Securing Europe's Biotechnology Future

Submission to the EU Biotech Act Call for Evidence

This submission welcomes the Commission's initiative for an EU Biotech Act. To realise Europe's potential as a global leader in biotech, we recommend fortifying this ambition through an integrated approach to innovation and security.

The strategic imperative of an innovative European biotechnology sector is undeniable; as demonstrated during the COVID-19 pandemic, sovereign production capacity is a direct determinant of crisis recovery and economic resilience. The stakes are high, as NATO (1) states, "*the next revolutionary technology cycle will be driven by synthetic biology. While the potential benefits from increased biotechnology use are substantial, especially for healthcare, the risks of harmful uses are also enormous*".

Concurrently, the convergence of AI with biotech and increased access to powerful AI and biological tools create novel dual-use risks that existing oversight cannot adequately address (2). Current regulatory frameworks remain fragmented and ill-adapted to this new reality (3).

Pillar 1: Building a Harmonised EU Biorisk Governance Framework

The threat of misuse is not theoretical. Both European security bodies and global health coalitions stress the urgency of updating oversight. The pan-European assessment of synthetic biology explicitly warns that "*the accelerated technological developments... raise concerns about the potential for misuse*" (4). Similarly, the Coalition for Epidemic Preparedness Innovations (5) stresses the need to "*ensure that biosafety and biosecurity risk identification and mitigation approaches keep pace with the evolution of the ways in which biological tools could accidentally or deliberately be misused*". Experts from the Community for European Research and Innovation for Security (CERIS) have identified the possibility of bioterrorism attacks among the top ten security priorities (6).

1. Recommendation: Codify Nucleic Acid Synthesis Screening

- We recommend that screening orders for dangerous sequences and know-your-customer procedures be made a binding legal requirement for all nucleic acid synthesis providers operating within the EU. To ensure verifiable compliance, we propose a system of annual third-party conformity assessment. This approach establishes a more robust assurance mechanism than alternative models, such as public self-attestation, and aligns with ongoing international efforts by industry and government partners.
- The primary objective is to create a harmonised system that establishes a level playing field for industry and ensures high standards of biosecurity across the single market (7), which could be achieved through a new legislative act or by amending an existing legal framework.
- Mandated screening for biosecurity risks answers industrial stakeholders' call for to ensure a secure, trustworthy and thus strong bioeconomy. The IGSC, representing over 40 synthesis companies, is itself calling for harmonization and safeguards (8). This is reinforced by the scientific community, with over 175 leading researchers

pledging to obtain DNA synthesis services only from providers that screen orders, as part of a series of commitments for responsible AI development in protein design (9, 10).
- Modern DNA/RNA synthesis screening processes integrate seamlessly with scientific workflows, and cost-effective solutions are offered by independent nonprofits, venture-backed startups, and established defence contractors (11).
- This measure addresses critical security gaps in global health security, aligning with findings from the WHO (12) on the limitations of current voluntary approaches and building on a broad consensus from key stakeholders.
- Although nucleic acid synthesis screening is a cost-effective and high-impact measure, it should be integrated into a broader, multi-layered EU biorisk governance framework.

2. Establish a European Biosecurity Expert Group

- We recommend the creation of an expert group to monitor emerging threats, foster preparedness, and continuously adapt risk management frameworks, an action consistent with proposals from the Joint Action TERROR assessment (4).

Pillar 2: Aligning EU Funding with Biosecurity and Synthesis Capacity

Effective governance requires financial instruments to ensure its implementation. Currently, Europe's biotechnology sector relies heavily on non-EU suppliers for critical synthetic biology components, creating vulnerabilities in both supply chains and security oversight. These financial instruments must therefore be directed towards addressing this core strategic vulnerability.

3. Recommendation: Introduce Biosecurity Conditionality in Research Funding

- We recommend making biosecurity compliance a prerequisite for biotechnology research grants like Horizon Europe and its successor, FP10. Specifically, funded biological research projects should procure synthesized nucleic acid synthesis from credible synthesis providers that conduct screening according to established industry standards and undergo regular third-party conformity assessment.
- This hardwires a "Preparedness-by-Design" approach consistent with the EU's evolving security and preparedness strategies (13, 14, 15) and requires updating EU guidance on dual-use research of concern (16), particularly at the AI-biology interface, while streamlining compliance through clear, unified standards that reduce administrative burden.

4. Recommendation: Dedicate Funding to Secure Industrial Capacity and Accelerate Research

- We recommend establishing dedicated EU funding to (a) strengthen the EU’s sovereign capacity for nucleic acid synthesis; and (b) consolidate and accelerate research in biotechnology.
- The EU faces strategic dependencies in biotech supply chains, particularly in nucleic acid synthesis capacity, causing week-long delays for critical applications like vaccine development.

By embedding these recommendations within the EU Biotech Act, the EU can create the secure foundation necessary for a thriving, competitive, and resilient European bioeconomy. The Biotech Act has to go hand in hand with the new CBRN Action Plan.

We thank you for the opportunity to contribute to this critical legislative initiative and stand ready to provide further input.

—

Signatories

Dr. Carlos Acevedo-Rocha, Senior Researcher, Technical University of Denmark

Laurent Bächler, Program Lead Biosecurity, Pour Demain, Belgium

Jens Berlips, SecureDNA Foundation, Switzerland

James Diggans, Chair, International Gene Synthesis Consortium, USA

Prof. Dr. Dr. Adrian Egli, Institute of Medical Microbiology University of Zurich, Switzerland

Prof. David Gisselsson Nord, Division of Clinical Genetics, Faculty of Medicine, Lund University, principal investigor of Greyzone Genomics, Sweden

John Halstead, Research Fellow, Centre for the Governance of AI, UK

Prof. Dr. Thomas V. Inglesby, MD, Director, Johns Hopkins Center for Health Security, Professor, Environmental Health and Engineering, Johns Hopkins Bloomberg School of Public Health, Joint Appointment, Medicine, Johns Hopkins School of Medicine, USA

James Mulhall, Research Associate, Alliance to Feed the Earth in Disasters (ALLFED), UK

Dr. Wladimir Labeikovsky, Co-Founder & Head of Data Operations, Ribbon Bio, Vienna, Austria

Prof. Dr. Panagiotis L. Kastritis, Institute of Biochemistry and Biotechnology, Martin-Luther University Halle-Wittenberg; ERA Chair for cryo-EM, Institute of Chemical Biology, National Hellenic, Research Foundation, Athens, Greece

Sophie Peresson, International Biosecurity & Biosafety Initiative for Science, Switzerland

Luisa Prisecaru, LL.M., Legal Affairs Specialist, Ribbon Bio, Vienna, Austria

Dr. Erwan Sallard, Nuffield Departement of Medicine, University of Oxford, UK

Eloise Todd, Executive Director & Co-Founder, Pandemic Action Network, Belgium

—

References

1. NATO. (2025). *Science and Technology Trends 2025-2045*, p. 6. https://sto-trends.com/executive-summary/
2. Baker, D., & Church, G. (2024). *Protein design meets biosecurity*. Science, 383(6681), 349. DOI: https://doi.org/10.1126/science.ado1671
3. OECD. (2025). *Synthetic biology in focus: Policy issues and opportunities in engineering life.* OECD Science, Technology and Industry Working Papers. https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/02/synthetic-biology-in-focus_42893a6a/3e6510cf-en.pdf
4. Breyer et al. (2024). *WP8 Novel Threats. Synthetic Biology - Risk assessments and recommendations for future governance guidelines.* TERROR Joint Action co-funded by the Health Programme of the EU, p. 6. https://www.jaterror.eu/wp-content/uploads/2024/11/8.2-Risk-assessments-and-recommendations-on-governance-guidelines-of-the-use-of-synthetic-biology.pdf
5. CEPI. (2024). *CEPI Biosecurity Strategy*, p. 8. https://static.cepi.net/downloads/2024-09/CEPI%20Biosecurity%20Strategy_Sep%202024_Online%20Version.pdf
6. CERIS Expert Group. (2024). *Building resilience in the civil security domain based on research and technology.* European Union. https://op.europa.eu/en/publication-detail/-/publication/1796b0bd-ad38-11ef-acb1-01aa75ed71a1/language-en
7. Engineering Biology Research Consortium. (2025). *Strengthening a Safe and Secure Nucleic Acid Synthesis Ecosystem: Outcomes of EBRC Stakeholder Engagement.* DOI: https://doi.org/10.25498/E4311B
8. International Gene Synthesis Consortium (IGSC). (2024). *Harmonized Screening Protocol v3.0.*

https://genesynthesisconsortium.org/wp-content/uploads/IGSC-Harmonized-Screening-Protocol-v3.0-1.pdf

9. Responsible AI x Biodesign. (2024). *Commitments to Drive Responsible AI Development*. https://responsiblebiodesign.ai/#commitments
10. Rivera, S., Hanke, M. S., Curtis, S., Cherian, N., Gitter, A., Gray, J. J., … Haydon, I. C. (2025). *Responsible Biodesign Workshop: AI, Protein Design, and the Biosecurity Landscape – Recommended Actions*. OSF Preprints. DOI: https://doi.org/10.31219/osf.io/yq48e_v1
11. SecureDNA. (2025). *Precision DNA screening.* https://securedna.org/precision-dna-screening/
12. WHO. (2022). *The Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research.* World Health Organization. https://www.who.int/publications/i/item/9789240056107
13. Niinistö, S. (2024). *Safer Together - Strengthening Europe's Civilian and Military Preparedness and Readiness.* European Commission. https://commission.europa.eu/document/download/5bb2881f-9e29-42f2-8b77-8739b19d047c_en?filename=2024_Niinisto-report_Book_VF.pdf
14. European Commission. (2025). *EU preparedness union strategy.* https://commission.europa.eu/topics/preparedness_en
15. European Commission. (2025). *Commission presents a European internal security strategy.* https://commission.europa.eu/news/commission-presents-european-internal-security-strategy-2025-04-01_en
16. European Commission. (2019). *EU Dual Use Research guidance.* https://trade.ec.europa.eu/consultations/documents/consul_183.pdf