Priorities to Uphold European Biosecurity in 2025

July 2025

centre for future generations

rani

RAND EUROPE

POUR DEMAIN

IBBIS
International Biosecurity and Biosafety Initiative for Science

Introduction

The European Union (EU) is focused on making Europe a faster, easier, and more attractive place to discover, develop, and manufacture biotechnology solutions. Safeguarding the wins from upcoming initiatives — increased productivity, larger innovation and scale, greater access to computing power — requires the EU to also increase its focus on biosecurity.

Biological threats — naturally occurring or manmade — are an increasing threat to the EU in our shifting geopolitical climate. The shifting security landscape also means Europe needs to strengthen its approach to chemical, biological, radiological, and nuclear materials (CBRN) risks, and understand what tomorrow's threats will be before they arrive. While COVID-19 put the spotlight on epidemics growing into global pandemics, attention must also be paid to the risks to Europe from the evolving biotechnology and biosecurity landscape.

The risks of the EU being subjected to a disease are increased by climate change, changing human interactions with nature, and by global travel. In addition, new technologies are transforming how humans interact with and gain access to biological agents. Advances in biotechnology, Artificial Intelligence (AI), and the capacity to engineer biological components of life, increase possibilities for scientific progress and innovation. However, these innovations also bring heightened risks of the release of biological agents either by accident or through weaponisation. These concerns are echoed by the Joint Action TERROR assessment, a collaborative effort representing 31 institutions across 17 European countries, which explicitly warns that "the accelerated technological developments within this field, combined with the widespread availability of knowledge and technology, raise concerns about the potential for misuse or the possibility of an intended incident".[1]

The countries with the largest biotechnology sectors globally have already established comprehensive frameworks that capitalise on biotechnology's capabilities to advance their economic and defense interests. These same actors have recognised the need to protect their technological and industrial base by advancing comprehensive biosecurity strategies. Harnessing the potential of this new technological landscape requires Europe to strengthen its collective biosecurity capacity — through strategic monitoring and oversight for the most pressing risks, and fostering safe-by-design approaches.

Overview of Biosecurity Landscape in the EU

The biotechnology landscape in the EU and globally is evolving at a rapid pace. Gene sequencing costs have dropped 180,000x since 2001[2], making technology widely accessible and enabling scientists and technological experts to understand more about human biology and virus pathology than ever before. The OECD predicts that within the next 5 years, "next-generation genome editing tools that are more accurate, efficient, and versatile could enable precise modifications at multiple genomic sites simultaneously, facilitating complex genetic reprogramming for new therapeutics or creating engineered microorganisms

[1] Didier Breyer et al. *D8.2: Synthetic Biology - Risk assessments and recommendations for future governance guidelines* (EU Joint Action Terror, 2024), 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

[2] "The cost of 66 different technologies over time." *Our World in Data*, December 12, 2023. https://ourworldindata.org/grapher/costs-of-66-different-technologies-over-time?country=~DNA+sequencing

with new capabilities whilst reducing errors."[3] Put simply by experts at RAND, "Biotechnology will continue to become more readily available, more capable, easier to use, and less expensive and require a smaller footprint."[4]

At the same time, AI and machine learning are continuing to shake up the technology landscape, with applications to facilitate rapid and more democratised access to ever larger datasets. This holds promise for increased information sharing, new possibilities for global scientific participation, and leveraging existing research for new gains.

But while these rapid advances in bio- and other converging technologies create tremendous new opportunities for human health and development, there is also increasing risk that these advances could be misused to cause harm — deliberately or inadvertently. In his report to the European Commission on how to enhance Europe's civilian and defence preparedness and readiness, Former Finnish Prime Minister Sauli Niinistö stated that, "Another pandemic remains a distinct possibility to be prepared for, given the possibility of transmutations of animal viruses, as well as accelerating biotechnological innovation facilitating the development of synthetic pathogens."[5] New biotechnology possibilities, aided by AI-driven systems are "creating new risks" for "future health preparedness and weaponisation by State or non-State actors."[6] Experts from the Community for European Research and Innovation for Security have also identified the possibility of bioterrorism attacks among the top ten security priorities.[7]

While experts acknowledge the increasing biosecurity risks posed by new technologies, including synthetic DNA, regulation is piecemeal and designed for a different and older set of technological capabilities. Currently companies and laboratories undertaking DNA synthesis technologies self-regulate. The International Gene Synthesis Consortium[8] (IGSC) is a well-intentioned global effort that brings together many firms working in the field to agree on and advance screening standards, however, not all DNA synthesis providers are part of the consortium, and this approach yields the regulation of potentially dangerous substances to a voluntary, industry-led process with only limited oversight. The World Health Organization's 2022 Global Guidance Framework for the responsible use of the life sciences highlighted DNA synthesis as a critical and illustrative example of challenges and gaps in the governance of biorisks.[9]

---

[3] Douglas KR Robinson and Daniel Nadal. *Synthetic biology in focus: Policy issues and opportunities in engineering life* (OECD Science, Technology and Industry Working Papers, 2025), 11. https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/02/synthetic-biology-in-focus_42893a6a/3e6510cf-en.pdf

[4] Daniel M. Gerstein, Bianca Espinosa and Erin N. Leidy. *Emerging Technology and Risk Analysis- Synthetic Pandemics* (RAND, 2024). https://www.rand.org/pubs/research_reports/RRA2882-1.html

[5] Sauli Niinistö. *Safer Together- Strengthening Europe's Civilian and Military Preparedness and Readiness* (European Commission, 2024) 16. https://commission.europa.eu/document/download/5bb2881f-9e29-42f2-8b77-8739b19d047c_en?filename=2024_Niinisto-report_Book_VF.pdf

[6] Niinistö. *Safer Together*. 33.

[7] CERIS Expert Group. *Building resilience in the civil security domain based on research and technology* (European Union, 2024). https://op.europa.eu/en/publication-detail/-/publication/1796b0bd-ad38-11ef-acb1-01aa75ed71a1/language-en

[8] "International Gene Synthesis Consortium." 2020. https://genesynthesisconsortium.org/

[9] Chief Scientist and Science Division. *The Global guidance framework for the responsible use of the life sciences: mitigating biorisks and governing dual-use research* (WHO, 2022). https://www.who.int/publications/i/item/9789240056107

As stressed in the Biosecurity Strategy for the Coalition for Epidemic Preparedness Innovation (CEPI)[10], in this dynamic technological environment, it is urgent 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 to cause harm."[11]

In line with CEPI and other expert analysis, three key considerations make urgent action on biosecurity imperative:

- The **rapid pace of change in the biotechnology sector** is set to continue, driven by advances in AI-powered biological tools, requiring ongoing risk assessments for biosecurity gaps and needs;
- **Different and changing abilities to access dangerous biological materials and fragments of high-consequence pathogens**, especially compared to other hazardous materials, continues to fuel risk of dangerous substances being misused;
- **Notably different levels of biosafety and biosecurity oversight, regulation, management, and risk mitigation** across jurisdictions and around the world creates a fragmented system that can allow core biosecurity risks to fall through the cracks in areas with limited oversight.

Together, these realities demand a European system built to continuously monitor and adapt to the promises and risks of a rapidly changing technological landscape, enshrine good governance and best practices for biosafety and biosecurity, and comprehensively and collectively address biological threats.

Policy Priorities for Near-term Action

As noted by the OECD, "biosecurity and biosafety hinges on fostering a culture of responsibility across all research stages and stakeholders." Recognising both the promise of new biotechnology advances, the potential for dangerous misuse, and critical gaps in the ecosystem, the EU must prioritise the following actions:

- **Advance a strategic biosecurity approach across EU initiatives.** Proactive coordination and promotion of biosecurity considerations across all relevant initiatives will allow Europe to both capitalise on its investment and focus on biotechnology and life sciences, and bolster European safety and security. Through coordinated efforts across civil preparedness, foreign and security policy, health, and defence, the EU should systematically outline strengths and gaps in biosecurity and biodefence competencies, and advance proposals to ensure the EU is equipped to counter the realities of biosecurity and bioweapons threats in 2025 and beyond.

- **Bolster prioritisation and funding for biosecurity efforts, including linking research funding to commitments for risk identification and mitigation. EU leaders must:**
    - **Elevate biosecurity as a strategic priority for national security policy-making and investments.** This includes updating and advancing targeted action plans and policies, such as the EU Action Plan for Chemical, Biological, Radiological, and Nuclear threats (CBRN), as well as advancing funding to advance and uphold biosafety and biosecurity through both health and defence spending.

[10] *CEPI Biosecurity Strategy* (CEPI, 2024) https://static.cepi.net/downloads/2024-09/CEPI%20Biosecurity%20Strategy_Sep%202024_Online%20Version.pdf
[11] *CEPI Biosecurity Strategy* (CEPI, 2024) 8.

- **Link funding from EU institutions supporting research with potentially high-consequence pathogens to adherence to biosecurity standards and protocols.** Biosecurity and biosafety must be incorporated into decision-making on funding proposals, especially biotechnology work at the AI interface.[12]

- **Reduce emerging risks in the biotechnology technology landscape, with particular attention to risks at the biotechnology and AI interface. EU leaders must:**
  - **Establish a permanent expert group within the EU Commission to continuously monitor and address emerging biosecurity challenges.** As opportunities and challenges in the biotechnology landscape continue to change at a rapid pace, compounded with rapid developments in converging technologies like AI, it is essential that European leaders have a continual, up-to-date assessment of advances and risks to inform policy and investment decisions.
  - **Advance oversight for synthesis screening, as well as tools to counter AI-aided efforts to camouflage access to and use of risky sequences of concern.** The EU currently lacks regulation to oversee DNA synthesis screening, which provides room for unmonitored access to and use of synthetic genetic materials capable of fueling a dangerous outbreak — including by nefarious actors. It is critical that the EU takes steps to protect against dangerous misuse of nucleic acid sequences. Action now would put the EU in a position of helping define international standards. Decision-makers should also consider advancing tools to address new risks of AI masking the use of and access to pathogen sequences that are high-risk.
  - **Mandate timely and comprehensive risk assessments by biological tool developers.** To ensure proper handling and protection against potential misuse — accidental or deliberate — all those working with potentially high-risk pathogens and/or AI biological tools that can equip others with high risk of misuse capabilities, must complete up-to-date and comprehensive risk assessments, taking into account changes in a dynamic biotechnology landscape. Such assessments are outside of the scope of the EU AI Act.
  - **Contribute to international coordination efforts to manage access to highly sophisticated biological design tools.** Stakeholders with access to highly sophisticated tools — with tremendous potential for both positive and nefarious use — must undergo thorough review and operate with the highest standards of biosafety and biosecurity when considering international deployment of their tools.
  - **Update EU guidelines for dual-use research of concern.** Current EU guidelines for dual-use research of concern were written in 2019.[13] Guidelines must be up-to-date and reflect current challenges and risks in the biotechnology landscape, especially those advanced by AI.

[12] Pour Demain. *Biotech: Make it safe to maximize progress.* October 29, 2024. https://www.pourdemain.ngo/en/post/biotech-make-it-safe-to-maximize-progress-1
[13] "EU Dual Use Research guidance." European Commission, 2019. https://trade.ec.europa.eu/consultations/documents/consul_183.pdf

Conclusion

Europe is readying itself to seize the transformative opportunities for growth, innovation, and strategic advantage that advances in biotechnology can bring. Fully realising and safeguarding these opportunities requires proactive biosecurity direction and oversight in the policy realm. As stressed by the Centre for Future Generations, "Good governance of developments in biotechnology is a vital part of safeguarding against the risk of bioweapons. As these technologies improve and become more accessible outside of regulated research laboratories, more groups could potentially use them to cause widespread damage."[14]

For the EU to appropriately balance both the tremendous promises and challenges of biotechnology, it is critical to advance the comprehensive planning, structures, and investments to respond to the risks we know now and stay attuned to risks of the future. A concerted effort to embed priorities to uphold European biosecurity will enable Europe to embrace and shape the future technological landscape.

[14] Braza and Noriega. "Biotechnology and the next pandemic part 1- Historical biothreats."