pillar. Faster and more harmonized clinical trial authorizations, single regulatory pathways for complex products, and the use of regulatory sandboxes signal a shift towards more adaptive governance. In areas like advanced therapy medicinal products, where regulatory expertise has matured unevenly across Europe, this could significantly reduce time-to-market.

But the Act also goes beyond healthcare. Early provisions for biotechnology in food and feed, including streamlined scientific advice, suggest a broader industrial vision. If fully realized, this could benefit Europe's fermentation and bio-based industries, which are increasingly central to sustainable production. These changes for broad biotechnology will come as a complement to the revision of rules governing new genomic technics (NGT) that has been voted and accepted in January 2026 and which will largely disrupt biotechnological innovation in the agricultural sector.

Acceleration versus assurance

Yet, speed is not a neutral variable. The push to accelerate innovation inevitably raises concerns about oversight, especially in a domain as sensitive as biotechnology. The EU has historically defined itself through a precautionary approach, particularly in areas involving genetic modification, data use, and patient safety. The Biotech Act does not abandon this European value, but it does reinterpret it.

By emphasizing regulatory sandboxes, adaptive pathways, and AI-enabled development, the Act moves towards a model of "controlled acceleration." The challenge will be its implementation. Faster procedures require not only legal changes but also administrative capacity, shared standards, and trust between and in institutions.

Without this, acceleration risks becoming uneven within the EU, benefiting a subset of actors while leaving others behind.

Ethical considerations also remain only partially addressed. Questions surrounding dual-use research, data governance, and equitable access to advanced therapies are acknowledged implicitly rather than properly addressed. This may be politically expedient, but it leaves unresolved tensions between innovation policy and broader societal values.

Biosecurity governance

Beyond questions of speed and industrial capacity, the Biotech Act also implicitly intersects with emerging biosecurity governance challenges. As biotechnology becomes more accessible and data-driven, regulatory systems are increasingly expected to integrate safeguards such as verification of legitimate use, monitoring of suspicious transactions in biological materials, and screening of synthetic DNA orders. These measures aim to reduce risks associated with dual-use research and the misuse of advanced biotechnologies, particularly in an era where automation and AI-assisted design lower barriers to biological engineering. While these mechanisms are not always considered as a priority in the legislative debate, they are central to how Europe differentiates its approach internationally: combining innovation support with traceability and upstream risk prevention rather than relying solely on downstream controls.

Medical devices and systemic resilience

The proposed reform of medical device regulation illustrates both the promise and the limits of the new approach. Europe has long been a major global player in this sector, yet current rules have generated significant compliance costs and delays, particularly for small and medium-sized enterprises. By simplifying procedures, digitalising assessments, and strengthening coordination through the European Medicines Agency, the Commission aims to restore predictability while maintaining high safety standards.

If successful, these reforms could improve supply continuity and reduce shortages, an issue that became very visible during recent public health crises. The creation of a list of critical devices and enhanced monitoring mechanisms points to a more strategic understanding of resilience, not as stockpiling alone, but as system design.

Health outcomes as industrial policy

Cardiovascular disease, the leading cause of premature deaths in the EU, has become a central focus of European health policy. In this context, the Commission increasingly links public health objectives to innovation policy and the integration of health data systems, notably through its digital health and chronic disease prevention strategies

This convergence of health policy and industrial strategy is deliberate. It reflects a growing recognition that societal challenges can anchor innovation ecosystems. However, it also raises questions about governance: who sets priorities, how success is measured, and whether innovation benefits are distributed equitably across member states.

Conclusion: an incomplete but consequential step

The Biotech Act is neither a silver bullet nor a radical rupture. It is better understood as a recalibration, an attempt to make European biotechnology faster, more investable, and more strategically aligned without dismantling existing safeguards. Industry responses have welcomed many of its elements, from extended intellectual property incentives to improved regulatory pathways, while pointing to notable gaps.

Ultimately, the Act's impact will depend less on its headline ambitions than on its execution. Harmonization across diverse national systems, sustained investment, and institutional learning will be critical. So will public engagement. Biotechnology operates at the intersection of science, economy, and ethics; hence, its legitimacy is crucial.

If the Biotech Act succeeds, it may help Europe reclaim a measure of technological sovereignty in a field that increasingly shapes global power. If it fails, it will reinforce a familiar pattern: strong ideas, constrained by fragmented implementation. Either way, it marks a recognition that in biotechnology, standing still is no longer an option.