July 2025

# Biotechnology: Advancing Germany's and Europe's Security

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# Overview

Biotechnology, or the leveraging of biological processes for technological advancement, is poised to transform key sectors of strategic national interest, including defense, healthcare, energy and agriculture. The rapid advancement of synthetic biology is driving innovation across the field, while a convergence with artificial intelligence (AI) is drastically lowering barriers to entry. This progress holds great promise for delivering societal and economic benefits like tackling health, food, biodiversity, and climate crises, but it also introduces complex risks and policy challenges.

From a security perspective, biotechnology presents four issues on which Germany and Europe need to take more deliberate action than has been taken to date. First, biotechnology opens up new avenues for military capability development that include enhancing warfighter performance and substituting or augmenting materials used for weapons and equipment. Second, it creates novel biosecurity and biosafety vulnerabilities, as state and non-state actors can use synthetic biology methods to deliberately design and deploy enhanced pathogens (in violation of established international norms) or to conduct research that could inadvertently result in the release of such pathogens. Third, because the development and deployment of biotechnologies rely on the collection of vast amounts of sensitive genomic data — data that is often inadequately protected — it can expose individuals and society to novel forms of espionage and sabotage. Lastly, the flipside of the technology's vast economic potential across sectors is new possibilities for economic statecraft and weaponization of interdependencies, especially given the great lengths the United States and China are willing to go to prevail in the field.

Europe holds a significant position in the global biotech landscape, mainly thanks to its strong research base, yet it faces mounting challenges compared to the US and China in terms of commercialization and adoption. The US leads in these regards thanks to substantial government and private sector funding, as well as its favorable regulatory environment. China, meanwhile, is investing heavily in state-driven initiatives that foster rapid advancement toward global leadership in the field, leveraging competition among researchers and businesses within a politically controlled setup. To keep pace, Europe must create a more conducive environment for biotech innovation, notably in terms of mobilizing public as well as private funding and fostering commercialization. At the same time, it must address escalating risks to its national and economic security, clarifying its ambitions in military capabilities, bolstering biosecurity and biosafety, safeguarding sensitive data, and reducing exposure to economic coercion and technological dependencies.

# Understanding Biotechnology

The Organisation for Economic Co-operation and Development (OECD) defines biotechnology as the "application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."[1] Biotechnology covers a multitude of use cases across several sectors, including healthcare, particularly disease prevention, diagnosis and treatment (e.g., developing [personalized] medicine or therapies); industrial production using living cells, including in the manufacture and processing of chemicals (e.g., biopolymers), materials

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[1] Friedrichs, Steffi and van Beuzekom, Brigitte, 2018, "Revised Proposal for the Revision of the Statistical Definitions of Biotechnology and Nanotechnology," OECD, p. 8, https://doi.org/10.1787/085e0151-en.

and energy (e.g., more sustainable biofuels); agriculture and food production, such as the development of transgenic or genetically modified organisms (e.g., to improve pest resistance or increase tolerance to adverse climate conditions), biofertilizers and alternative protein sources; and environmental, with applications like biosensing (e.g., toxin detection) and bioremediation.[2] "We are entering the age of biotechnology, a time when biology is the basis of innovation," reads the final report of the US National Security Commission on Emerging Biotechnology; "Every strategic sector — including defense, healthcare, agriculture, energy, and manufacturing — can be advanced by biotechnology."[3]

Biotechnology innovation is driven not only by its potentially enormous direct economic impact — which one 2020 McKinsey study estimated to be as high as $2-4 trillion per year globally over the next two decades[4] — but also by its capacity to address some of the world's most pressing challenges. Besides enabling novel products and making production processes cheaper and more efficient, biotechnology applications across sectors can help people and the planet cope with extreme climate or reduce the environmental impact of the goods and services produced. They do so by improving the circularity and sustainability of the bioeconomy (the system of economic activity generated with biological resources).[5]

**Synthetic biology is projected to have a disruptive, revolutionary impact in the civilian and military realms within the next 20 years.**

Many biotechnology use cases are driven by innovations in genetic engineering. Genetic engineering, broadly, refers to the manipulation of an organism's genome.[6] Synthetic biology (synbio; sometimes also called engineering biology), a multidisciplinary field within biotechnology[7] that builds on classical molecular-biological modification, is drastically changing what is possible and it is projected to "have a disruptive, revolutionary impact within the next 20 years, in both the civilian and military realm."[8] Setting it apart from traditional genetic engineering focused on modifying a small number of genes, synbio involves combining existing genes and transferring them into production organisms (redesign) in an ever quicker, cheaper, more accurate, and more reliable way, allowing for far more sophisticated modifications.[9] It also encompasses the design and creation of novel synthetic (i.e., artificial) biological organisms or

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[2] For an overview of current and projected use cases see: Robinson, Douglas and Nadal, Daniel, 2025, "Synthetic Biology in Focus: Policy Issues and Opportunities in Engineering Life," OECD, pp. 11—24, https://doi.org/10.1787/3e6510cf-en; DiEuliis, Diane, Imperiale, Michael, and Berger, Kavita, 2024, "Biosecurity Assessments for Emerging Transdisciplinary Biotechnologies: Revisiting Biodefense in an Age of Synthetic Biology," *Applied Biosafety* 29, no. 3, p. 1, https://doi.org/10.1089/apb.2024.0005.

[3] National Security Commission on Emerging Biotechnology, 2025, "Charting the Future of Biotechnology: An Action Plan for American Security and Prosperity," p. 7, https://www.biotech.senate.gov/wp-content/uploads/2025/04/NSCEB-Full-Report-%E2%80%93-Digital-%E2%80%934.28.pdf.

[4] Chui, Michael, Evers, Matthias, Manyika, James, Zheng, Alice, and Nisbet, Travers, 2020, "The Bio Revolution: Innovations Transforming Economies, Societies, and Our Lives," McKinsey, p. 8, https://www.mckinsey.com/~/media/mckinsey/industries/life%20sciences/our%20insights/the%20bio%20revolution%20innovations%20transforming%20economies%20societies%20and%20our%20lives/may_2020_mgi_bio_revolution_report.pdf.

[5] Yang, Ana, Throp, Henry, and Sherman, Suzannah, 2024, "How Strategic Collaboration on the Bioeconomy Can Boost Climate and Nature Action," Chatham House, pp. 4—13, https://doi.org/10.55317/9781784136253.

[6] McMillan, Fiona, Ilsley, Jane, Adams, Bronwyn, and Heinemann, Jessica, 2019, "The Littlest Factories: From Genes to Enzymes, How Do Cells Make Products We Use?" University of Queensland, p. 11, https://aibn.uq.edu.au/files/20188/STBC%20-%20Volume%201%20-%20Advanced%20Biomanufacturing-web.pdf.

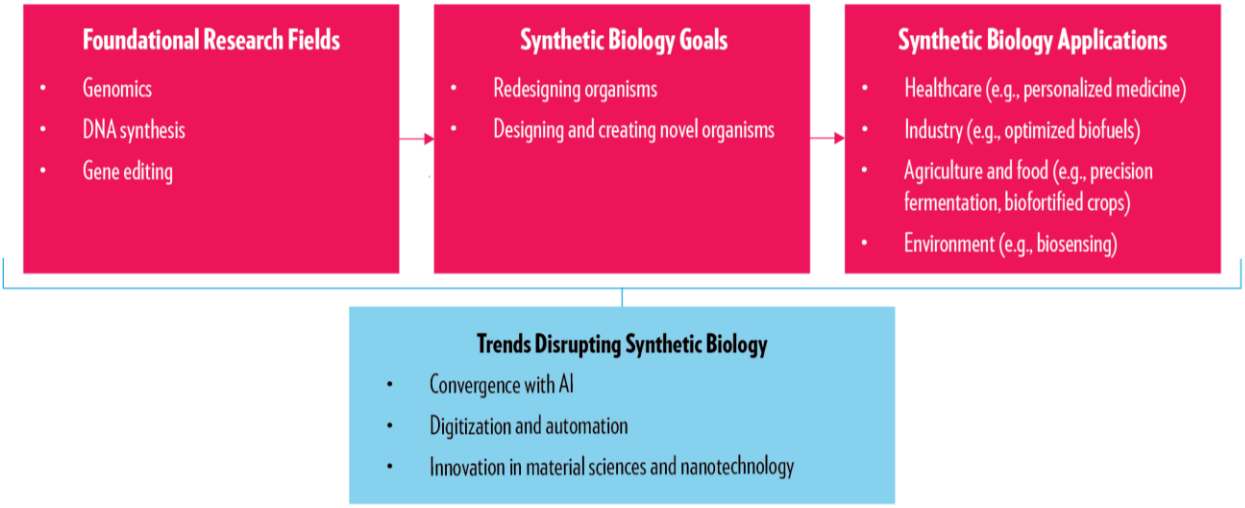
[7] Robinson and Nadal, 2025, "Synthetic Biology in Focus: Policy Issues and Opportunities in Engineering Life," p. 9

[8] Sweeney, Jordan, Bayliss, Daniel, Butcher, Fiona, Calabro, Salvatore, Cox, Lucas et al., 2025, "Science and Technology Trends 2025-2045," NATO, p. 6, https://www.nato.int/nato_static_fl2014/assets/pdf/2025/4/pdf/250409-STO-Trends-en.pdf.

[9] Roberts, M. A. J., Cranenburgh, R. M., Stevens, M. P., and Oyston P. C. F., 2013, "Synthetic Biology: Biology by Design," *Microbiology* 159, no. 7, 1219—20, https://doi.org/10.1099/mic.0.069724-0; Sauter, Arnold, Albrecht, Steffen, von Doren, Davy, König, Harald, Reiß, Thomas et al., 2015, "Synthetic biology - the next phase of biotechnology and genetic engineering," Office of Technology Assessment at the German Bundestag, https://publikationen.bibliothek.kit.edu/1000134320.

systems. While this capability is already partially realized (e.g., minimal synthetic cells), fully *de novo* artificial life is only projected to become possible in the long term.[10]

Figure 1. Overview of Synthetic Biology




Synbio is at the core of fundamental transformations in biotechnologies that drastically aggravate its foreign and security policy relevance, integrating progress in three research fields (see Figure 1):

- Genomics, the study of the entire genome of an organism, including the mapping of all its genes, their functions, and its structure. Key here is sequencing, which involves determining the exact order of nucleotides in a gene or the entire genome. Sequencing has become rapidly cheaper and decentralized in the past two decades, since the Human Genome Project first decoded the human genome sequence in 2000.[11] As a consequence, large amounts of genomic data can now be collected relatively quickly.

- Gene synthesis, the practice of creating DNA sequences, has seen jumps in ease-of-use, accuracy and efficiency alongside more limited drops in costs. Notwithstanding, writing DNA remains several orders of magnitude more expensive than reading it.[12]

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[10] J. Craig Venter Institute, n.d. "First Minimal Synthetic Bacterial Cell," accessed June 02, 2025, https://www.jcvi.org/research/first-minimal-synthetic-bacterial-cell; Robinson and Nadal, 2025, "Synthetic Biology in Focus: Policy Issues and Opportunities in Engineering Life," p. 11; Sauter et al., 2015, "Synthetic biology - the next phase of biotechnology and genetic engineering.

[11] Grinstein, Jonathan, 2023, "The Long and Winding Road: On-Demand DNA Synthesis in High Demand," *Genetic Engineering and Biotechnology News,* July 27, 2023 https://www.genengnews.com/topics/genome-editing/the-long-and-winding-road-on-demand-dna-synthesis-in-high-demand/; Lin, Herbert S. and Giles, Martin, 2025, "The Stanford Emerging Technology Review 2025," Stanford University, p. 41, https://setr.stanford.edu/sites/default/files/2025-01/SETR2025_web-240128.pdf; National Human Genome Research Institute, 2021, "The Cost of Sequencing a Human Genome," accessed May 15, 2025, https://www.genome.gov/about-genomics/fact-sheets/Sequencing-Human-Genome-cost; Shinomiya, Nariyoshi and Tanaka, Kiwako , 2025, "The Security Implications of Developments in Biotechnology," International Institute for Strategic Studies, p. 6, https://www.iiss.org/globalassets/media-library---content--migration/files/research-papers/2025/02/the-security-implications-of-developments-in-biotechnology-report.pdf.

[12] Braza, Faouzi and Noriega, Ashley, 2025, "Biotechnology and the next pandemic part 2: innovation or threat?" Centre for Future Generations, accessed April 8, 2025, https://cfg.eu/biotechnology-and-the-next-pandemic-part-2-innovation-or-threat/; Carlson, Rob, 2025, "DNA Synthesis and Sequencing Costs and Productivity for 2025," Synthesis, accessed June 03, 2025, https://www.synthesis.cc/synthesis/2025/5/dna-synthesis-and-sequencing-costs-and-productivity-for-

- Gene editing, refers to making precise modifications to DNA sequences. This field has been revolutionized by the CRISPR/Cas9 method, which uses RNA to direct the Cas9 protein to make cuts at specific spots in repeated DNA sequences. The cell's own DNA repair mechanism is then used to insert, delete and replace certain DNA segments, including with synthesized ones. CRISPR/Cas9 has significant advantages over previous methods, including ease of use, speed and cost-efficiency.[13] Ongoing research aims to further reduce unintended changes at non-targeted sites in the genome (off-target effects).[14]

These tools are projected to become even more accurate, efficient, versatile, and affordable in the coming years.[15]

# Intersection of Biotechnology with Other Tech Fields

**Recent and ongoing advances in AI are considered one of the single greatest enablers of scientific progress in biotechnologies.**

Biotechnology benefits from innovations in, and increasing convergence with, other technological domains. At the most fundamental level, this reflects the accelerating digitization and automation of biotech research and applications, which is part of a broader trend known as biodigital convergence.[16] A clear example of this is biofoundries: facilities that automate physical assembly and testing in synbio, helping to accelerate research and reduce costs.[17] Cloud labs are another advancement. These highly automated off-site research facilities allow researchers to plan and conduct entire experiments across a range of scientific disciplines and have already seen some adoption in the pharmaceutical industry.[18] Finally, biocomputing leverages cells and cellular components for computational tasks like storing, retrieving and processing data.[19]

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2025; Grinstein, Jonathan D., 2023, "The Long and Winding Road: On-Demand DNA Synthesis in High Demand."; Hoose, Alex, Vellacott, Richard, Storch, Marko, Freemont, Paul S., and Ryadnov, Maxim G., 2023, "DNA Synthesis Technologies to Close the Gene Writing Gap," *Nature Reviews Chemistry* 7, no. 3, 144—61, https://doi.org/10.1038/s41570-022-00456-9; Hughes, Randall A. and Ellington, Andrew D., 2017, "Synthetic DNA Synthesis and Assembly: Putting the Synthetic in Synthetic Biology," *Cold Spring Harbor Perspectives in Biology* 9, no. 1, a023812, https://doi.org/10.1101/cshperspect.a023812; Langenkamp, Max, 2024, "Securing Benchtop DNA Synthesizers," Institute for Progress, accessed April 24, 2025, https://ifp.org/securing-benchtop-dna-synthesizers/.

[13] Gaj, Thomas, Sirk, Shannon, J., Shui, Sai-lan, and Liu, Jia, 2016, "Genome-Editing Technologies: Principles and Applications," *Cold Spring Harbor Perspectives in Biology* 8, no. 1, a023754, https://doi.org/10.1101/cshperspect.a023754.

[14] Albrecht, Steffen, König, Harald, and Sauter, Arnold, 2021, "Human genome editing," Office of Technology Assessment at the German Bundestag, https://publikationen.bibliothek.kit.edu/1000141085; Roberts, Rebecca, 2025, "Alternatives to CRISPR-Cas9: Nucleases for Next-Gen Therapy," Synthego, https://www.synthego.com/blog/alternatives-to-crispr-cas9-nucleases-for-next-gen-therapy#alternatives-to-crispr-cas-9-in-therapeutic-development.

[15] Robinson and Nadal, 2025, "Synthetic Biology in Focus: Policy Issues and Opportunities in Engineering Life," p. 11; Roche, 2025, "Roche Unveils a New Class of Next-Generation Sequencing with Its Novel Sequencing by Expansion Technology," accessed May 26, 2025, https://www.roche.com/investors/updates/inv-update-2025-02-20.

[16] Government of Canada, 2024, "The Biodigital Convergence: Cross-Cutting Policy Implications," accessed April 23, 2025, https://horizons.service.canada.ca/en/2024/12/24/biodigit-convergence-implication/index.shtml.

[17] Bobier, Jean-Francois, Cerisy, Tristan, Coulin, Anne-Douce, Bleecher, Crystal, Sassoon, Victoria et al., 2024, "Breaking the Cost Barrier in Biomanufacturing," Boston Consulting Group, pp. 3—4, https://doi.org/10.1089/ind.2024.58943.jfb; Holowko, Maciej B., Frow, Emma K., Reid, Janet C., Rourke, Michelle, and Vickerset, Claudia E., 2021, "Building a biofoundry," *Synthetic Biology* 6, no. 1, ysaa026, https://doi.org/10.1093/synbio/ysaa026.

[18] Arias, D. Sebatian and Taylor, Rebecca E., 2024, "Scientific Discovery at the Press of a Button: Navigating Emerging Cloud Laboratory Technology," *Advanced Materials Technologies* 9, no. 16, 2400084, https://doi.org/10.1002/admt.202400084.

[19] Chui et al., 2020, "The Bio Revolution: Innovations Transforming Economies, Societies, and Our Lives," pp. 151—53.

Recent and ongoing advances in AI will be among the greatest enablers of scientific progress in biotechnologies in the near future. AI has already spurred innovations across subfields.[20] Bioinformatics tasks, such as analyzing and interpreting large amounts of data, predicting biological outcomes, mathematical modelling, and computer-aided design and analysis, are now being transformed by AI. Currently, two broad categories of AI applications in biotechnology can be distinguished: foundational models and AI-enabled biological tools.

- Foundational models: These classic large language models (LLMs) significantly lower the access barrier to design, plan and execute scientific experiments by distilling public information into actionable steps.[21]

- AI-enabled biological tools: These are models that have been trained on biological data (e.g., amino-acid sequences of proteins).[22] Among them are biodesign tools that can design new proteins or predict the three-dimensional structure of a protein from the sequence of its amino acids. Deepmind's Alphafold is the most prominent example.[23] There are also non-design tools such as host-pathogen interaction prediction tools, experimental planning or simulation tools, or AI-enabled biosensing tools, where AI assists in the selection of suitable biomarkers, signal transduction and analysis and interpretation of data.[24]

Combining these two elements, AI's capacity to facilitate analysis, pattern recognition, inference and prediction enables it to fundamentally enhance the entire design-build-test-learn cycle in biotechnology.

Downstream biotech applications will also become more accessible due to innovations in material sciences. Techniques like 3D bioprinting can be applied in drug discovery or tissue regeneration in the short term, while offering solutions to broader health and environmental challenges in the longer term.[25] Similar to AI, innovations in nanotechnology could have an

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[20] Holzinger, Andreas, Keiblinger, Katharina, Holub, Petr, Zatloukal, Kurt, and Müller, Heimo, 2023, "AI for Life: Trends in Artificial Intelligence for Biotechnology," *New Biotechnology* 74, 16—24, pp. 17—20, https://doi.org/10.1016/j.nbt.2023.02.001; National Security Commission on Emerging Biotechnology, 2024, "White Paper 2: Emerging Technologies," https://www.biotech.senate.gov/wp-content/uploads/2024/01/NSCEB_AIxBio_WP2_Examples.pdf.

[21] Boiko, Daniil A., MacKnight, Robert, and Gomes, Gabe, 2023, "Emergent Autonomous Scientific Research Capabilities of Large Language Models," Cornell University ArXiv, https://doi.org/10.48550/arXiv.2304.05332.

[22] Rose, Sophie, Moulange, Richard, Smith, James, and Nelson, Cassidy, 2024, "The Near-Term Impact of AI on Biological Misuse," Centre for Long-Term Resilience, p. 10, https://doi.org/10.71172/1ktf-xpxm.

[23] Jumper, John, Evans, Richard, Pritzel, Alexander, Green, Tim, Figurnov, Michael et al., 2021, "Highly Accurate Protein Structure Prediction with AlphaFold," *Nature* 596, 583—89, https://doi.org/10.1038/s41586-021-03819-2.

[24] Flynn, Connor D. and Chang, Dingran, 2024, "Artificial Intelligence in Point-of-Care Biosensing: Challenges and Opportunities," *Diagnostics* 14, no. 11, 1100, https://doi.org/10.3390/diagnostics14111100; Rose, Sophie and Nelson, Cassidy, 2023, "Understanding AI-Facilitated Biological Weapon Development," Centre for Long-Term Resilience, pp. 5—6, https://www.longtermresilience.org/wp-content/uploads/2024/09/AI-Facilitated-Biological-Weapon-Development-Website-Copy-1.pdf.

[25] Brockmann, Kolja, Bauer, Sibylle, and Boulanin, Vincent, 2019, "BIO PLUS X: Arms Control and the Convergence of Biology and Emerging Technologies," Stockholm International Peace Research Institute, pp. 5—12, https://www.sipri.org/sites/default/files/2019-03/sipri2019_bioplusx_0.pdf; Harley, William S., Li, Chi Chung, Toombs, Joseph, O'Connell, Cathal D., Taylor, Hayden K. et al., 2021. "Advances in Biofabrication Techniques towards Functional Bioprinted Heterogeneous Engineered Tissues: A Comprehensive Review," *Bioprinting* 23: e00147, https://doi.org/10.1016/j.bprint.2021.e00147; MacAdam, Aidan, Chaudry, Emaan, McTiernan, Christopher D., Cortes, David, Suuronen, Erik J. et al., 2022, "Development of in Situ Bioprinting: A Mini Review," *Frontiers in Bioengineering and Biotechnology* 10, 940896, https://doi.org/10.3389/fbioe.2022.940896.

enormous impact across biotechnology applications.[26] Nanotechnology's focus on the fabrication and utilization of nanoscale, biocompatible synthetic materials and devices suggests that further integration of both technology domains will offer new ways to manipulate biological systems, improve biosensing or deliver drugs.[27]

# Europe's Struggle to Translate Research Excellence into Biotech Leadership

Globally, biotechnology research and industry activity are mainly concentrated in North America, East Asia and Europe. Based on the overall volume of scientific outputs, clinical trials, patent filings, and investment, it is clear that Europe is falling behind the US — and increasingly, China — despite its strong individual research institutions and companies. It struggles to translate scientific potential into practical use and commercial success, due in part to lower public investment and difficulties in mobilizing private capital to scale up innovations.

## Global Research and Development Landscape

A 2024 index in *Nature* found that the US is dominating biological sciences: it is home to 47 of the top 100 global institutes in this field, compared to just 17 in China and only 13 in the European Union (or 23 in Europe, if the United Kingdom, Switzerland and Norway are included).[28] In a 2022 analysis of the top 10 percent of most-cited scientific publications in the fields of biotechnology and genetics, conducted by the OECD, the EU ranked third globally (if the UK, Switzerland and Norway were included in Europe's numbers, it would have come in second).[29] According to this analysis, the EU accounted for an average of 15.2 percent of the top 10 percent of most-cited papers (or 20.2 percent with the UK, Switzerland and Norway), behind China (43.5 percent) and the US (17.3 percent), with China registering a surge in scientific output in recent years amid steadily declining numbers in the EU and the US. Germany is the top performer in the EU, accounting for 3.6 percent of the most influential papers in these fields, thanks to its strong research institutions like the Max Planck Society and Helmholtz Association of German Research Centers; however, Germany still ranks below countries like India and the UK according to this metric. Other trackers of high-impact research outputs also list China

**Europe is falling behind the US and increasingly, China, despite having strong individual research institutions and companies.**

[26] Winstead, Nicholas, 2020, "The Applications and Implications of Nanotechnology," American University, accessed April 15, 2025, https://www.american.edu/sis/centers/security-technology/the-applications-and-implications-of-nanotechnology.cfm.

[27] Fernandes, Rúben, 2025, "The Convergence of Nanotechnology and Biotechnology in Modern Medicine," *Nanomaterials* 15, no. 3, 182, https://doi.org/10.3390/nano15030182; Goswami, Akul, Garg, Sandini, Bhatt, Ekta, Chaudhary, Vishal, and Danget, Shweta, 2024, "Review—Nanotechnology-Based Biosensors for Biomedical Applications," *Journal of The Electrochemical Society* 171, no. 9, 097508, https://doi.org/10.1149/1945-7111/ad7908.

[28] Nature, 2025, "2024 Research Leaders: Leading Institutions in Biological Sciences," accessed May 9, 2025, https://www.nature.com/nature-index/research-leaders/2024/institution/all/biological-sciences/global.

[29] OECD, n.d., "Bibliometric Indicators, by Field," accessed May 5, https://rb.gy/za48qn.

and the US as the two dominant players in biotechnology across subfields.[30] China's dominance in synbio is particularly pronounced.

In another sign of dominance within early-phase research and development, a 2023 survey found that biopharma companies headquartered in the US and China accounted for 34 percent and 28 percent, respectively, of clinical trials launched globally. This puts them both ahead of Europe, which accounted for just 23 percent.[31] This reflects a marked change from just ten years earlier: back in 2013, China's share of biopharma clinical trials accounted for just 3 percent of the global total, while Europe was responsible for 38 percent.

When it comes to patents, the US and Chinese applicants once again top the charts. In 2024, they ranked first and second globally, with 36.4 percent and 19.1 percent of Patent Cooperation Treaty (PCT) biotechnology patent publications filed, respectively.[32] The EU ranked third, with 14.3 percent (or 21.6 percent in the whole of Europe), followed by Japan (9.2 percent) and South Korea (7.4 percent). Within the EU, Germany and France are responsible for most patents across biotech subfields.[33] As with the other metrics of impact, China's share of patents has increased significantly in the past decade from just 4.9 percent in 2014, while the European share saw a marked decrease over the same period.[34] Figures from the World Intellectual Property Organization (WIPO) on direct national filings also show Chinese and US entities ranking far ahead of Europe in terms of patent grants.[35] While in the past, patents granted in China were primarily filed in other countries before being filed in China, China has developed into a prominent primary location for patent protection.[36] Interestingly, EU member states have been found to have a significantly higher ratio of patents being filed by foreign entities compared to the US.[37]

## Global Commercial Landscape

Assessing the funding and investment landscape in biotechnology is less easy, as data is often not granular enough. Yet, available data for public funding for medical research shows that the US government spent several times the amount of the EU from 2017 to 2021.[38] Beijing, for its part, is estimated to have spent more than $100 billion on life sciences research and development (R&D) in total and above 2.6 billion euros on biotechnology research in 2023.[39]

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[30] Wong Leung, Jennifer, Robin, Stephan, and Cave, Danielle, 2024, "ASPI's Two-Decade Critical Technology Tracker:The rewards of long-term research investment," Australian Strategic Policy Institute, p. 43. https://ad-aspi.s3.ap-southeast-2.amazonaws.com/2024-08/ASPIs%20two-decade%20Critical%20Technology%20Tracker_1.pdf?VersionId=1p.Rx9MIuZyK5A5w1SDKIpE2EGNB_H8r.

[31] IQVIA, 2024, "Global Trends in R&D 2024: Activity, Productivity, and Enablers," p. 16, https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2024-activity-productivity-and-enablers.

[32] WIPO, 2025, "PCT - 5a - PCT Publications by Technology," https://rebrand.ly/871ul3e.

[33] Reiß, Thomas, Aichinger, Heike, Bührlen, Bernhard, Frietsch, Rainer, Kroll, Henning, 2023, "Technologische Souveränität Pharma/Biotech: Studie zur Wettbewerbsfähigkeit und technologischen Souveränität Deutschlands im Pharmasektor," p. 33, 44, 54, 64, 74, https://publica-rest.fraunhofer.de/server/api/core/bitstreams/9cad240b-d77c-455d-b0b4-5eb7de9269bf/content.

[34] WIPO, 2025, "PCT - 5a - PCT Publications by Technology."

[35] WIPO, 2025, "Patent - 5 - Patent Grants by Technology – Total count by applicant's origin," https://rebrand.ly/wofo69s.

[36] Carlson, Rob, 2020, "Two Worlds, Two Bioeconomies: The Impacts of Decoupling US–China Trade and Technology Transfer," Johns Hopkins University Applied Physics Laboratory, p. 12, https://www.jhuapl.edu/sites/default/files/2022-12/Carlson_Wehbring-Biotech.pdf; WIPO, 2025, "Patent- 5 - Patent grants by technology - Total count by filing office," https://rebrand.ly/zmaqgjx.

[37] Reiß et al., 2023, "Technologische Souveränität Pharma/Biotech: Studie zur Wettbewerbsfähigkeit und technologischen Souveränität Deutschlands im Pharmasektor," p. 82.

[38] Seboio Health Policy Consulting, 2023, "Attracting Life Science Investments in Europe," p. 29, https://www.europabio.org/wp-content/uploads/2023/10/Life-Science-Attractiveness-2023-October-22-Final.pdf.

[39] Brown, Alexander and Groenewegen-Lau, Jeroen, 2025, "Lab Leader, Market Ascender: China's Rise in Biotechnology," Mercator Institute for China Studies, p. 8, https://merics.org/sites/default/files/2025-

Chinese public procurement contracts in strategic sectors also go exclusively to national companies; this is in comparison to 70 percent in the US and 8 to 12 percent in the EU.[40]

Globally, biotechnology has evolved into an industry in which private investment in R&D is higher than government investment. Here again, US companies dominate. Figures from the biopharma industry show that US firms have spent $25 billion more than their EU counterparts and more than $50 billion more than their Chinese counterparts in 2020.[41] Since then, the gap between the US on the one hand and the EU and China on the other seems to have only grown.[42] Correspondingly, aggregate revenue streams from biotechnology companies in the US are estimated to be almost five times higher than those of European companies.[43] Data on equity raised in the life science industry between 2016 and 2022 also show that the EU is lagging behind the US — which accounts for around two-thirds of global investment — and China.[44]

Overall, private investment in biotechnology has been on a downward trajectory in recent years, driven in part by tighter capital markets and a recalibration following high pandemic-era expenses.[45] Notably, while global venture capital (VC), crucial in bringing biotechnology innovations to the market, remains above pre-pandemic levels, it has seen a decline since 2021, indicating a reassessment of the sector's immediate commercial prospects.[46] This holds for the synbio industry as well, for which global VC numbers peaked at over $20 billion in 2021, before falling to under $7 billion in 2023. Again, US biotechnology companies have received the largest share of VC investment (62.1 percent of the total $44 billion in 2020), putting it far ahead of China (18.9 percent), which has seen strong growth since 2000, and Europe, whose share dropped to 14.5 percent that year.[47]

The outstanding position of the US biotechnology market is also reflected in the size of Initial Public Offerings (IPO), which are four to five times larger on US exchanges than on European

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04/MERICS%20Report%20Biotech_04-2025.pdf; Moore, Scott, 2020, "China's Role in the Global Biotechnology Sector and Implications for U.S. Policy," Brookings, p. 1, https://www.brookings.edu/wp-content/uploads/2020/04/FP_20200427_china_biotechnology_moore.pdf.

[40] European Parliament Committee on Industry, Research and Energy, 2025, "Draft Report on European Technological Sovereignty and Digital Infrastructure," p. 10, https://www.europarl.europa.eu/doceo/document/ITRE-PR-768180_EN.pdf.

[41] Wilsdon, Tim, Armstrong, Hannah, Sablek, Antun, and Cheng, Peter, 2022, "Factors Affecting the Location of Biopharmaceutical Investments and Implications for European Policy Priorities," Charles River Associates, pp. 12—13, https://www.efpia.eu/media/676753/cra-efpia-investment-location-final-report.pdf.

[42] Clarivate, 2024, "A Decade of Innovation, a Decade to Come," pp. 32—34 https://clarivate.com/life-sciences-healthcare/wp-content/uploads/sites/4/dlm_uploads/2025/01/Clarivate_10_years_of_Innovation_in_China_Report_v.11.pdf; European Commission, 2024, "EU Companies Lead Global R&D Investment Growth, Breaking Decade-Long Trend - European Commission," accessed May 11, 2025, https://joint-research-centre.ec.europa.eu/jrc-news-and-updates/eu-companies-lead-global-rd-investment-growth-breaking-decade-long-trend-2024-12-18_en; US International Trade Administration, n.d., "Biopharmaceuticals Industry," accessed May 27, 2025, https://www.trade.gov/selectusa-biopharmaceuticals-industry.

[43] EY Germany, 2024, "How Can AI Be the Key to Unlocking New Opportunities in the German Biotech Sector? German Biotechnology Report 2024," p. 32, https://www.ey.com/content/dam/ey-unified-site/ey-com/de-de/noindex/ey-german-biotechnology-report-2024-how-can-ai-be-the-key.pdf?mkt_tok=NTIwLVJYUC0wMDMAAAGaM_HQvZ1P9vMnFIftGpxTL7itRjBU8brjfeaD4jvFaK6cTwKd1mepw6JEYKXZ0tTc7BYZaFrscYv17fOrL4Zuezkv7MaUJsI7goetwYidnlwJOd_6QE0.

[44] Seboio Health Policy Consulting, 2023, "Attracting Life Science Investments in Europe," 32.

[45] Capra, Emily, Fougner, Christian, Leclerc, Olivier, Mäkitie, Ahti, and Suberski, Anthony , 2023, "What Early-Stage Investing Reveals about Biotech Innovation," p. 2, https://www.mckinsey.com/~/media/mckinsey/industries/life%20sciences/our%20insights/what%20early%20stage%20investing%20reveals%20about%20biotech%20innovation/what-early-stage-investing-reveals-about-biotech-innovation.pdf?shouldIndex=false.

[46] Kranjec, Jastra, 2024, "VC Funding in Biotech Remains Above Pre-Pandemic Levels with $136.3B Raised in 2023," Stocklytics, accessed May 6, 2025, https://stocklytics.com/content/vc-funding-in-biotech-remains-above-pre-pandemic-levels-with-136-3b-raised-in-2023/.

[47] National Center for Science and Engineering Statistics, 2022, "SKTI-24: Total Biotechnology Venture Capital Raised, by Selected Country and Region: 2000–20," accessed April 16, 2025, https://ncses.nsf.gov/pubs/nsb20226/data.

exchanges, though funding levels have fallen drastically since 2021.[48] In terms of market capitalization, US biotechnology companies also recorded levels almost five times higher than their European counterparts in 2023, even though there have been several prominent bankruptcies in the synbio industry in recent years, as non-healthcare synbio firms struggle to become profitable.[49] Chinese biotechnology companies are also being drawn to the markets, with seven out of the world's ten biggest biopharma IPOs from 2018 to 2020 originating in China.[50] China-based biotechnology firms have seen a 100-fold increase in market value from 2016 to 2021, but often rely on the much larger European and US markets for their revenue. (The Chinese market accounted for under 5 percent of global biotech revenues in 2023.)[51]

All in all, thanks to the significantly higher investment and growth in their biotech market, the US has almost twice as many companies as Europe.[52] Although there exist individual leading players, European biotechnology companies often lack access to sufficient levels of VC, private-equity or IPO funding.[53]

## Leading Countries' Strategies and Policies

Based on the indicators discussed, the US is currently leading biotechnology globally, profiting from a mature innovation ecosystem based on ample capital, talent and research infrastructure.[54] While lacking an official comprehensive biotechnology strategy (the recently published final report of the bipartisan National Security Commission on Emerging Biotechnology comes closest), the US government has recognized the technology's relevance for national and economic security and has launched a number of initiatives to promote the industry. Notably, the 2022 CHIPS and Science Act calls for a national genomic sequencing

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[48] Capra et al., 2023, "What Early-Stage Investing Reveals about Biotech Innovation," p. 2; Evers, Matthias, Stein-Asmussen, Antonia, Szlezak, Nicole, and Zempet, Alexandra, 2023, "Europe's Bio Revolution: Biological Innovations for Complex Problems," p. 15, https://www.mckinsey.com/~/media/mckinsey/industries/life%20sciences/our%20insights/europes%20bio%20revolution%20biological%20innovations%20for%20complex%20problems/europes-bio-revolution-biological-innovations-for-complext-problems-vf.pdf?shouldIndex=false.

[49] EY Germany, 2024, "How Can AI Be the Key to Unlocking New Opportunities in the German Biotech Sector? German Biotechnology Report 2024," p. 32; Service, Robert F., 2024, "Synthetic Biology, Once Hailed as a Moneymaker, Meets Tough Times," *Science*, August 22, 2024, https://www.science.org/content/article/synthetic-biology-once-hailed-moneymaker-meets-tough-times.

[50] Han, Kiki, Le Deu, Franck, Zhang, Fangning, and Zhou, Josie, 2021, "The Dawn of China Biopharma Innovation," McKinsey, p. 2, https://www.mckinsey.com/~/media/mckinsey/industries/life%20sciences/our%20insights/the%20dawn%20of%20china%20biopharma%20innovation/the-rise-of-biopharma-innovation-in-china-vf.pdf?shouldIndex=false.

[51] Ascher, Jan, Chen, Bihe, Curschellas, Corina, Mattsson, Anna, and Perl, Ari, 2023, "Five Ways Biopharma Companies Can Navigate the Deal Landscape," Mc Kinsey, p. 6, https://www.mckinsey.com/~/media/mckinsey/industries/life%20sciences/our%20insights/five%20ways%20biopharma%20companies%20can%20navigate%20the%20deal%20landscape/five-ways-biopharma-companies-can-navigate-the-deal-landscape_vf.pdf?shouldIndex=false ; Grand View Research, 2025, "China Biotechnology Market Size & Outlook, 2030," accessed June 4, 2025, https://www.grandviewresearch.com/horizon/outlook/biotechnology-market/china; Grand View Research, 2025, "Europe Biotechnology Market Size & Outlook, 2030," accessed June 4, 2025, https://www.grandviewresearch.com/horizon/outlook/biotechnology-market/europe; Grand View Research, 2025, "The United States Biotechnology Market Size & Outlook, 2030," accessed June 4, 2025, https://www.grandviewresearch.com/horizon/outlook/biotechnology-market/united-states; Mercator Institute for China Studies, n.d., "Chinese Biotech Companies Make Their Major Income Abroad," https://merics.org/de/china-tech-observatory/biotechnology.

[52] Evers et al., 2023, "Europe's Bio Revolution: Biological Innovations for Complex Problems," p. 7.

[53] Evers et al., 2023, "Europe's Bio Revolution: Biological Innovations for Complex Problems," pp. 8—9.

[54] Chilukuri, Vivek, 2025, "Make America the Biopower," Center for a New American Security, p. 1, https://s3.us-east-1.amazonaws.com/files.cnas.org/documents/Make-America-the-Biopower.pdf ; Feldman, Amy and Au-Yeung, Angel, 2021, "The Inside Story Of How SoftBank-Backed Zymergen Imploded Four Months After Its $3 Billion IPO," *Forbes*, October 13, 2021, https://www.forbes.com/sites/amyfeldman/2021/10/13/the-inside-story-of-how-softbank-backed-zymergen-imploded-four-months-after-its-3-billion-ipo/ ; Reuters, 2023, "Biotech Firm Amyris Files for Bankruptcy in US," August 10, 2023, https://www.reuters.com/business/biotech-firm-amyris-files-bankruptcy-us-2023-08-10/.

strategy and a National Engineering Biology R&D Initiative.[55] An executive order on biotechnology, issued in the same year, intended to kick off a whole-of-government approach to fostering biotechnological development, tasking various agencies with outlining strategic priorities regarding the use of biotechnology to address climate, health and supply chain challenges while promoting biosecurity and biosafety.[56] In response to the executive order, agencies were quick to compile a list of "Bold Goals for US Biotechnology and Biomanufacturing".[57]

In addition, the US Department of Defense (DoD) has for years recognized the relevance of biotechnology in providing the means to produce substitute or enhanced products critical for the military supply chain. It has invested in several biotechnology programs, including through the Defense Advanced Research Projects Agency (DARPA).[58] The DoD significantly stepped up these efforts after the executive order's release and published its own Biomanufacturing Strategy in 2023. Since 2023, the US has also cooperated with India, Japan and Australia on developing biotechnologies through the Quad Investors Network.[59]

In a separate policy stream, the US government has moved to address biological threats arising from naturally occurring and accidental incidents as well as deliberate attacks. In 2018, during Donald Trump's first term, he unveiled a National Biodefense Strategy, which was updated again in 2022.[60] In 2023, the National Science Advisory Board for Biosecurity proposed a framework for the oversight of research posing biosafety or biosecurity risks, and the DoD provided its assessment of the biological threat landscape through 2035 in its Biodefense Posture Review.[61]

Also in 2023, President Biden released an Executive Order on Artificial Intelligence, which called for "addressing AI systems' most pressing security risks — including with respect to biotechnology," and greater action on evaluating the capabilities of AI to cause harm to

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[55] US Congress, 2022, "Public Law 117–167 117th Congress," pp. 235—36, 239, https://www.congress.gov/117/plaws/publ167/PLAW-117publ167.pdf.

[56] White House, 2022, "Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," accessed May 6, 2025, https://bidenwhitehouse.archives.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/.

[57] White House, 2023, "Bold Goals for U.S. Biotechnology and Biomanufacturing: Harnessing Research and Development to Further Societal Goals," accessed May 6, 2025, https://bidenwhitehouse.archives.gov/wp-content/uploads/2023/03/Bold-Goals-for-U.S.-Biotechnology-and-Biomanufacturing-Harnessing-Research-and-Development-To-Further-Societal-Goals-FINAL.pdf.

[58] Alia-Novobilski, Marisa, 2017, "Tri-Service Effort Leverages Synthetic Biology Expertise to Address Future Warfighter Needs," Wright-Patterson AFB, accessed May 6, 2025, https://www.wpafb.af.mil/News/Article-Display/Article/1326042/tri-service-effort-leverages-synthetic-biology-expertise-to-address-future-warf/; Chilukuri and Kelley, 2025, "Biopower: Securing American Leadership in Biotechnology," pp. 15—18; Gibbons, Henry S. and Crumbley, Anna M., 2024, "Accelerating Transition of Biotechnology Products for Military Supply Chains," *Joint Force Quarterly* 113, 14—25, p. 15, https://digitalcommons.ndu.edu/cgi/viewcontent.cgi?article=1003&context=joint-force-quarterly; Rozo, Michelle, 2024, "U.S.-China Economic and Security Review Commission Hearing on 'Current and Emerging Technologies in U.S.-China Economic and National Security Competition': Prepared Statement by Michelle Rozo, Vice Chair National Security Commission on Emerging Biotechnology," p. 206, https://www.uscc.gov/sites/default/files/2024-02/February_1_2024_Hearing_Transcript.pdf; US Department of Defense, 2023, "Biomanufacturing Strategy," https://media.defense.gov/2023/Mar/22/2003184301/-1/-1/1/BIOMANUFACTURING-STRATEGY.PDF; US Department of Defense, 2024, "DOD Announces First Award for the Distributed Bioindustrial Manufacturing Program," accessed April 16, 2025, https://www.dodmantech.mil/News/News-Display/Article/3839308/dod-announces-first-award-for-the-distributed-bioindustrial-manufacturing-progr/https%3A%2F%2Fwww.dodmantech.mil%2FNews%2FNews-Display%2FArticle%2F3839308%2Fdod-announces-first-award-for-the-distributed-bioindustrial-manufacturing-progr%2F.

[59] Quad Investors Network, n.d. "Vision," Quad Investors Network, accessed May 13, 2025, https://quadinvestorsnetwork.org.

[60] White House, 2022, "National Biodefense Strategy and Implementation Plan," https://www.acq.osd.mil/ncbdp/docs/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf.

[61] US Department of Defense, 2023, "2023 Biodefense Posture Review," https://media.defense.gov/2023/Aug/17/2003282337/-1/-1/1/2023_biodefense_posture_review.pdf; US National Science Advisory Board for Biosecurity, 2023, "Proposed Biosecurity Oversight Framework for the Future of Science," https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf.

biosecurity. The executive order called for a framework for synthetic nucleic acid screening.[62] Senators had previously attempted to get the US government to establish gene synthesis screening protocols.[63]

In 2025, the second Trump Administration rescinded Biden's biotechnology and AI executive orders; instead, it issued its own executive order calling for an updated, stricter nucleic acid synthesis screening framework while suspending federal funding for gain-of-function research — research that seeks to analyze infectious agents, including by making them more transmissible — in the US temporarily, and in countries like China indefinitely.[64]

China, too, has developed into a notable player in biotechnology. Developing a strong biotechnology sector has been an objective of Chinese Communist Party leadership since at least 2006, and biotechnology has regularly featured in high-level documents such as the Made in China 2025 strategy and the country's Five-Year-Plans.[65] Chinese leadership has drastically stepped up its efforts in recent years, adopting a Biosecurity Law in 2020 that identified biotechnology as a priority sector for innovation-driven economic growth, and issuing a five-year plan for the bioeconomy in 2022, aimed at increasing technological independence and biosecurity.[66] Beijing has expanded the scope of support to agricultural, industrial and environmental biotechnology, but healthcare biotechnology is by far the largest segment, with medical AI receiving particular attention.[67] Certain US researchers and the US International Security Advisory Board suggest China's military-civil fusion strategy also includes biotechnology,[68] while Craig Singleton of the Foundation for Defense of Democracies even

China, too, has developed into a notable player in biotechnology.

[62] US Federal Register, 2023, "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence," accessed May 2, 2025, https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence; US National Science and Technology Council, 2024, "Framework for Nucleic Acid Synthesis Screening," p. 5, https://bidenwhitehouse.archives.gov/wp-content/uploads/2024/04/Nucleic-Acid_Synthesis_Screening_Framework.pdf.

[63] US Congress, 2023, "Text - S.2356 - 118th Congress (2023-2024): Gene Synthesis Safety and Security Act," https://www.congress.gov/bill/118th-congress/senate-bill/2356/text; US Congress, 2023, "S.2400 - 118th Congress (2023-2024): Securing Gene Synthesis Act," https://www.congress.gov/bill/118th-congress/senate-bill/2400.

[64] White House, 2025, "Fact Sheet: President Donald J. Trump Achieves Improved Safety and Security of Biological Research," May 7, 2025, https://www.whitehouse.gov/fact-sheets/2025/05/fact-sheet-president-donald-j-trump-achieves-improved-safety-and-security-of-biological-research/; White House, 2025, "Improving the Safety and Security of Biological Research," May 7, 2025, https://www.whitehouse.gov/presidential-actions/2025/05/improving-the-safety-and-security-of-biological-research/.

[65] Barbosu, Sandra, 2024, "How Innovative Is China in Biotechnology?," Information Technology and Innovation Foundation, pp. 27—28, https://itif.org/publications/2024/07/30/how-innovative-is-china-in-biotechnology/; Gryphon Scientific and Rhodium Group, 2019, "China's Biotechnology Development: The Role of US and Other Foreign Engagement," pp. 35—38, https://www.govinfo.gov/content/pkg/GOVPUB-Y3-PURL-gpo154585/pdf/GOVPUB-Y3-PURL-gpo154585.pdf; Puglisi, Anna and Rask, Chryssa, 2024, "China, Biotechnology, and BGI," Center for Security and Emerging Technology, pp. 94—96, https://cset.georgetown.edu/publication/china-biotechnology-and-bgi/.

[66] Brown and Groenewegen-Lau, 2025, "Lab Leader, Market Ascender: China's Rise in Biotechnology," p. 4; Center for Security and Emerging Technology, 2021, "Outline of the People's Republic of China 14th Five-Year Plan for National Economic and Social Development and Long-Range Objectives for 2035," p. 11, 13, https://cset.georgetown.edu/wp-content/uploads/t0284_14th_Five_Year_Plan_EN.pdf; China Law Translate, 2020, "Biosecurity Law of the P.R.C.," accessed May 13, 2025, https://www.chinalawtranslate.com/biosecurity-law/.

[67] Brown and Groenewegen-Lau, 2025, "Lab Leader, Market Ascender: China's Rise in Biotechnology," p. 5; Schuerger, Caroline, Venkatram, Vikram, and Quinn, Katherine, 2024, "China and Medical AI: Implications of Big Biodata for the Bioeconomy," Center for Security and Emerging Technology, https://cset.georgetown.edu/publication/china-and-medical-ai/.

[68] Kania, Elsa and VornDick, Wilson, 2019, "China's Military Biotech Frontier: CRISPR, Military-Civil Fusion, and the New Revolution in Military Affairs," Jamestown Foundation, https://jamestown.org/program/chinas-military-biotech-frontier-crispr-military-civil-fusion-and-the-new-revolution-in-military-affairs/?utm_source=chatgpt.com; US Department of State, 2024, "Adherence to and Compliance with Arms Control, Nonproliferation, and Disarmament, Agreements and Commitments," p. 23, https://www.state.gov/wp-content/uploads/2024/04/2024-Arms-Control-Treaty-Compliance-Report.pdf; US Department of State, 2024, "Report on Biotechnology in the People's Republic of China's Military-Civil Fusion Strategy," https://www.state.gov/wp-content/uploads/2024/11/ISAB-Report-on-Biotechnology-in-the-PRC-MCF-Strategy_Final.pdf.

asserts that China's largest genomics firm, BGI Group, was directly involved in research by China's People's Liberation Army (PLA).[69]

Beyond the US and China, there are a number of other noteworthy players in the biotechnological field. The UK is a prominent hub for biotechnology innovation, profiting from sizeable government investment.[70] As a result, the UK is responsible for a significant share of scientific publications and patents in the field, and leads Europe in life-science start-up funding.[71] Still, like other EU countries, it struggles to convert outstanding fundamental science into commercial products.[72] Switzerland also has a strong and growing biotechnology market, drawing on excellent research groups and the legacy of a strong pharma sector.[73] Japan, South Korea and India, too, are promising players and are all hoping to grow their sectors through government-led initiatives.[74]

Most other nations outside of Europe, meanwhile, are reliant on imports of biotechnology goods and services since they do not have the means to provide the environment necessary for cutting-edge innovation. This raises pressing questions about unequal access to the benefits provided by biotechnologies and concerns about poorer countries' limited capacities to address the risks associated with these new technologies.

## The EU's Biotechnology Industry

According to a report prepared for the European Association for Bioindustries, biotechnology is already a factor in the EU's economy. It accounts for 1.6 percent of the industrial sector's gross domestic product (GDP), directly employing roughly 240,000 people.[75] Moreover, the EU's biotechnology industry has grown by 4.7 percent between 2008 and 2022, with industrial biotechnology seeing the highest growth over that period.[76] The industry accounted for 3.4 percent of all extra-EU exports in 2022, mainly through healthcare biotechnology.[77] With exports almost double the size of imports, the biotechnology industry generated a trade surplus of 51.7 billion euros in that year.[78]

Europe is home to several leading biotechnology players. Around half of European biotechnology companies focus on health-related applications, with prominent examples including BioNTech (Germany), Genmab (Denmark) and Argenx (Netherlands). There are

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[69] Singleton, Craig, 2025, "Biotech Battlefield: Weaponizing Innovation in the Age of Genomics," Foundation for Defense of Democracies, pp. 13—21, https://www.fdd.org/wp-content/uploads/2025/01/fdd-monograph-biotech-battlefield-weaponizing-innovation-in-the-age-of-genomics.pdf

[70] UK Department for Science, Innovation and Technology, 2023, "National Vision for Engineering Biology," https://assets.publishing.service.gov.uk/media/656de8030f12ef07a53e01ac/national_vision_for_engineering_biology.pdf ; UK Government, 2023, "UK Biological Security Strategy," https://assets.publishing.service.gov.uk/media/64c0ded51e10bf000e17ceba/UK_Biological_Security_Strategy.pdf.

[71] Bhandari, Mayank, Cooney, David, Devereson, Alex, Moss, Rachel, and Thaker, Shail, 2021, "The UK Biotech Sector: The Path to Global Leadership," McKinsey, https://www.mckinsey.com/industries/life-sciences/our-insights/the-uk-biotech-sector-the-path-to-global-leadership#/; Sweeney et al., 2025, "Science and Technology Trends 2025-2045," p. 25.

[72] Bhandari et al., 2021, "The UK Biotech Sector: The Path to Global Leadership."

[73] Federal Council of the Swiss Federation, 2024, "Record Funding for Swiss Biotechnology," accessed May 13, 2025, https://www.kmu.admin.ch/kmu/en/home/aktuell/news/2024/rekordfinanzierung-fuer-schweizer-biotechnologie.html.

[74] Chilukuri and Kelley, 2025, "Biopower: Securing American Leadership in Biotechnology," pp. 40—42; Indian Ministry of Science and Technology, 2021, "National Biotechnology Development Strategy [2021-2025]," https://www.europabio.org/wp-content/uploads/2023/09/India_NATIONAL-BIOTECHNOLOGY-DEVELOPMENT-STRATEGY_01.04.pdf ; Sweeney et al., 2025, "Science and Technology Trends 2025-2045," p. 25.

[75] Haaf, Andreas and Sale, Vera, 2025, "Measuring the Economic Footprint of the Biotechnology Industry in the European Union," WifOR Institute, p. 6, 10, https://www.europabio.org/wp-content/uploads/2025/03/WifOR_EuropaBio2025.pdf.

[76] Haaf and Sale, 2025, "Measuring the Economic Footprint of the Biotechnology Industry in the European Union," p. 8.

[77] Haaf and Sale, 2025, "Measuring the Economic Footprint of the Biotechnology Industry in the European Union," p. 14.

[78] Haaf and Sale, 2025, "Measuring the Economic Footprint of the Biotechnology Industry in the European Union," p. 14.

also leading firms operating across biotechnology sub-sectors, such as Novozymes (Denmark). In addition to dedicated biotech companies, larger European pharmaceutical and life sciences firms, like Merck KGaA (Germany) and Novo Nordisk (Denmark), also maintain significant biotechnology operations.

However, these positive indicators largely reflect the EU's established strengths in more mature biotechnology sectors, particularly healthcare, and the performance of a limited number of standout companies. They mask deeper structural weaknesses across the wider biotechnology ecosystem when compared to the US or China. The EU is struggling to develop vibrant innovation hubs that effectively facilitate the conversion of ideas and initiatives of scientific excellence to market-ready applications. This shortfall hampers the growth of biotech start-ups and their ability to flourish.[79] Often, this comes down to an insufficiently conducive innovation environment, including regulatory obstacles and barriers to accessing funding and talent. Existing, risk-sensitive rules, shaped by widely held political and public concerns around new genomic techniques, are a deliberate political choice, yet also contribute to scaling difficulties and market hesitancy. At the same time, structural limitations in European capital markets, such as highly risk-averse prudential regulations for pension funds and insurance companies and fragmented venture capital markets, significantly hamper the availability of risk capital and constrain investment in innovative sectors like biotechnology. The EU has also failed to identify and react to emerging chokepoints in the field, such as domestic sequencing capacity.

The EU has fundamentally recognized the biotechnology industry's outstanding strategic relevance for economic and national security.

This is despite the fact that the EU has fundamentally recognized the biotechnology industry's outstanding strategic relevance for economic and national security. It published a Life Sciences and Biotechnology Strategy in 2002, following up with a Bioeconomy Strategy in 2012.[80] Moreover, under its Horizon 2020 program, which ran from 2014 to 2020, the EU established the Bio-Based Industries Joint Undertaking.[81] Its activities were taken over by the Circular Bio-based Europe Joint Undertaking in 2021, which operates as a 2 billion euro public-private partnership aimed at improving circularity and sustainability of the bioeconomy until 2031.[82]

The European Commission (the Commission) also issued the Clinical Trials Regulation in 2022 to harmonize processes across member states and improve transparency.[83] It followed up with a communication on boosting biotechnology in March 2024, promising to simplify regulatory frameworks, encourage more investments, and strengthen international cooperation.[84] Notably, China is not among the countries listed as potential partners for enhanced collaboration. Yet, research collaborations between China and Europe will likely

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[79] Nisslein, Maximilian, von Bronk, Benedikt, de Véricourt, Francis, and Kurth, Torsten, 2024, "Biotech Innovation Hubs in Germany – Divided and Conquered?," Boston Consulting Group, pp. 3—4, https://esmt.berlin/faculty-research/sites/faculty/files/2024-02/Biotech_Innovation_Hubs%20in%20Germany-divided%2Bconquered-Whitepaper%202024-02-02.pdf.

[80] European Commission, 2002, "Life sciences and biotechnology: A strategy for Europe," https://ec.europa.eu/biotechnology/pdf/com2002-27_en.pdf; European Commission, 2012, "A bioeconomy strategy for Europe," https://op.europa.eu/en/publication-detail/-/publication/26b789d4-00d1-4ee4-b32e-2303dfd2207c.

[81] European Commission, 2023, "BBI JU - Bio-Based Industries Joint Undertaking," accessed May 27, 2025, https://knowledge4policy.ec.europa.eu/organisation/bbi-ju-bio-based-industries-joint-undertaking_en .

[82] European Commission, 2023, "CBE JU - Circular Bio-Based Europe Joint Undertaking," accessed May 27, 2025, https://knowledge4policy.ec.europa.eu/organisation/cbe-ju-circular-bio-based-europe-joint-undertaking_en.

[83] Bamford, Chris and Arias, Carolina, 2023, "The EU Clinical Trials Regulation: Experiences from the First 18 Months," IQVIA, https://www.iqvia.com/-/media/iqvia/pdfs/library/publications/2311bamfordarias.pdf.

[84] European Commission, 2024, "Building the Future with Nature: Boosting Biotechnology and Biomanufacturing in the EU," p. 20, https://research-and-innovation.ec.europa.eu/document/download/47554adc-dffc-411b-8cd6-b52417514cb3_en.

continue in biotechnology subfields as there remains great interest from European research institutions and academics in partnering with their Chinese counterparts.[85]

In March 2025, the Commission proposed the Critical Medicines Act to secure the supply of critical medicines across the bloc. The Act is based on the Union List of Critical Medicines, which was developed by the EU to help prevent supply issues for essential drugs; it includes both innovative and generic medicines across therapeutic areas like vaccines and medicines for rare diseases. Reflecting the Act's focus on supply security for widely used, established treatments, 92 percent of the listed medicines are generics, with relatively few biologics (medicines derived from living organisms) and biosimilars (similar, but not identical, versions of biologics).[86]

The coming months will see further action from the EU on these topics, with a new bioeconomy strategy set to be published by the end of 2025 and a Biotech Act now expected for 2026.[87] While there is hope that both will boost the European biotechnology industry, there are also concerns that the Directorate General for Health and Food Safety leading on the latter file might limit it primarily to healthcare biotechnology.[88]

Other strategic documents also recognize shortcomings in promoting the European biotechnology industry while protecting against risks to biosecurity, biosafety and economic security; yet, none so far have initiated specific actions to mitigate these risks, such as nucleic acid synthesis screening, which are being called for by civil society actors.[89] It remains to be seen how much biosecurity risks will feature in an impending report by the European Parliament on EU biotechnology, which is set to include sections on leveraging research, boosting innovation and enhancing competitiveness.[90] Whether AI-enabled biological tools are covered by the EU's AI Act is another open question.[91]

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[85] Datenna, 2024, "Navigating Challenges and Risks in Sino-European Academic Collaborations," p. 19, https://www.datenna.com/wp-content/uploads/2024/08/Datenna-Report-Navigating-Challenges-and-Risks-in-Sino-European-Academic-Collaborations.pdf; Max-Planck Gesellschaft, 2024, "'In These Challenging Times, We as Scientists Must Stand United,'" accessed May 12, 2025, https://www.mpg.de/23671503/50-years-mpg-cas-cooperation.

[86] European Commission, 2025, "Critical Medicines Act," accessed April 30, 2025, https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/critical-medicines-act_en; Troein, Per, Newton, Max, Travaglio, Marco, and Stoddard, Kelsey, 2024, "Beneath the Surface: Unravelling the True Value of Generic Medicines," IQVIA, p. 13, https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/iqvia-true-value-of-generic-medicines-04-24-forweb.pdf?utm_source=chatgpt.com.

[87] European Commission, 2024, "Europe's Choice - Political Guidelines for the next European Commission 2024-2029," https://commission.europa.eu/document/download/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en?filename=Political%20Guidelines%202024-2029_EN.pdf.

[88] Nicoletti, Barbara, 2025, "New European Biotech Act: Which Way Forward?" European Parliamentary Research Service, p. 1, https://www.europarl.europa.eu/RegData/etudes/BRIE/2025/772866/EPRS_BRI(2025)772866_EN.pdf.

[89] European Commission, 2025, "On ProtectEU: A European Internal Security Strategy," p. 17, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025PC0148; European Commission,, 2025, "White Paper for European Defence – Readiness 2030," p. 5, https://commission.europa.eu/document/download/e6d5db69-e0ab-4bec-9dc0-3867b4373019_en?filename=White%20paper%20for%20European%20defence%20%E2%80%93%20Readiness%202030.pdf; Pour Demain, International Biosecurity and Biosafety Initiative for Science, RAND Europe, and Pandemic Action Network, 2024, "Brief: Biosecurity & Nucleic Acid Synthesis," https://www.pourdemain.ngo/post/brief-biosecurity-nucleic-acid-synthesis-1.

[90] European Parliament, 2025, "Draft Report on the Future of the EU Biotechnology and Biomanufacturing Sector: Leveraging Research, Boosting Innovation and Enhancing Competitiveness," https://www.europarl.europa.eu/doceo/document/ITRE-PR-768143_EN.pdf; European Parliament, 2025, "Future of the EU biotechnology and biomanufacturing sector: leveraging research, boosting innovation and enhancing competitiveness," accessed June 24, 2025, https://oeil.secure.europarl.europa.eu/oeil/en/procedure-file?reference=2025/2008(INI).

[91] Moulange, Richard, Wünn, Tina, and Nelson, Cassidy, 2025, "Biological Tools and the EU AI Act," Centre for Long-Term Resilience, https://www.longtermresilience.org/reports/biological-tools-and-the-eu-ai-act/.

Germany hosts promising biotechnology hubs in Berlin, Heidelberg and Munich,[92] making it one of the main EU countries with strengths in the field alongside France, Belgium and Denmark.[93] However, they have not given rise to translation and commercialization attempts at scale. Previous governments adopted a National Bioeconomy Strategy and Pharma Strategy to promote the biotechnology industry and improve framework conditions for local upscaling.[94] The incoming government then promised to make Germany the most innovative biotechnology location globally, following sustained calls from industry for a more innovation-friendly environment, resembling those voiced at the European level.[95]

# Biotechnology's Foreign and Security Policy Relevance

Biotechnology innovations have implications across four dimensions relevant to foreign and security policy: (1) military capabilities, (2) biosecurity and biosafety, (3) data security, and (4) questions of societal and economic development, including exposure to dependencies and coercion risks.

## Military Capabilities

Biotechnology, and particularly synbio, has military applications which involve both enhancing or impairing warfighter performance (human enhancement/degradation) and enhancing warfighter systems:

- Warfighter performance: Beyond optimizing health monitoring and performance levels, the operational readiness of troops can be directly influenced using biotechnology innovations that promote maximum physical and cognitive capabilities through precision medicine, counter fatigue and stress by balancing the human gut microbiome, or speeding recovery by

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[92] Nisslein et al., 2024, "Biotech Innovation Hubs in Germany – Divided and Conquered?" p. 6.

[93] Chilukuri and Kelley, 2025, "Biopower: Securing American Leadership in Biotechnology," 37; Debaere, Jan, Moretti Violato, Natalia, Debelle, Clara, De Wolf, Gilles, and Van den Bergh, Scout, 2024, "Decoding the Dynamics: A Deep Dive into the Belgian Biomanufacturing Landscape," PWC, pp. 4—5, https://www.pwc.be/en/fy25/documents/biomanufacturing-whitepaper.pdf; Frietsch, Rainer, Rammer, Christian, Schubert, Torben, Garcia Chavez, Cecilia, Gruber, Sonia et al., 2024, "Innovationsindikator 2024," BDI, Fraunhofer ISI, Roland Berger, ZEW, pp. 37—39, https://www.innovationsindikator.de/fileadmin/innovationsindikator-2024/pdf/Innovationsindikator-2024.pdf.

[94] German Government, 2020, "Nationale Bioökonomiestrategie," https://www.bmbf.de/SharedDocs/Publikationen/DE/7/31576_Nationale_Biooekonomiestrategie_Langfassung.pdf?__blob=publicationFile&v=6 ; German Government, 2023, "Verbesserung Der Rahmenbedingungen Für Den Pharmabereich in Deutschland: Handlungskonzepte Für Den Forschungs- Und Produktionsstandort," https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/P/Pharmastrategie/231213_Kabinett_Strategiepapier.pdf.

[95] BDI, 2024, "Deutschland mit einer bio-basierten Wirtschaft zukunftsfähig machen," accessed May 12, 2025, https://bdi.eu/publikation/news/deutschland-mit-einer-bio-basierten-wirtschaft-zukunftsfaehig-machen; Bio Deutschland, 2024, "Position Paper of BIO Deutschland: From Research to Commercialisation - Expanding Technology Transfer and Translation in Germany," accessed May 12, 2025, https://www.biodeutschland.org/en/position-papers/position-paper-of-bio-deutschland-from-research-to-commercialisation-expanding-technology-transfer-and-translation-in-germany.html; CDU, CSU, and SPD, 2025, "Verantwortung für Deutschland – Koalitionsvertrag zwischen CDU, CSU und SPD," p. 6, https://www.spd.de/fileadmin/Dokumente/Koalitionsvertrag2025_bf.pdf.

genetically engineering wound healing therapies.[96] At the same time, biotechnology innovations offer adversaries new ways to specifically target military personnel with bioweapons if data about an individual soldier's susceptibility to diseases or physical endurance were to end up in the wrong hands. (Currently, this kind of bioweaponry is still cost-prohibitive.)[97] There is still no broadly accepted framework for evaluating the trade-offs between the immediate advantages and potential longer-term risks of biotechnologies for warfighters.

- Warfighter systems: Synbio can also be used to develop biosynthetic materials for use in military equipment that has improved performance — such as heat resistance, robustness and elasticity — or to generate alternative supplies for products like jet fuel.[98]

These military applications have received increasing interest from a range of actors, like the US DoD and NATO, which published its first strategy on biotechnology and human enhancement technologies in 2024.[99] The PLA has also acknowledged the importance of military applications of biotech: the PLA National Defense University's 2020 Science of Military Strategy reads, "With the development of modern biotechnology, the national security territory will be further expanded from the traditional land, sea, air, space, network, and electricity fields to the biological field."[100]

Considering that other players are developing capabilities to leverage biotechnology for improving warfighter performance and warfighter systems, Germany and Europe need to clarify what they can and want to achieve in terms of military applications, both through their involvement in NATO and beyond. As many applications are yet to prove themselves in the field, it is crucial that policymakers at both levels closely monitor progress by other countries to inform their understanding of the future usability of these technologies and their willingness to develop and deploy them.

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[96] Cryan, John, 2020, "Understanding the Multidirectional Axes of Communication between the Gut Microbiome and the Brain to Augment Human Performance," Air Force Research Laboratory, https://apps.dtic.mil/sti/pdfs/AD1104391.pdf; Peters, Matthew D., 2021, "AFOSR Advances Science of Wound-Healing Technology," US Air Force, accessed April 28, 2025, https://www.af.mil/News/Article-Display/Article/2484965/afosr-advances-science-of-wound-healing-technology/.

[97] Winkler, John D., Marler, Timothy, Posard, Marek N., Cohen, Raphael S., and Smith, Meagan L., 2019, "Reflections on the Future of Warfare and Implications for Personnel Policies of the U.S. Department of Defense," RAND, p. 22, https://www.rand.org/pubs/perspectives/PE324.html.

[98] Gibbons and Crumbley, 2024, "Accelerating Transition of Biotechnology Products for Military Supply Chains."; Kraig Biocraft Laboratories, 2014, "Spider Silk," accessed May 28, 2025, https://www.kraiglabs.com/spider-silk/; US Department of Defense, 2024, "DOD Releases Five Awards for Distributed Bioindustrial Manufacturing Program," accessed May 28, 2025, https://www.defense.gov/News/Releases/Release/Article/3855207/dod-releases-five-awards-for-distributed-bioindustrial-manufacturing-program/; US Department of Defense, 2024, "DoD Releases 12 Awards for Distributed Bioindustrial Manufacturing Program," accessed May 28, 2025, https://www.defense.gov/News/Releases/Release/Article/3904890/dod-releases-12-awards-for-distributed-bioindustrial-manufacturing-program/https%3A%2F%2Fwww.defense.gov%2FNews%2FReleases%2FRelease%2FArticle%2F3904890%2Fdod-releases-12-awards-for-distributed-bioindustrial-manufacturing-program%2F.

[99] Dale-Huang, Alexis and Beauchamp-Mustafaga, Nathan, 2024, "Chinese Military Thinking at the Crossroads of Biological Security,

Biotechnology, and Global Health," in *Under the Microscope; China's Evolving Biotechnology Ecosystem,* ed. Nadège Rolland, pp. 41—52. https://www.nbr.org/wp-content/uploads/pdfs/publications/sr114_underthemicroscope_dec2024.pdf; DIANA, n.d., "About," accessed May 12, 2025, https://www.diana.nato.int/about-diana.html; Gibbons and Crumbley, 2024, "Accelerating Transition of Biotechnology Products for Military Supply Chains," p. 15; NATO, 2024, "Summary of NATO's Biotechnology and Human Enhancement Technologies Strategy," accessed May 12, 2025, https://www.nato.int/cps/en/natohq/official_texts_224669.htm.

[100] China Aerospace Studies Institute, 2022, "In Their Own Words: Science of Military Strategy 2020," p. 167, https://www.airuniversity.af.edu/Portals/10/CASI/documents/Translations/2022-01-26%202020%20Science%20of%20Military%20Strategy.pdf.

## Biosecurity and Biosafety

As discussed above, synbio holds tremendous potential to drive positive change across healthcare, agriculture and environmental sustainability — but its rapid advancement also introduces significant risks with serious implications for international security. Because the know-how and materials driving synbio innovation are inherently dual-use, developments in this field give rise to biosecurity risks like the design of pathogens with increased virulence and transmissibility, expanded or targeted host range or enhanced resistance.[101]

**Barriers to genetic modification are being lowered by innovation, making it increasingly accessible to state and non-state actors without substantial resources.**

Meanwhile, ongoing innovations in synthetic biology are steadily lowering the barriers to genetic modification, making it increasingly accessible to state and non-state actors without substantial resources. And because many applications of synbio are still outside of conventional safety oversight and regulatory frameworks, modified or artificial pathogens could be used to attack societies directly or indirectly (e.g. through targeting food supply) with limited prospects for clear attribution.[102] Due to the scale of these risks, NATO has classified biotechnology as one of nine priority Emerging and Disruptive Technologies, asserting that synthetic bioweapons could be as harmful as nuclear weapons in the long run.[103] NATO's biotechnology strategy outlines how it intends to safeguard against threats from adversarial use of these innovations.[104]

The accelerating convergence of AI and biotechnology is further amplifying risks to biosecurity in two distinct ways.[105] On the one hand, widely used LLMs have been shown to make rare yet public information about potential bioweapons available to virtually anyone, and these tools excel in laboratory problem-solving.[106] There is, however, no consensus on the degree to which these LLMs can themselves replace hands-on laboratory training.[107]

On the other hand, AI-enabled biological tools could be used for a host of harmful purposes. This raises pressing questions about who should be allowed access to these tools.[108] So far, there are shortages in the quality and quantity of data needed to train the underlying models for these applications and to test their predictions. Using the tools also requires a substantial level of expertise, limiting the range of users.[109] Yet, as AI models become more capable of interacting with laboratory instruments and bio-design tools become more accessible, the

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[101] Brockmann, Bauer, and Boulanin, 2019, "BIO PLUS X: Arms Control and the Convergence of Biology and Emerging Technologies," p. 4; Lentzos, Filippa, 2020, "How to Protect the World from Ultra-Targeted Biological Weapons," Bulletin of the Atomic Scientists, accessed May 27, 2025, https://thebulletin.org/premium/2020-12/how-to-protect-the-world-from-ultra-targeted-biological-weapons/.

[102] National Security Commission on Emerging Biotechnology, 2024, "Gene Synthesis Security," https://www.biotech.senate.gov/press-releases/gene-synthesis-security/.

[103] NATO, 2024, "NATO Releases First International Strategy on Biotechnology and Human Enhancement Technologies," accessed May 12, 2025, https://www.nato.int/cps/en/natohq/news_222980.htm; Sweeney et al., 2025, "Science and Technology Trends 2025-2045," p. 24.

[104] NATO, 2024, "Summary of NATO's Biotechnology and Human Enhancement Technologies Strategy."

[105] Drexel, Bill and Withers, Caleb, 2024, "AI and the Evolution of Biological National Security Risks," Center for a New American Security, pp. 13—25, https://s3.us-east-1.amazonaws.com/files.cnas.org/documents/AIBiologicalRisk_2024_Final.pdf.

[106] Chow, Andrew R., 2025, "Exclusive: AI Bests Virus Experts, Raising Biohazard Fears," *TIME*, April 22, 2025, https://time.com/7279010/ai-virus-lab-biohazard-study/; Rollet, Charles, 2025, "Anthropic CEO Says DeepSeek Was 'the Worst' on a Critical Bioweapons Data Safety Test," TechCrunch, accessed April 25 2025, https://rebrand.ly/90sjb22.

[107] Drexel and Withers, 2024, "AI and the Evolution of Biological National Security Risks," pp. 15—19; Soice, Emily H., Rocha, Rafael, Cordova, Kimberlee, Specter, Michael, and Esvelt, Kevin M., 2023, "Can Large Language Models Democratize Access to Dual-Use Biotechnology?" Cornell University ArXiv, https://doi.org/10.48550/arXiv.2306.03809.

[108] Callaway, Ewen, 2024, "AI Protein-Prediction Tool AlphaFold3 Is Now More Open," *Nature* 635, 531—32, https://doi.org/10.1038/d41586-024-03708-4.

[109] Lin and Giles, 2025, "The Stanford Emerging Technology Review 2025," p. 46; National Security Commission on Emerging Biotechnology, 2024, "AIxBio White Paper 3: Risks of AIxBio," https://www.biotech.senate.gov/press-releases/aixbio-white-paper-risks-of-aixbio/.

range of users and use cases will likely broaden substantially.[110] On the plus side, AI also offers enormous potential for monitoring and detecting threats much more rapidly.[111]

The threats associated with biotechnology do not only come from foreign powers and nefarious actors; domestic biotechnology — and particularly synbio — research also comes with biosafety risks[112] such as the unintentional exposure to or release of pathogens, toxins or genetically modified biological materials, which could lead to the spread of highly infectious pathogens or the loss of biodiversity.[113] For example, researchers working on nascent synthetic DNA-modifying gene drives — which would ensure certain genes are inherited at a disproportionately elevated frequency — have found it difficult to make convincing cases about this technology's biosafety. It has so far proven impossible to fully rule out accidental, unintended and irreversible changes in genomes or their spread beyond the target population with potentially devastating environmental effects.[114] The biosafety risks from this kind of legitimate research are increasing because of the rapidly rising number of laboratories dealing with pathogens and the availability of do-it-yourself (DIY) synbio tools.[115]

**Existing multilateral governance frameworks are fragmented, often non-binding, limited in scope, or lacking resources, verification and monitoring mechanisms.**

There is currently no binding, holistic global framework governing interstate practices to limit the risks posed by biotechnology innovation. While there are several international treaties and multistakeholder initiatives that address biosecurity and biosafety — mainly framed around nonproliferation and arms control — they are often criticized for being fragmented, non-binding, narrowly scoped, and for lacking the resources, verification and monitoring mechanisms to keep pace with rapidly advancing and increasingly accessible technologies.[116]

The most fundamental treaty, the Bioweapons Convention (BWC), entered into force in 1975, prohibiting the development, production, acquisition, transfer, stockpiling, and use of biological and toxin weapons.[117] With 188 state parties, the BWC has a fairly wide reach, yet it has important gaps as it allows the use of biological substances below an unspecified threshold and fails to address non-state actors. Efforts to implement confidence-building measures have

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[110] Braza and Noriega, 2025, "Biotechnology and the next pandemic part 2: innovation or threat?"; Nguyen, Britney, 2024, "Former Meta Scientists Unveiled an AI Model That Can Generate New Proteins," *Quartz*, August 6, 2024, https://qz.com/ex-meta-ai-model-generate-protein-evolutionary-scale-1851582445.

[111] Yi, Jiyoon, Wisuthiphaet, Nicharee, Raja, Pranav, Nitin, Nitin, and Earles, J. Mason, 2023, "AI-Enabled Biosensing for Rapid Pathogen Detection: From Liquid Food to Agricultural Water," *Water Research* 242, 120258, https://doi.org/10.1016/j.watres.2023.120258.

[112] Patrick, Stewart and Barton, Josie, 2024, "Mitigating Risks from Gene Editing and Synthetic Biology: Global Governance Priorities," p. 7, https://carnegie-production-assets.s3.amazonaws.com/static/files/Patrick_Barton-Biotech%20Governance-final.pdf.

[113] Robinson and Nadal, 2025 "Synthetic Biology in Focus: Policy Issues and Opportunities in Engineering Life," p. 34.

[114] Church, George, n.d. "Gene Drives," Wyss Institute, accessed April 28, https://wyss.harvard.edu/technology/gene-drives/; König, Harald, Kolleck, Alma, and Sauter, Arnold, 2024, "Gene Drives: Technologien zur Verbreitung genetischer Veränderungen in Populationen," Office of Technology Assessment at the German Bundestag, pp. 5—8, https://doi.org/10.5445/IR/1000179980; Olejarz, Jason W. and Nowak, Martin A., 2024, "Gene Drives for the Extinction of Wild Metapopulations," *Journal of Theoretical Biology* 577, 111654, https://doi.org/10.1016/j.jtbi.2023.111654; Van Woensel, Lieve and Van Steerteghem, Jens, 2018, "What If We Genetically Engineered an Entire Species?" European Parliamentary Research Service, https://www.europarl.europa.eu/RegData/etudes/ATAG/2018/624270/EPRS_ATA(2018)624270_EN.pdf.

[115] Kaiser, Jocelyn, 2023, "Growing Number of High-Security Pathogen Labs around World Raises Concerns," *Science*, March 17, 2023, https://www.science.org/content/article/growing-number-high-security-pathogen-labs-around-world-raises-concerns ; Kaminska, Izabella, 2021, "Bioterror: The Dangers of Garage Scientists Manipulating DNA," *Financial Times*, September 21, 2021, https://www.ft.com/content/9ac7f1c0-1468-4dc7-88dd-1370ead42371.

[116] Langer, Ronit and Sharma, Shruti, 2020, "The Blessing and Curse of Biotechnology: A Primer on Biosafety and Biosecurity," Carnegie Endowment for International Peace, https://carnegieendowment.org/research/2020/11/the-blessing-and-curse-of-biotechnology-a-primer-on-biosafety-and-biosecurity?lang=en.

[117] United Nations, n.d. "Biological Weapons", accessed May 14, 2025, https://disarmament.unoda.org/biological-weapons/.

repeatedly failed because countries like the US and, more recently, Russia have blocked the required consensus.[118]

Other prominent international regimes include the Australia Group, an informal group of 43 countries aligning their use of export controls on dual-use materials to prevent the proliferation of chemical and biological weapons, and UN Security Council Resolution 1540, which prohibits the transfer of bioweapons and related technologies to non-state actors.[119] The World Health Organization (WHO) also has guidelines for dual-use research in the life sciences, and there are regimes like the Cartagena Protocol on Biosafety (governing the movement of genetically modified organisms) that address specific risk cases.[120] Ethical aspects of these technologies, while similarly not sufficiently governed by international regulatory frameworks, go beyond the scope of this brief and will not be discussed in more detail.

The various risks associated with biotechnology innovation have so far received limited attention from European policymakers, also in comparison to their counterparts in the US (see above). Under the EU's Economic Security Strategy, biotechnologies have been included in a short-list of technology areas posing the most sensitive and immediate threats related to technology security and leakage in 2023.[121] Yet, the status of the risk assessment kicked off back then is unclear.

Despite receiving some attention in Germany's 2023 National Security Strategy, Germany's actions on biosecurity or biosafety have also featured less prominently in national debates and regulations. Internationally, Germany has supported third countries in strengthening their biosecurity and biosafety infrastructure through the Global Biosecurity Program, on which it spent 60 million euros between 2013 and 2022.[122] Whether this approach is suitable to cope with the challenges posed by innovations in biotechnology is questionable. Ongoing research projects, such as one being conducted by the Office of Technology Assessment at the German Bundestag (the lower house of the German federal parliament) on risks arising from the biotechnology-AI-nexus, will likely increase pressure on German authorities to come up with reasonable countermeasures to biotechnological threats.[123]

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[118] Patrick and Barton, 2024, "Mitigating Risks from Gene Editing and Synthetic Biology: Global Governance Priorities," pp. 12—14.

[119] Langer and Sharma, 2020, "The Blessing and Curse of Biotechnology: A Primer on Biosafety and Biosecurity."; United Nations, 2004. "UN Security Council Resolution 1540 (2004)," https://disarmament.unoda.org/wmd/sc1540/.

[120] Langer and Sharma, 2020, "The Blessing and Curse of Biotechnology: A Primer on Biosafety and Biosecurity."; World Health Organization, 2022, "Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-Use Research," https://iris.who.int/bitstream/handle/10665/362313/9789240056107-eng.pdf?sequence=1.

[121] Breyer, Didier, 2024, "WP8 Novel Threats: D8.2: Synthetic Biology - Risk Assessments and Recommendations for Future Governance Guidelines," pp. 24—25, 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; European Commission, 2023, "Commission Recommendation of 3.10.2023 on Critical Technology Areas for the EU's Economic Security for Further Risk Assessment with Member States," https://defence-industry-space.ec.europa.eu/document/download/31c246f2-f0ab-4cdf-a338-b00dc16abd36_en?filename=C_2023_6689_1_EN_ACT_part1_v8.pdf

[122] German Federal Foreign Office, 2023, "The German Biosecurity Programme," accessed May 5, 2025, https://www.auswaertiges-amt.de/en/aussenpolitik/themen/239362-239362; German Government, 2023, "National Security Strategy: Robust. Resilient. Sustainable. Integrated Security for Germany," p. 36, 45, https://www.nationalesicherheitsstrategie.de/National-Security-Strategy-EN.pdf; Wissenschaftliche Dienste des deutschen Bundestages, 2021, "Zu Entwicklungen in der Biosicherheitspolitik seit 2014: Initiativen in der Wissenschaft und auf internationaler Ebene," p. 10.

[123] German Foundation for Peace Research, n.d., "Synthetische Biowaffen – Biosicherheitsbewertung der Konvergenz synthetischer Biologie mit neuen/innovativen Technologien," accessed April 15, 2025, https://bundesstiftung-friedensforschung.de/blog/synthetische-biowaffen/; Office of Technology Assessment at the German Bundestag, 2024, "Biotechnology and Artificial Intelligence: Risks from Research for Security and Proliferation of Biological Weapons," accessed May 6, 2025, https://www.tab-beim-bundestag.de/english/biotechnology-and-health_biotechnology-and-artificial-intelligence-risks-from-research-for-security-and-proliferation-of-biological-weapons.php.

To effectively mitigate concerns over biosecurity and biosafety, Germany and the EU should — as part of a broader reassessment of the risks and potential of biotechnologies from a security perspective — initiate detailed threat and capability assessments and strengthen prevention and resilience measures as well as research and innovation. This should involve better coordination between governments, industry and academia on (1) understanding and defining the nature and severity of risks (e.g., which combinations of sequences or which customers are concerning), (2) pairing oversight and monitoring regimes (e.g., safety and reporting requirements and nucleic acid synthesis screening) with assistance and guidance for institutional biosecurity and biosafety efforts and research (in Germany, for instance, self-regulation in academia has so far been prioritized by a majority in parliament and the government[124]), and (3) developing feasible guardrails (in particular with regards to AI-Bio technologies and digitalization of research) and necessary restrictions (e.g., export controls on certain dual use biotechnologies).

At the same time, the EU should bolster early warning and detection capabilities (biosurveillance) as well as rapid response systems and capabilities to enable the attribution of attacks. This approach reflects a key pillar of deterrence by denial in biotechnology: reducing the likelihood that hostile actors can successfully deploy biotech-enabled weapons in the first place.[125] The EU should deepen exchange with like-minded countries that have established systematic mechanisms for monitoring biological risks, such as the UK's Biothreats Radar.[126]

Efforts on the multilateral level must flank those made domestically and bilaterally. Given the limitations of existing frameworks, Germany and the EU should prioritize pragmatic avenues for progress, such as the WHO Hub for Pandemic and Epidemic Intelligence, to strengthen biosurveillance and cross-border early warning systems. In parallel, they should aim to find new avenues for harmonizing biosecurity and biosafety standards for the growing number of laboratories and cloud labs working with dangerous pathogens (in particular BSL-4 and BSL-3 laboratories equipped to work with the most dangerous pathogens), setting up mandatory screening frameworks for synthetic nucleic acid sequences and the customers purchasing them, and establishing guardrails to prevent AI misuse for the development of bioweapons (noting that the EU AI Act does not clearly define whether AI-enabled biological tools fall within its scope, and recognizing that EU-only guardrails may have limited global impact if not mirrored internationally and could inadvertently constrain innovation potential for European companies if not carefully calibrated).[127] These are important steps in addressing the risks associated with the accelerating diffusion of synbio capabilities. Because synbio innovations make it impossible to rely solely on restricting access to bioweapons, bolstering defensive capabilities also needs to be a priority.

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[124] Wissenschaftliche Dienste des deutschen Bundestages, 2021, "Zu Entwicklungen in der Biosicherheitspolitik seit 2014: Initiativen in der Wissenschaft und auf internationaler Ebene," pp. 5—7, https://www.bundestag.de/resource/blob/867488/5218c2645266b5a8753d780534001376/WD-8-073-21-pdf-data.pdf.

[125] Bajema, Natasha E., Beaver, William, and Parthemore, Christine, 2021, "Toward a Global Pathogen Early Warning System: Building on the Landscape of Biosurveillance today, https://councilonstrategicrisks.org/wp-content/uploads/2021/07/Toward-A-Global-Pathogen-Early-Warning-System_2021_07_20-1.pdf.

[126] UK Government, 2023, "Dowden: world-class crisis capabilities deployed to defeat biological threats of tomorrow," accessed June 05, 2025, https://www.gov.uk/government/news/dowden-world-class-crisis-capabilities-deployed-to-defeat-biological-threats-of-tomorrow.

[127] Carter, Sarah R., Wheeler, Nicole E., Isaac, Chris, and Yassif, Jaime M., 2024, "Developing Guardrails for AI Biodesign Tools," Nuclear Threat Initiative, https://www.nti.org/wp-content/uploads/2024/11/NTIBio_Paper_Developing-Guardrails-for-AI-Biodesign-Tools_FINAL.pdf; Patrick and Barton, 2024, "Mitigating Risks from Gene Editing and Synthetic Biology: Global Governance Priorities," p. 2, 18—24; Pour Demain et al., 2024, "Brief: Biosecurity & Nucleic Acid Synthesis," https://www.pourdemain.ngo/en/post/brief-biosecurity-nucleic-acid-synthesis.

## Data Security

Biotechnology research is reliant on access to highly sensitive, personal genomic data and using biotechnology applications often involves collecting this kind of data. Access to genomic data, whether obtained through voluntary provision (e.g., for medical purposes or genealogical research), theft or collecting environmental DNA shed by every human, could enable malicious actors to engage in espionage, sabotage or actions that conflict with economic and national security interests.[128]

**Access to genomic data could enable malicious actors to engage in espionage, sabotage or actions that conflict with economic and national security interests.**

The Chinese government considers human genetic data a national resource under state control,[129] and companies with ties to the Chinese government have been accused of systematic data harvesting. Although it is unclear whether it was the result of state-directed efforts or not, Chinese entities, obligated to share any data with federal authorities when requested for national security reasons, have been able to acquire genomic data from people outside of China by establishing themselves in the global gene sequencing market and investing in firms dealing with genomic data.[130]

Some governments have taken steps to protect their citizens' genomic data: both Beijing and Washington have imposed restrictions on foreign collection, storage and access to such information.[131] However, vulnerabilities remain. For example, third parties might gain access to extensive DNA databases created by private genomics companies, such as in the case of US firm 23andMe, which its owners had to sell after it faced bankruptcy.[132] In addition to national security concerns and individual vulnerability to blackmail and other crimes, a lack of

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[128] Needham, Kirsty and Baldwin, Clare, 2021, "China's Gene Giant Harvests Data from Millions of Pregnant Women," *Reuters*, July 7, 2021, https://www.reuters.com/investigates/special-report/health-china-bgi-dna/; Thormählen, Åsa, 2025, "Greyzone Genomics: Assessing the Risks of DNA Technology in Global Power Struggles," Pufendorf Institute for Advanced Studies, accessed May 18, 2025, https://www.pi.lu.se/en/article/greyzone-genomics-assessing-risks-dna-technology-global-power-struggles; Whilde, Jenny and Farrell, Jessica A, 2023, "You Shed DNA Everywhere You Go – Trace Samples in the Water, Sand and Air Are Enough to Identify Who You Are, Raising Ethical Questions about Privacy," *The Conversation*, May 15, 2023, http://theconversation.com/you-shed-dna-everywhere-you-go-trace-samples-in-the-water-sand-and-air-are-enough-to-identify-who-you-are-raising-ethical-questions-about-privacy-205557.

[129] Lexmann, Miriam, Olekas, Juozas, Groothuis, Bart, Bütikofer, Reinhard, and Fotyga, Anna, 2024, "When It Comes to Genomics, de-Risking with China Is Not Enough," *Euronews*, May, 31, 2024, https://www.euronews.com/my-europe/2024/05/31/when-it-comes-to-genomics-de-risking-with-china-is-not-enough; McKibbin, Kyle and Shabani, Mahsa, 2023, "Genomic Data as a National Strategic Resource: Implications for the Genomic Commons and International Data Sharing for Biomedical Research and Innovation," *Journal of Law, Medicine & Ethics* 51, no. 2, 301—313, pp. 303—304, https://doi.org/10.1017/jme.2023.77; National Counterintelligence and Security Center, 2021, "China's Collection of Genomic and Other Healthcare Data from America: Risks to Privacy and U.S. Economic and National Security," https://www.dni.gov/files/NCSC/documents/SafeguardingOurFuture/NCSC_China_Genomics_Fact_Sheet_2021revision20210203.pdf.

[130] Brown and Groenewegen-Lau, 2025, "Lab Leader, Market Ascender: China's Rise in Biotechnology," p. 15; Kratz, Agatha, Zenglein, Max J., Brown, Alexander, Sebastian, Gregor, and Meyer, Armand, 2024, "Dwindling Investments Become More Concentrated: Chinese FDI in Europe - 2023 Update," p. 12, 14—15, https://merics.org/sites/default/files/2024-08/merics-rhodium-group-chinese-fdi-in-europe-2023.pdf ; Liu, Cecily, 2017, "Success? It's in Their DNA," *China Daily*, May 26, 2017, https://europe.chinadaily.com.cn/epaper/2017-05/26/content_29506420.htm?utm_source=chatgpt.com; Plucinska, Joanna, 2021, "Exclusive-Polish Gene Project Moves to Drop Chinese Tech on Data Concerns," *Euronews*, September 22, 2021, https://www.euronews.com/next/2021/09/22/us-health-china-bgi-poland-exclusive.

[131] Bērziņa-Čerenkova, Una, Ferrari, Elena, Palkova, Karina, and Voo, Julia, 2024, "Genomic Data: Regaining and Maintaining the Advantage in Biotechnologies," in *Making Europe's Digital Technological Strengths Indispensable to China*, ed. Tim Rühlig, p. 158, https://dgap.org/system/files/article_pdfs/DPC%20-%20GESAMT_Final.pdf; China Law Translate, 2020, "Biosecurity Law of the P.R.C."; Pittman, F. Paul, Anderson, Hope, Lim, David H., and Wang, Yuhan, 2025, "DOJ Issues Final Rule Prohibiting and Restricting Transfers of Bulk Sensitive Personal Data," White and Case, accessed May 7, 2025, https://www.whitecase.com/insight-alert/doj-issues-final-rule-prohibiting-and-restricting-transfers-bulk-sensitive-personal; Wu, Yi, 2023, "China's Human Genetic Resources Regulation: New Implementation Rules," China Briefing, accessed June 5, 2025, https://www.china-briefing.com/news/chinas-human-genetic-resources-regulation-implementation-rules-key-points-for-foreign-stakeholders/.

[132] Hernandez, Joe, 2025, "23andMe Is Filing for Bankruptcy. Here's What It Means for Your Genetic Data," *NPR*, March 24, 2025, https://www.npr.org/2025/03/24/nx-s1-5338622/23andme-bankruptcy-genetic-data-privacy.

regulatory oversight could enable private actors like insurers or employers to exploit such data to discriminate based on individuals' genetic information.

In the EU, generic privacy frameworks like the General Data Protection Regulation (GDPR) stipulate that explicit consent must be obtained from people whose genetic data is processed for research purposes, and robust security measures must be taken to protect their data. Member states are granted the right to impose further conditions or specify certain provisions, including for scientific research.[133] This has resulted in differing regulation, interpretation and enforcement across member states, leading to regulatory gaps and increased complexity of cross-border data sharing.[134] Laws in Germany, like the Federal Data Protection Act, for instance, grant exceptions to explicit consent for processing sensitive data for scientific research.[135]

In addition to addressing specific gaps and clarification needs (also reducing uncertainty among stakeholders), Germany and Europe should develop a holistic perspective on how, when and with whom genomic data should be shared internationally to better protect its security without unnecessarily hindering legitimate research and business efforts. This will likely entail fostering EU-based alternatives for genomic research services. Moreover, Europe should actively promote secure pooling and sharing of sensitive data within Europe, developing solutions that uphold high standards of security, privacy and ethical oversight. Research funding could be used by EU institutions to incentivize data sharing and use that aligns with European values and interests.

## Societal and Economic Significance and Coercion Risks

**Biotechnology has great potential to offer societal and economic benefits.**

Biotechnology has great potential to offer societal and economic benefits by helping to prevent and overcome health and food crises and offering solutions for the dual climate and biodiversity crises.[136] It promises to enable economies to reduce their reliance on unsustainable petrochemical resources by providing alternative energy sources in hard-to-abate sectors, and also advance carbon reduction and sequestration.[137] While important questions about equitable access to and fair distribution of benefits from advanced biotechnologies arise, these are beyond the scope of this brief.

Biotechnology's potential is reflected in its rapidly growing economic relevance. In 2024, the global biotechnology market reached a size of almost $1.7 trillion. Some project that, by 2030,

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[133] European Parliament and Council of the European Union, 2016, "Regulation (EU) 2016/679 of the European Parliament and of the Council - of 27 April 2016 - on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation)," art. 9 (2) (j), art. 9 (4), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679.

[134] Bērziņa-Čerenkova et al., 2024, "Genomic Data: Regaining and Maintaining the Advantage in Biotechnologies," pp. 162—63.

[135] Bundesministerium der Justiz und für Verbraucherschutz, n.d., "Bundesdatenschutzgesetz (BDSG): § 27 Datenverarbeitung zu wissenschaftlichen oder historischen Forschungszwecken und zu statistischen Zwecken," art. 27 (1), https://www.gesetze-im-internet.de/bdsg_2018/__27.html.

[136] Candelon, François, Gombeaud, Matthieu, Stokol, Georgie, Patel, Vinit, Gourévitch, Antoine et al., 2022, "Synthetic Biology Is About to Disrupt Your Industry," Boston Consulting Group, p. 2, 7—8, https://web-assets.bcg.com/pdf-src/prod-live/synthetic-biology-is-about-to-disrupt-your-industry.pdf; Onyeaka, Helen, Miri, Taghi, Obileke, KeChrist, Hart, Abarasi, Anumudu, Christian et al., 2021, "Minimizing Carbon Footprint via Microalgae as a Biological Capture," *Carbon Capture Science & Technology* 1, 100007, https://doi.org/10.1016/j.ccst.2021.100007; Yang, Throp, and Sherman, 2024, "How Strategic Collaboration on the Bioeconomy Can Boost Climate and Nature Action," p. 4.

[137] Fu, Bing, Mao, Xianwen, Park, Youngchan, Zhao, Zhiheng, Yan, Tianlei et al., 2023, "Single-Cell Multimodal Imaging Uncovers Energy Conversion Pathways in Biohybrids," *Nature Chemistry* 15, no. 10, 1400–1407, https://doi.org/10.1038/s41557-023-01285-z; Lynggaard, Christina, Guldberg Frøslev, Tobias , Johnson, Matthew S., Tange Olsen, Morten, and Bohmann, Kristine, 2023, "Airborne Environmental DNA Captures Terrestrial Vertebrate Diversity in Nature," *Molecular Ecology Resources* 24, no. 1, e13840, https://doi.org/10.1111/1755-0998.13840.

it will disrupt industries that account for around a third of global GDP.[138] Although it is comparatively small, the global synbio market, valued at $15.4 billion in 2023, is also expected to see sustained growth in the coming years, reaching $61.6 billion in 2029.[139] While its exact potential is difficult to estimate, it seems certain that the biotechnology industry will be of enormous economic relevance in the foreseeable future.

The flipside of this major potential is that biotech is also likely to acquire a key role in economic statecraft, including by coercive means. As biotechnology becomes more deeply embedded in global value chains, its implications for economic security demand closer attention — especially because many biotechnology innovations believed to have disruptive potential are still at a nascent stage of development.

There are already dependencies across the biotechnology industry that make Europe vulnerable to economic coercion. The US and China dominate EU imports of crucial tools used in biotechnology, such as reagents, personal protective equipment and laboratory instruments and equipment.[140] Moreover, non-European companies hold strong positions in key segments of the biotechnology value chain, like fermented biochemicals, biologics and biosimilars.[141] Contract research, development and manufacturing organizations (CRDMO) play a crucial role here; these organizations have traditionally been dominated by South Korea, the EU and the US, but Chinese companies have expanded their presence in recent years.[142] US companies are reportedly already heavily dependent on the services of Chinese CRDMOs, and the same is likely to apply to many of their European counterparts.[143]

US-headquartered companies still lead in healthcare biotechnology, producing almost twice as many new chemical or biological entities as European firms between 2014 and 2018.[144] The US and China together also dominate goods and services indispensable to synbio. This includes gene sequencers (the global market leader is US-based Illumina, accounting for about 90 percent of the US and European markets of this bottleneck technology, foundational for synbio),[145] sequencing as a service, and to a lesser degree, gene synthesis.[146] All of this

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[138] BioSpace, 2025, “Biotechnology Market Size to Worth Around USD 3.54 Trillion by 2033,” accessed May 8, 2025, https://www.biospace.com/press-releases/biotechnology-market-size-to-worth-around-usd-3-54-trillion-by-2033; Candelon, François and Gombeaud, Matthieu, 2021, “Commentary: Synthetic Biology Could Help Business Save the Planet,” *Fortune*, August 6, 2021, https://fortune.com/2021/08/06/synthetic-biology-plant-based-meats-bioengineering-environmental-impact/.

[139] BCC Research, 2024, “Global Synthetic Biology Market Size and Industry Analysis,” accessed May 8, 2025, https://www.bccresearch.com/market-research/biotechnology/synthetic-biology-global-markets.html.

[140] Eurostat, n.d., “EU Trade since 1988 by HS2-4-6 and CN8,” accessed June 5, 2025, https://ec.europa.eu/eurostat/databrowser/view/ds-045409__custom_16914538/bookmark/table?lang=en&bookmarkId=57862379-fc86-4d94-ba7c-55f03aa44033.

[141] Brown and Groenewegen-Lau, 2025, “Lab Leader, Market Ascender: China’s Rise in Biotechnology,” p. 14.

[142] European Commission, 2021, “Strategic Dependencies and Capacities: Accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions,” p. 65, https://commission.europa.eu/system/files/2021-05/swd-strategic-dependencies-capacities_en.pdf; GlobalData Healthcare, 2024, “BIOSECURE Act Could Impact US Biopharma Drugs with Half in Clinical-Stage Development,” Pharmaceutical Technology, accessed May 4, 2025, https://www.pharmaceutical-technology.com/analyst-comment/biosecure-act-could-impact-us-biopharma-drugs/; Nelson, Millie, 2022, “WuXi Bio Grabs Larger Piece of the Bio CDMO Pie,” *BioProcess International*, March 24, 2022, https://www.bioprocessintl.com/global-markets/wuxi-bio-grabs-larger-piece-of-the-bio-cdmo-pie.

[143] Chen, Eliot, 2024, “WuXi Waylaid,” *The Wire China*, August 25, 2024, https://www.thewirechina.com/2024/08/25/wuxi-waylaid-wuxi-apptec-biosecure-act/.

[144] European Federation of Pharmaceutical Inudstries and Associations, 2019, “The Pharmaceutical Industry in Figures,” p. 8, https://www.efpia.eu/media/413006/the-pharmaceutical-industry-in-figures.pdf; Han et al., 2021, “The Dawn of China Biopharma Innovation,” pp. 2—3. In this context, it should be noted that the well-reported dominance of the production of active pharmaceutical ingredients of China and India mainly concerns small-molecule generics, which are not considered biotechnology products.

[145] Budel, Stephane, 2024, LinkedIn, https://www.linkedin.com/posts/budel_decibio-ngs-dxbook-2024-competitive-landscape-activity-7205974444576542720--jxs/?utm_source=share&utm_medium=member_desktop&rcm=ACoAACrHJScBbR-bX2ZbQxh1KwMhVI6wVL9XxCg.

[146] Brown and Groenewegen-Lau, 2025, “Lab Leader, Market Ascender: China’s Rise in Biotechnology,” p. 15; Coherent Market Insights, 2025, “DNA Synthesizer Market Trends, Share and Forecast, 2025-2032,” accessed April 26, 2025,

means that European biotech companies are heavily dependent on the continued availability of these inputs.

Overall, the pharmaceutical industry is a key driver of the US trade deficit vis-à-vis the EU.[147] However, so far, the sector has not been impacted by the Trump administration's ongoing tariff actions. This could be due in part to the heavy presence of US pharma companies in countries like Ireland. However, if the industry were to face greater scrutiny, the repercussions would affect not only countries that are heavily reliant on (bio)pharma exports but also the biotechnology industry as a whole. China, too, has seen increased interest as a market by pharma multinational corporations (MNCs) in recent years, but most pharma MNCs saw their sales in China peak in 2021, and the revenue share derived from China remains limited.[148]

**Tensions over biotechnology have been building in recent years.**

Tensions over biotechnology have been building in recent years as key players recognize the immense strategic potential of this area. The US, for one, is taking a security-centric perspective on biotechnology. Yet, its approach reveals the difficulty of balancing the tradeoffs between mitigating biosecurity and biosafety risks and maintaining its competitive edge over China in terms of technological advancement. For a long time, the latter concerns dominated: Washington decided to blacklist several units of Chinese gene sequencing giant BGI Group in 2020 and 2023, as well as 34 Chinese corporate and research entities allegedly working on "biotechnology processes to support Chinese military end uses" in 2021.[149] It also launched the Biopharma Coalition with the EU, India, Japan, and South Korea to coordinate on biopharma supply chain resilience in 2024.[150] The BIOSECURE Act, though stalled in the Senate since October 2024, would essentially prohibit federal agencies and entities receiving federal funds from contracting with several companies of concern in the biologics supply chain. The act specifically mentions five Chinese companies: BGI, MGI, Complete Genomics, WuXi AppTec, and WuXi Biologics.[151] This Act reflects concerns about US pharma companies' dependencies on Chinese CRDMOs, worry over China's access to sensitive genomic data, and arguably a broader intent to slow down China's biotechnology innovation ecosystem. In January 2025, the US Commerce Department imposed controls on the exports of certain biotechnology equipment needed to develop biological design tools to China.[152]

In Donald Trump's second term in office, China continues to receive much attention. With the America First Investment Policy, the Trump administration announced new or expanded restrictions on outbound biotech investments to China and Chinese investments in US

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https://www.coherentmarketinsights.com/market-insight/dna-synthesizer-market-5913; Rozo, 2024, "U.S.-China Economic and Security Review Commission Hearing on 'Current and Emerging Technologies in U.S.-China Economic and National Security Competition': Prepared Statement by Michelle Rozo, Vice Chair National Security Commission on Emerging Biotechnology," p. 201.

[147] Burke-Kennedy, Eoin, 2025, "Is Big Pharma's powerful US lobby shielding Ireland from the worst of Donald Trump's tariffs?" *Irish Times*, July 4, 2025, https://www.irishtimes.com/business/economy/2025/07/04/is-big-pharmas-powerful-us-lobby-shielding-ireland-from-the-worst-of-donald-trumps-tariffs/.

[148] Cheung, Rachel, 2024, "The Tipping Point," *The Wire China*, November 11, 2024, https://www.thewirechina.com/2024/11/10/the-tipping-point-foreign-companies-china/.

[149] Alper, Alexandra and Shepardson, David, 2023, "US Adds Units of China's BGI, Inspur to Trade Blacklist," *Reuters*, March 16, 2023, https://www.reuters.com/markets/us/us-adds-chinese-genetics-company-units-trade-blacklist-2023-03-02/. US Federal Register, 2021, "Addition of Certain Entities to the Entity List and Revision of an Entry on the Entity List," https://www.govinfo.gov/content/pkg/FR-2021-12-17/pdf/2021-27406.pdf.

[150] White House, 2024, "Fact Sheet: Biden-Harris Administration's Actions to Advance American Biotechnology and Biomanufacturing," accessed April 25, 2025, https://bidenwhitehouse.archives.gov/ostp/news-updates/2024/06/25/fact-sheet-biden-harris-administrations-actions-to-advance-american-biotechnology-and-biomanufacturing/.

[151] US Congress, 2024, "Text - H.R.8333 - 118th Congress (2023-2024): BIOSECURE Act," https://www.congress.gov/bill/118th-congress/house-bill/8333/text/rfs.

[152] Shepardson, David, 2025, "US Imposing New Export Controls on Biotech Equipment over China Concerns," *Reuters*, January 15, 2025, https://www.reuters.com/technology/us-imposing-new-export-controls-biotechnology-equipment-2025-01-15/.

technology.[153] The administration has also indicated that it considers bio-manufacturing critical to its manufacturing ecosystem, which is needed to maintain what it calls an "effective security umbrella."[154] The final report of the bipartisan National Security Commission on Emerging Biotechnology, published in April 2025, primarily focuses on creating the necessary conditions to out-innovate China: it suggests a sustained technological edge is a precondition for economic and military strength.[155] It calls for $15 billion in public investment in this field, despite recent budget cuts by the US National Institutes of Health, the main funder of biomedical research in the US.[156] At the same time, the report also calls for a new entity in the Commerce Department charged with making sure that any biotech innovation takes place under a modernized safety and security regime.[157] Trump's executive order on biological research further demonstrates the administration's commitment to strictly regulating frontier biotechnology research. Whether or not Washington will be able to strike the right balance between promoting and regulating domestic innovation remains to be seen. The intention to slow down Chinese innovation in the field, however, seems to persist.

Beijing, too, has adopted a security-centric approach to biotechnologies, hoping to gain a technological edge over the US. It seems committed to assisting Chinese players in expanding their dominance on their home market while also inflicting pain on competitors abroad. Sizeable government support, paired with inbound investment, particularly from Europe and the US, has helped Chinese biotech companies like BGI Group mature to a point of domestic dominance.[158] (The BGI Group subsidiary MGI Tech is now the dominant provider of gene sequencing equipment in China.)[159] At the same time, in February 2025, the Chinese government banned BGI's main US competitor, Illumina, from exporting to China.[160] Export controls imposed in April 2025 by China's Ministry of Commerce on seven rare earth elements (samarium, gadolinium, terbium, dysprosium, lutetium, scandium, and yttrium), require companies to obtain special licenses to export and could also have knock-on effects on the biopharma market.[161]

Yet, China's artificially downsized domestic medication market, designed to keep healthcare costs for its ageing population in check, has limited R&D funds for the biopharma industry, making Chinese firms reliant on overseas partners and sales, in particular in North America and Europe.[162] As a consequence, Chinese companies have sought to expand global market share and increase regulatory recognition.[163] While they have had some success, they are now facing increasing pushback. According to claims by BGI's Director and Executive Vice

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[153] White House, 2025, "America First Investment Policy," accessed April 15, 2025, https://www.whitehouse.gov/presidential-actions/2025/02/america-first-investment-policy/.

[154] White House, 2025, "Fact Sheet: President Donald J. Trump Declares National Emergency to Increase Our Competitive Edge, Protect Our Sovereignty, and Strengthen Our National and Economic Security," accessed April 15, 2025, https://www.whitehouse.gov/fact-sheets/2025/04/fact-sheet-president-donald-j-trump-declares-national-emergency-to-increase-our-competitive-edge-protect-our-sovereignty-and-strengthen-our-national-and-economic-security/.

[155] National Security Commission on Emerging Biotechnology, 2025, "Charting the Future of Biotechnology: An Action Plan for American Security and Prosperity."

[156] Gilbert, Daniel, 2025, "Biotech Start-Ups Struggle as Trump Throttles NIH Funding," *The Washington Post*, April 6, 2025, https://www.washingtonpost.com/business/2025/04/06/nih-funding-biotech-startups/.

[157] National Security Commission on Emerging Biotechnology, 2025, "Charting the Future of Biotechnology: An Action Plan for American Security and Prosperity," pp. 117—18.

[158] Chilukuri and Kelley, 2025, "Biopower: Securing American Leadership in Biotechnology," p. 43; Gryphon Scientific and Rhodium Group, 2019, "China's Biotechnology Development: The Role of US and Other Foreign Engagement," pp. 45—55.

[159] Brown and Groenewegen-Lau, 2025, "Lab Leader, Market Ascender: China's Rise in Biotechnology," p. 15.

[160] Kelly, Susan, 2025, "Illumina Placed on China's Unreliable Entity List," MedTech Dive, accessed May 2, 2025, https://www.medtechdive.com/news/Illumina-China-tariffs-unreliable-entity-list/739310/

[161] LabNews Media, "China's Rare Earth Export Controls: Impact on US Industries with Focus on Medical and Biotech Sectors," accessed May 7, 2025, https://lab-news.de/chinas-rare-earth-export-controls-impact-on-us-industries-with-focus-on-medical-and-biotech-sectors/.

[162] Zhou, Xinda, Hua, Ang, Wang, Xintong, and Guo, Xin, 2025, "In Depth: How China's Pricing Regime Penalizes Innovative Drugmakers," *Caixin Global,* June 14, 2024, https://www.caixinglobal.com/2024-06-14/in-depth-how-chinas-pricing-regime-penalizes-innovative-drugmakers-102206130.html.

[163] Han et al., 2021, "The Dawn of China Biopharma Innovation," pp. 7—8; Puglisi and Rask, 2024, "China, Biotechnology, and BGI," pp. 32—35.

President, the German government has also already adopted an internal policy ruling out the use of BGI equipment or services in Germany.[164] Meanwhile, other Chinese companies, such as WuXi Apptec and WuXi Biologics, which have developed into CRDMOs with significant revenue streams in overseas markets, are further expanding their presence in Germany, while also being confronted by increasing scrutiny in the US.[165]

Despite the uncertainty of US restrictions on Chinese involvement in biotech supply chains and market access and market size constraints in China, some US and European biopharma firms have decided to further double down on the Chinese market.[166] In light of expiring patents in China, large European biopharma companies have ramped up acquisitions, out-licensing deals, and R&D investments in China, demonstrating that biotechnology innovation is now also increasingly being spearheaded in China.[167]

**Existing and emerging dependencies put Europe at risk of economic coercion.**

In sum, the immense societal and economic benefits promised by biotechnologies, as well as the coercion risks that accompany them, underscore the urgent need for Germany and the EU to adopt a more strategic approach. Especially given the US's and China's aggressive pushes towards technological supremacy — through government support, market closure and restrictions on trade and investment — existing and emerging dependencies put Europe at risk of economic coercion.

Addressing this problem requires increased monitoring of supply chains and shortening of the reaction time to the emergence of critical dependencies. The EU needs to proactively diversify critical supply chains by partnering with trusted allies in Europe and Asia on inputs, equipment and manufacturing capacity. It remains unclear whether European companies could profit from the US firms severing ties with Chinese biotechnology companies, as Washington has signaled that affiliations with Chinese entities could jeopardize access to US markets. So far, the EU has largely taken a hands-off approach to Chinese investments in Europe, as well as the business and academic ties European actors maintain with Chinese entities.

These efforts need to go hand in hand with strengthening the framework conditions that are necessary to build a more dynamic innovation ecosystem capable of bringing biotech innovations to market at a greater scale in the EU and Germany.[168] Strengthening the European biotech industry will require improved funding conditions, upgraded infrastructure, and the right balance between investing in innovation and implementing

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[164] Jia, Yuxuan and Han, Andy, 2024, "BGI's Mei Yonghong on China's Past, Present, & Future in Science & Technology," *The East Is Read*, December 21, 2024, https://eastisread.substack.com/p/bgis-mei-yonghong-on-chinas-past?publication_id=1151841&utm_medium=email&utm_campaign=email-share&isFreemail=true&triedRedirect=true.

[165] Algazy, Jeffrey, Le Deu, Franck, Li, Sydnie, Zhang, Fangning, and Zhou, Josie, 2022, "Vision 2028: How China Could Impact the Global Biopharma Industry," McKinsey, p. 8, https://www.mckinsey.com/~/media/mckinsey/industries/life%20sciences/our%20insights/vision%202028%20how%20china%20could%20impact%20the%20global%20biopharma%20industry/vision-2028-how-china-could-impact-the-global-biopharma-industry.pdf ; Chen, 2024, "WuXi Waylaid."; Damerow, Anna, 2025, "Expansion at the Munich Site: WuXi AppTec Opens State-of-the-Art Testing Laboratory in the Gräfelfing Life Science Center," Invest in Bavaria, accessed May 6, 2025, https://invest-in-bavaria.com/en/blog/post/expansion-at-the-munich-site-wuxi-apptec-opens-state-of-the-art-test-laboratory-in-the-graefelfing-life-science-center; Philippidis, Alex, 2024, "StockWatch: CDMOs Tumble as Congress Takes Aim at Chinese Biotechs," *Genetic Engineering and Biotechnology News*, March 22, 2024, https://www.genengnews.com/topics/bioprocessing/stockwatch-cdmos-tumble-as-congress-takes-aim-at-chinese-biotechs/; Reuters, 2024, "Trade Association Survey Shows 79% of US Biotech Companies Contract with Chinese Firms," May 8, 2024, https://www.reuters.com/business/healthcare-pharmaceuticals/trade-association-survey-shows-79-us-biotech-companies-contract-with-chinese-2024-05-08/.

[166] Brown and Groenewegen-Lau, 2025, "Lab Leader, Market Ascender: China's Rise in Biotechnology," p. 16; Loftus, Peter, 2025, "Behind Moderna's Quiet Gamble on China," *Wall Street Journal*, January 9, 2025, https://www.wsj.com/health/pharma/moderna-is-gambling-on-china-as-other-u-s-companies-pull-back-34969206.

[167] Brown and Groenewegen-Lau, 2025, "Lab Leader, Market Ascender: China's Rise in Biotechnology," p. 10, 16—17.

[168] Nisslein et al., 2024, "Biotech Innovation Hubs in Germany – Divided and Conquered?," pp. 4—5; Reiß et al., 2023, "Technologische Souveränität Pharma/Biotech: Studie zur Wettbewerbsfähigkeit und technologischen Souveränität Deutschlands im Pharmasektor," p. 7.

responsible regulation (for instance, the EU's rejection of gene-editing in agriculture seems to be slowly easing; yet, any future regulatory revisions must be based on inclusive stakeholder dialogues to ensure that biotech innovation and commercialization remain within agreed-upon boundaries.)[169,170] This entails improving access to risk capital, facilitating talent development and attraction, and investing in strategic infrastructure.

Protecting Europe's competitive edge also means safeguarding access to critical data and intellectual property (IP). For instance, mass leakage of European genomic data could give foreign competitors, who carefully control their own data, an economic advantage.[171] Similarly, leakage of sensitive technologies and IP, whether through cross-border academic or business collaborations or foreign acquisitions, potentially endangers sustained technological competitiveness. These trends raise important questions about how to balance research security with academic freedom, patentability and stronger investment screening (inward and outward).

While shoring up domestic capabilities and safeguarding innovation are essential, they must be embedded within a broader strategic vision — one that considers Europe's global positioning, influence, and resilience in an increasingly competitive biotechnology landscape. The EU risk assessment focused on tech security and tech leakage is a good first step, but taking a more holistic view on opportunities and risks remains key. Achieving "strategic indispensability" in certain areas at the global level would enable Europe to exert influence and deter coercive action by other powers while ensuring that technological progress continues to be driven within certain ethical boundaries and its benefits are shared somewhat equitably. Europe's diverse data pool has already been identified as a chokepoint that it could leverage.[172]

But Europe must move fast. So far, biotech innovations have not provided one player with unique capabilities for an extended period. Some believe this will change soon. In its closing report, the US National Security Commission on Emerging Biotechnology states: "There will be a ChatGPT moment for biotechnology, and if China gets there first, no matter how fast we run, we will never catch up."[173] While the reality in biotechnology might ultimately prove less deterministic, Europe must quickly clarify its priorities.

# Conclusion

Biotechnology is an emerging domain with transformative potential across many strategic sectors. Advancements in synthetic biology propelled by AI are significantly accelerating innovation and reducing barriers to entry, constituting a potential force multiplier in both civilian and military domains. These trends bring both unprecedented opportunities and complex risks for foreign and security policy across four dimensions: (1) the military, (2) biosecurity and biosafety, (3) data security, and (4) economic statecraft and weaponized interdependence.

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[169] Stokstad, Erik, 2024, "European Parliament Votes to Ease Regulation of Gene-Edited Crops," *Science*, February 7, 2024, https://www.science.org/content/article/european-parliament-votes-ease-regulation-gene-edited-crops.

[170] Centre for Future Generations, 2025, "CFG's Response to the European Commission's Call for Evidence for the 2025 Strategic Foresight Report," pp. 13—14, https://cfg.eu/strategic-foresight-report-submission/.

[171] Bērziņa-Čerenkova et al., 2024, "Genomic Data: Regaining and Maintaining the Advantage in Biotechnologies," pp. 155—56.

[172] Bērziņa-Čerenkova et al., 2024, "Genomic Data: Regaining and Maintaining the Advantage in Biotechnologies," p. 158.

[173] National Security Commission on Emerging Biotechnology, 2025, "Charting the Future of Biotechnology: An Action Plan for American Security and Prosperity," p. 8.

Worryingly, Europe is currently trailing behind the US and, increasingly, China, in fostering a competitive biotechnology industry, despite being home to strong individual research institutions and companies. It particularly struggles with translating scientific potential into global biotech leadership amid persistent funding constraints. Moreover, policymakers have yet to sufficiently address the various risks associated with biotechnology innovation. As recognition of biotechnology's strategic importance grows across Europe, policymakers must concentrate on fostering a more conducive environment for biotechnology innovation and commercialization while simultaneously tackling mounting risks to its national and economic security. In ongoing negotiations and the development of strategic documents related to biotechnology, European leaders should prioritize the following actions.

- In the context of biotechnology's military relevance:
    - Define envisioned capabilities, both independently and with partners, and determine the resources needed to achieve them.
    - Systematically monitor developments in military biotechnology.
    - Build an understanding of future biotechnology use cases and assess Europe's political and ethical willingness to develop and deploy them.
- On biosecurity and biosafety:
    - Conduct multi-stakeholder threat and capability assessments to develop consensus on the nature and severity of risks, approaches to balance oversight and monitoring regimes with support for institutional risk management efforts, and the design of appropriate guardrails and restrictions.
    - Enhance early warning, detection and rapid response capabilities.
    - Work at the multilateral level towards harmonized biosecurity and biosafety standards for BSL-4 and BSL-3 laboratories and cloud labs, mandatory screening frameworks for synthetic nucleic acid sequencing, and guardrails for the use of AI.
- Regarding data security:
    - Work towards a more coherent regulatory framework for genomic data.
    - Specify how, when and with whom genomic data can be shared internationally.
    - Promote high-standard, secure pooling and sharing solutions within Europe.
- Related to economic statecraft and the weaponization of interdependence:
    - Expand the monitoring of biotechnology supply chains and shorten the response time to emerging critical dependencies.
    - Diversify biotechnology supply chains with allies in Europe and Asia.
    - Improve the framework conditions for biotechnology innovation in Europe by reducing regulatory and financing barriers, strengthening strategic infrastructure, facilitating access to talent, and safeguarding critical data, IP, and technologies.

# Acknowledgments

This piece is published as part of the GPPi project "Critical and Emerging Technologies: Sharpening the Strategic Agenda in Germany and Europe," which is funded by the German Federal Foreign Office. It solely reflects the analysis and opinions of its authors. The authors greatly benefited from inputs from Oskar Galeev and comments from GPPi colleague Thorsten Benner. Any errors and omissions are the authors' responsibility.

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