

# Issue Brief

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## A Strategic Inflection Point in AI-Biotechnology Policy:

Comparative Analysis of ROK's National AI-Biotechnology Strategy and the EU Biotech Act, with Policy Implications

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## Abstract

In December 2025, the Republic of Korea and the European Union (EU) announced major policy initiatives—the National AI-Biotechnology Strategy and the EU Biotech Act, respectively—positioning advanced biotechnology and AI-enabled life sciences at the core of their strategic agendas. South Korea’s strategy emphasizes transforming research and industrial ecosystems through artificial intelligence, primarily to accelerate drug discovery, improve success rates, and enhance industrial productivity. It prioritizes developing AI-biotechnology models across five key domains, supported by dedicated computing and data infrastructures. By contrast, the EU Biotech Act constitutes a comprehensive, full-value-chain policy framework spanning drug development, advanced therapies, biomanufacturing, and market access. The Act redefines biotechnology as a strategic asset tied to technological sovereignty and economic security, while simultaneously embedding safeguards against misuse and dual-use risks. Through mechanisms such as regulatory sandboxes, legitimate-need assessments, and the statutory codification of nucleic acid synthesis screening (NASS), the EU institutionalizes a dual-track approach that integrates innovation promotion with safety, security, and biosecurity. These divergent approaches yield critical policy implications. As AI-biotechnology convergence accelerates globally, they will influence international regulatory alignment, technological trustworthiness, and future biosecurity governance. The EU framework highlights the need for South Korea to integrate biosecurity, risk governance, and international norm compatibility into its AI-biotechnology strategies—not as innovation constraints, but as enablers of sustainable, credible technological leadership.

### Keywords

Biosecurity, Biotechnology, AI-Biotechnology, Data Governance

# A Strategic Inflection Point in AI-Biotechnology Policy: Comparative Analysis of ROK's National AI-Biotechnology Strategy and the EU Biotech Act, with Policy Implications

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The government of the Republic of Korea formally approved the National AI-Biotechnology Strategy on December 18, 2025, at the Second Ministerial Meeting on Science and Technology, following an inter-ministerial drafting process. Framing the current period as a critical “golden time” amid intensifying global competition for AI-enabled biotechnology leadership, the strategy articulates a vision for comprehensively transforming the nation’s bio-research and industrial ecosystems through artificial intelligence, with the ultimate goal of establishing South Korea as a global AI-biotechnology hub.

In parallel, the European Commission unveiled its long-anticipated EU Biotech Act proposal on December 16, 2025. This legislative initiative aims to position Europe as a “world-leading health biotechnology hub” and a “biotech powerhouse.” Structured as an integrated regulatory and industrial policy package, the Act encompasses the entire health biotechnology value chain—from drug discovery and advanced therapy medicinal products to biomanufacturing and market entry. This approach reflects a broader institutional shift within the EU, reconceptualizing advanced biotechnology not merely as an industrial sector, but as a strategic technology integral to technological sovereignty, economic security, and biosecurity.

As the digital-biological convergence era dawns, bolstering South Korea's AI-biotechnology capabilities—and the supporting legal and institutional frameworks—requires close examination of peer strategies in advanced economies and regional blocs like the EU, which are poised to compete in global markets. Direct one-to-one comparisons must, however, account for structural differences: the EU's Biotech Act is a legislative proposal with prospective binding force, whereas South Korea's National AI-Biotechnology Strategy is a non-binding strategic roadmap outlining medium- to long-term directions. Equating them at the level of legal instruments would thus be analytically misleading.

Both documents nonetheless share a fundamental recognition that the convergence of artificial intelligence and biotechnology will decisively shape future national competitiveness and security landscapes. At the macro-strategic level—particularly regarding problem diagnosis and overarching orientations for addressing structural challenges—the two frameworks remain meaningfully comparable. While both place advanced biotechnology and AI-biotechnology at the forefront of national strategy, they diverge in policy logics and design priorities. South Korea adopts a “performance-acceleration” paradigm focused on research efficiency and industrial competitiveness. The EU, conversely, pursues a “system-building” approach that institutionalizes regulatory reform, biosecurity safeguards, and misuse-prevention mechanisms alongside industrial advancement.

These contrasting approaches carry important policy implications as AI-biotechnology convergence enters a phase of rapid diffusion. In

particular, they raise critical questions concerning international regulatory alignment, the institutional assurance of technological trustworthiness, and the design and operation of future biosecurity governance architectures. Against this backdrop, this paper does not seek to undertake a granular comparison of specific legal provisions. Instead, it analyzes Korean and EU AI-biotechnology policy documents at the level of strategic orientation and broader policy discourse, with the aim of identifying the structural challenges and strategic choices that South Korea's AI-biotechnology policy is likely to confront in the period ahead.

## **Background and Overview of the Strategies**

South Korea's National AI-Biotechnology Strategy seeks to establish the nation as a global AI-biotechnology hub by integrating artificial intelligence into bio-research and industrial ecosystems. It identifies the construction of an innovative AI-biotechnology ecosystem as a core task, strategically linking AI-biotechnology foundation models, bio-medical data assets, and high-performance computing with experimental infrastructure. The strategy outlines phased development of AI-biotechnology models to enhance research efficiency and industrial competitiveness across five priority domains: drug discovery, brain science and anti-aging, medical devices, biomanufacturing, and agri-food (green) biotechnology.

The EU Biotech Act, by contrast, adopts a full-value-chain approach to health biotechnology—from drug development, advanced therapy medicinal products, and biomanufacturing—aimed at making Europe a world-leading health biotechnology powerhouse. Stemming from a

critical assessment **that** the European Union has been losing ground to the United States and China in the development and commercialization of innovative biopharmaceuticals, it cites structural barriers including fragmented financing, regulatory bottlenecks, and innovation constraints. The Act positions AI and data as pivotal enablers of biotechnological innovation, framing itself as a “first-stage” health biotechnology initiative. Importantly, the proposal signals a broader, phased legislative trajectory: follow-on legislation is planned for 2026 to extend the regulatory and policy framework to additional biotechnology domains, including agriculture, energy, defense, and industrial applications. This phased strategy signals the EU’s intent to build an integrated and scalable governance architecture that can evolve in tandem with technological convergence and the expansion of application areas.

## **Divergent Strategic Approaches**

### **A. Conceptualizing Core Bottlenecks**

South Korea and the EU fundamentally differ in diagnosing constraints on biotechnological advancement. South Korea emphasizes biotechnology’s inherent challenges—long development timelines, high costs, uncertainty, and low success rates. Accordingly, its policy focus is less concerned with questions of ownership or control over foundational models and more oriented toward prioritizing AI to overcome research inefficiencies through large-scale bio-medical data learning. This accelerates discovery, interpretation, and prediction of complex biological phenomena while boosting productivity, speed, and success rates.

The EU, however, identifies distinct strategic risks from AI-biotechnology's rapid maturation and industrial scaling. From the EU perspective, the concentration of leading models and core technologies outside Europe—developed predominantly under private-sector leadership—creates structural vulnerabilities. As a multi-state union, the EU views the lack of cross-border data interoperability, the absence of integrated platforms among member states, and fragmented research and computing infrastructure as critical bottlenecks undermining its competitiveness in the global AI-biotechnology landscape.

These differing diagnoses yield contrasting policy solutions and design logics. South Korea's national project integrates bio-foundation models—the “cognitive core” of AI-biotechnology—with agentic AI systems positioned as “AI research partners.” This transition to automated research paradigms addresses structural inefficiencies through multimodal, multiscale bio-foundation models for drug discovery and agentic AI for autonomous compound design, evaluation, and validation. The strategy develops domain-specific “specialized AI models” across its five priority sectors.

The EU pursues an infrastructure-centric roadmap integrating RAISE<sup>1)</sup> (talent and resources), Data Labs (data), and AI Factories (computing)<sup>2)</sup>. Through shared European platforms, pooled resources, and ecosystem governance, it aims to structurally reduce external reliance and private-sector dominance, building “EU-origin” or “EU-led”

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1) **RAISE** refers to *Resource for Artificial Intelligence Science in Europe*, a newly launched initiative established in November 2025. The initiative aims to strengthen Europe's AI scientific capacity by coordinating talent, resources, and infrastructure at the continental level.

2) Federico Guerrini, “*Europe's AI Continent Action Plan: Gigafactories, Data Labs, and Green AI*,” *Forbes*, April 9, 2025.

AI-biotechnology models via continent-wide public coordination.

## **B. Data Governance: Controlled Autonomy vs. Open Integration Autonomy**

The divergence between South Korea and the EU becomes even more pronounced in the design of their data governance frameworks. Extending its “sovereign AI” strategy<sup>3)</sup>, South Korea places strong emphasis on building autonomous AI platforms in the advanced biotechnology domain. Centered on the K-BDS (National Integrated Bio Data Platform), the government aims to secure more than seven million datasets by 2030. For sensitive data, priority is given to controlled utilization environments through closed-network cloud systems and the application of regulatory exemptions. From mid-2026, South Korea plans to deploy its sixth-generation supercomputer for AI-biotechnology research, gradually expand secure, bio-specialized high-performance computing (HPC) environments for sensitive data analysis, and over the longer term, explore the potential adoption of quantum computing. In this respect, South Korea’s approach can be characterized as a control-oriented model prioritizing security-focused technological autonomy through the development of proprietary platforms.

The EU, by contrast, adopts an open, federated public-infrastructure model. Seeking global leadership at the continental scale, the EU treats the integration and interoperability of data and resources as foundational strategic prerequisites. Its AI-biotechnology data governance framework emphasizes the creation of a single data

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3) Jung-Hyun Yoon, “Exploring a Korean-Style Sovereign AI National Strategy,” *Strategic Report*, No. 349, December 2025, Institute for National Security Strategy (INSS).

market, aimed at establishing a European AI-biotechnology platform. A central institutional pillar of this approach is the European Health Data Space (EHDS), enabling standardized, cross-border access to and governance of individuals' electronic health data across EU member states, while institutionalizing the reuse of pseudonymized health data for public-interest purposes such as research, innovation, policymaking, and regulation. Through this mechanism, the EU effectively aspires to construct the world's largest virtual health database.

Data Labs embedded within AI Factories create an integrated data governance structure that supports federated data linkage, curation, standardization, and compliance assistance with EU-level data protection requirements (e.g. GDPR<sup>4</sup>). To underpin this architecture technologically, the EU has articulated plans to establish a continent-wide public AI computing market centered on EuroHPC-based AI Factories and Gigafactories, reinforcing its open yet coordinated approach to AI-biotechnology infrastructure development.

### C. Biosecurity and the Regulatory Sandboxes

The starkest divergence between South Korea's National AI-Biotechnology Strategy and the EU Biotech Act lies in the presence—or absence—of an explicit biosecurity framework. South Korea's strategy sidelines biosecurity, addressing security through a cybersecurity lens, emphasizing “sensitive” data protection, closed-network systems, and

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4) **GDPR** stands for the *General Data Protection Regulation*, the EU's comprehensive and stringent legal framework governing the protection of personal data and privacy.

secure research environments. At the current stage, the strategy prioritizes the construction of a lawful and secure foundation for the use of data and research infrastructure, while a concrete policy roadmap for institutionalizing safety, security, and misuse-prevention mechanisms associated with advanced biotechnological innovation has yet to be articulated.

The EU advances an open AI-biotechnology strategy while simultaneously acknowledging the dual-use and misuse risks inherent in AI-enabled biological technologies. On this basis, the EU explicitly underscores the need for “special mitigation measures” to address such risks. In particular, it has legally codified biosecurity and misuse-prevention mechanisms—most notably nucleic acid sequence screening. This offers a clear institutional example of a dual-track approach that simultaneously promotes AI-driven innovation while embedding safety and security safeguards. Moreover, in the context of international cooperation, the EU frames the “balance between openness and vigilance” as a core research security principle, identifying the prevention of unwanted technology transfer and excessive external dependency as strategic policy objectives. Against this backdrop, the EU has proposed the establishment of member state-level regulatory sandboxes<sup>5)</sup> linked to ex ante and ex post evaluation and verification mechanisms. This design reflects an effort to reconcile experimental regulatory flexibility with systematic oversight and accountability.

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5) A **Regulatory Sandbox** refers to a policy mechanism that allows innovative technologies or services to be tested and validated under temporary exemptions or suspensions of existing legal and regulatory requirements, subject to predefined conditions such as time, scope, and scale. The purpose of a regulatory sandbox is to enable experimentation in a controlled environment—often described metaphorically as an “innovation playground” —where firms can pursue innovation without immediate regulatory burden, while regulators gather empirical evidence to inform the development of proportionate and evidence.

In South Korea, discussions regarding the introduction of regulatory experimentation and sandbox mechanisms similar to those adopted in Europe are also gaining momentum and are likely to be expanded through subsequent policy initiatives. Nevertheless, given Korea’s strategic emphasis on accelerating drug discovery, automating biomanufacturing, and scaling agentic AI applications, issues related to dual-use risks and biosecurity are likely to emerge organically as salient policy concerns. This suggests that Korea’s AI-biotechnology strategy will, over the medium- to long-term, face increasing pressure to evolve from a technology-acceleration-centered approach toward a more integrated framework that incorporates security and regulatory governance alongside innovation.

〈Table 1〉 Key Differences between the EU’s and South Korea’s AI-Biotechnology Strategies

Dimension	EU	Korea
Strategic Approach	An independent strategy centered on institutions and infrastructure to revitalize the advanced biotechnology sector	Securing leadership in global biotechnology markets through AI-driven acceleration of research and industrial development
Perceived Core Bottlenecks	Dependence on non-EU, privately led AI-biotechnology models; fragmentation of data and research infrastructure	High costs, long development timelines, and low success rates inherent in biological research
Policy Solutions (Models & Infrastructure)	Building a shared EU-wide ecosystem through the integration of RAISE – Data Labs – AI Factories	Automating and enhancing research through bio-foundation models combined with agentic AI
Data and Computing Governance	An open, federated, continent-scale public AI infrastructure built on EHDS and EuroHPC	A sovereign, control-oriented infrastructure centered on K-BDS and secure high-performance computing (HPC)
Biosecurity / Regulatory Sandbox	Full institutionalization of dual-use and misuse risk mitigation alongside AI promotion, including member state-level regulatory sandboxes	A data-security-centered approach; biosecurity and regulatory sandbox frameworks remain follow-on policy tasks

## Strategic Implications: The Emerging Need for Biosecurity Governance

As <Table 1> illustrates, EU's and South Korea's approaches to advanced AI-biotechnology reveal clear divergence in strategic orientation. The EU places primary emphasis on long-term system-building, while South Korea prioritizes a performance-acceleration strategy for tangible short- to medium-term outcomes. Anchored in the RAISE framework, the EU seeks to establish an integrated governance architecture encompassing public AI computing infrastructure (AI Factories), shared data spaces such as the European Health Data Space (EHDS), and comprehensive ethical, security, and trustworthiness guidelines. This mitigates member-state fragmentation and secures continent-wide global leadership—achieving strategic autonomy not only through technological development, but also through holistic institutional, infrastructural, and normative design.

By contrast, South Korea's National AI-Biotechnology Strategy integrates sector-specific model development across five priority domains with bio-specialized high-performance computing (HPC) infrastructure, the National Integrated Bio Data Platform (K-BDS), closed-network cloud-based secure research environments, and targeted legal and regulatory revisions. Its direct policy objectives are to accelerate drug development timelines, improve success rates, and enhance industrial productivity. This state-led, hub-centric approach offers clear advantages in emerging fields, particularly in its capacity to induce rapid market entry and early-mover advantages through visible performance gains.

However, AI-biotechnology innovation demands parallel regulatory and security frameworks. The EU explicitly foregrounds the risks of misuse and dual-use inherent in AI-enabled biological technologies within its legislative proposal, most notably through the legal codification of nucleic acid synthesis screening (NASS). AI-biotechnology has progressed beyond analyzing discrete biological entities (viruses or bacteria) to designing or synthesizing nucleic acids (DNA and RNA)—the fundamental building blocks of life. Under these conditions, the uncontrolled circulation of nucleic acid sequences containing pathogenic or toxic information, or their synthesis by unauthorized individuals or facilities, poses a realistic security risk, including the potential creation of novel pathogens or bioterrorism agents.

In response, the EU Biotech Act mandates a comprehensive NASS framework at the statutory level for the first time globally. This framework includes: (i) access restrictions on biotechnology products of concern (Article 43); (ii) obligations to verify legitimate need (Article 44); (iii) mandatory sequence screening for benchtop nucleic acid synthesis equipment (Article 45); and (iv) mechanisms for detecting and reporting suspicious transactions (Article 46). This represents a paradigmatic example of the concurrent design of AI promotion and biosecurity safeguards, and it is likely to serve as an important reference point in future international norm-setting processes.

South Korea, for its part, has demonstrated a strong policy commitment to fostering convergence technologies at the intersection of biotechnology and artificial intelligence, as reflected

in initiatives such as the world's first Synthetic Biology Promotion Act and National AI-Biotechnology Strategy. Nevertheless, as agentic AI systems and automated research environments become more widespread, governance mechanisms related to NASS, synthetic biology safety management, and autonomous laboratory systems can no longer be treated as downstream or secondary policy tasks. Rather, they must be addressed as simultaneously designed components of innovation policy.

Given that foundational research on NASS is already underway within South Korea's national life science research institutes, policymakers face an urgent need to accelerate the institutionalization of safety and security mechanisms alongside AI-biotechnology performance gains. This dual imperative carries significant implications for South Korea's medium- to long-term science and technology strategy and broader national security posture, as AI-biotechnology represents both a critical engine of future growth and a potential source of emerging security risks.

***The views and opinions expressed in this report are those of the author(s) and do not necessarily reflect the official position of INSS.***