Global Essay Competition 2024

Title: From Scarcity to (Bio)Security: Reshaping Oversight for the Biotech Revolution

Essay:

Humanity teeters upon a biological revolution as innovations in synthetic biology, gene editing, and bioengineering surge forward with dizzying momentum.[1] These advances offer visionary solutions to humanity's most intractable challenges – from treating diseases to remediating the environment to ensuring food security. CRISPR-based diagnostics possess untapped potential for public health capacity building globally.[2] Microbial engineering enhances renewable biofuel production critical for the clean energy transition.[3] Genome editing facilitates drought-resistant crops that can feed growing populations on a warming planet.[4]

Yet, they also increase capabilities that enable the manipulation of pathogens and even the building blocks of life on a scale and accuracy previously unfathomable, allowing us to edit entire genomes or even synthesise novel organisms. In the absence of proper oversight, advancing biotechnologies may potentially lower barriers for permanently altering human genetics or engineering biological weapons with devastating and irreversible consequences. This stark "dual-use" duality leaves regulatory mechanisms drastically outpaced by possible risks arising from deliberate misuse or unintended outcomes of well-intentioned innovation.

As global regulatory oversight becomes increasingly scarce compared to accelerating and decentralising risks, we stand at a crossroads for humanity's collective project of biological discovery – will advancing biotechnologies manifest as existential threats or conduits of flourishing? This analysis spotlights oversight scarcity in emerging biotechnological innovations as a pivotal challenge, then explores solutions spanning increased barriers against misuse to integrating ethical responsibility into research culture itself. It ultimately proposes an agile, balanced strategy integrating security and ethics into the very architecture of biotechnological progress. By doing so, we can harness the tremendous potential of biotechnological innovation while steering it away from catastrophe through coordinated oversight - converting risks into an opportunity to redefine technological responsibility.

Scarcity of Oversight

The current state of oversight in biological research is characterised by a complex and multi-layered framework designed to ensure that research is conducted ethically, safely, and responsibly. Institutional Review Boards (IRBs), Institutional Biosafety Committees (IBCs), and national and international regulatory agencies like the National Institutes of Health (NIH) in the United States and the World Health Organisation, among others, play pivotal roles in overseeing various aspects of biological research. These bodies enforce guidelines and regulations concerning, among many areas, human[5] and animal welfare,[6] biosecurity, dual-use research,[7] and genetic engineering.[8]

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[1] Lionel Clarke and Richard Kitney, 'Developing Synthetic Biology for Industrial Biotechnology Applications', *Biochemical Society Transactions* 48, no. 1 (20 February 2020): 113–22, https://doi.org/10.1042/BST20190349.

[2] Jenny Rooke, 'Synthetic Biology as a Source of Global Health Innovation', *Systems and Synthetic Biology* 7, no. 3 (1 September 2013): 67–72, https://doi.org/10.1007/s11693-013-9117-3.

[3] Zihe Liu, Junyang Wang, and Jens Nielsen, 'Yeast Synthetic Biology Advances Biofuel Production', *Current Opinion in Microbiology* 65 (1 February 2022): 33–39, https://doi.org/10.1016/j.mib.2021.10.010.

[4] Demi Sargent et al., 'Synthetic Biology and Opportunities within Agricultural Crops', *Journal of Sustainable Agriculture and Environment* 1, no. 2 (2022): 89–107, https://doi.org/10.1002/sae2.12014.

[5] Ezekiel J. Emanuel et al., 'The Declaration of Helsinki', in *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press, 2008).

[6] I Anna S Olsson et al., 'Protecting Animals and Enabling Research in the European Union: An Overview of Development and Implementation of Directive 2010/63/EU', *ILAR Journal* 57, no. 3 (1 May 2016): 347–57, https://doi.org/10.1093/ilar/ilw029.

[7] World Health Organisation, 'Emerging Technologies and Dual-Use Concerns: A Horizon Scan for Global Public Health' (Geneva: World Health Organisation, 2021), https://iris.who.int/bitstream/handle/10665/346862/9789240036161-eng.pdf.

[8] Felicity Keiper and Ana Atanassova, 'Regulation of Synthetic Biology: Developments Under the Convention on Biological Diversity and Its Protocols', *Frontiers in Bioengineering and Biotechnology* 8 (2020), https://www.frontiersin.org/articles/10.3389/fbioe.2020.00310.

Despite these oversight mechanisms, there remain notable gaps due to the global and interdisciplinary nature of modern research and the challenges in regulating research with potential for both beneficial and malicious applications. Furthermore, the already rapid pace of biotechnological advancement is only likely to accelerate with the convergence of artificial intelligence, which can speed up the design-build-test-learn cycles in synthetic biology.[9] This These gaps underscore the need for continuous adaptation of oversight frameworks to address emerging ethical, safety, and security concerns in a way that balances innovation with precaution.

Risks of inadequate oversight

Without commensurate oversight, advancing biotechnologies harbour profound risks spanning from biosafety mishaps to ethical dilemmas. Insufficient transparency, regulations and risk mitigation surrounding cutting-edge biological research could enable catastrophic outcomes that endanger public health.

On the biosafety front, lack of oversight over dual-use research raises the spectre of lab accidents and lab-associated infections that risk exposing the public to dangerous pathogens. The smallpox samples found in an unsecured NIH storage room in Bethesda in 2022 illustrate the danger of improper handling procedures and institutional oversight failures that could enable lab leaks.[10] Risky gain-of-function experiments to enhance transmissibility or lethality of pathogens could also lead to accidental releases triggering outbreaks if not properly supervised.[11]

Equally disquieting are deliberate efforts to misuse advances in genetic engineering for bioterrorism. The democratization of technologies like CRISPR lowers barriers for malign actors to engineer bioweapons without checks.[12] The advent of benchtop devices to synthesise DNA, which enable the rapid and cost-effective synthesis of genetic material, can be misused by allowing individuals or groups to create pathogens from scratch without needing access to the natural organism.[13] Lax oversight also allows dubious experimentation enhancing known pathogens via gain-of-function techniques, effectively generating novel biological threats. Even absent malintent, such manipulations cultivate higher-risk environments.

Finally, radical biotechnological innovations involving human genome editing, neural implants, and artificial embryogenesis make urgent ethical guardrails to steer science away from unintended consequences. Clinical trials already underway to genetically modify human embryos could enable new forms of inequality, discrimination and inter-generational risk without the guidance of ethics boards and governance. Powerful neurotechnologies prompt profound moral questions around consent, privacy and human augmentation as well.

This landscape underscores how biotechnology's rapid advances require parallel developments in oversight to mitigate risks to biosafety, biosecurity, and bioethics while ensuring that society maximizes its benefits. Reasonable oversight measures aim to nurture such beneficial trajectories for emerging innovations rather than obstruct progress entirely.

Striving for More: Enhancing Oversight Mechanisms

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[9] Sarah R Carter et al., 'The Convergence of Artificial Intelligence and the Life Sciences' (Nuclear Threat Initiative, October 2023), https://www.nti.org/analysis/articles/the-convergence-of-artificial-intelligence-and-the-life-sciences/.

[10] U.S. Department of Health and Human Services, 'CDC Media Statement on Newly Discovered Smallpox Specimens', CDC, 8 July 2014, https://archive.cdc.gov/www_cdc_gov/media/releases/2014/s0708-NIH.html.

[11] Marc Lipsitch and Thomas V. Inglesby, 'Moratorium on Research Intended To Create Novel Potential Pandemic Pathogens', *mBio* 5, no. 6 (12 December 2014): 10.1128/mbio.02366-14, https://doi.org/10.1128/mbio.02366-14.

[12] Darakhshan Javaid et al., 'CRISPR/Cas9 System: A Reliable and Facile Genome Editing Tool in Modern Biology', *Molecular Biology Reports* 49, no. 12 (1 December 2022): 12133–50, https://doi.org/10.1007/s11033-022-07880-6.

[13] Sarah R. Carter, Jamie M. Yassif, and Christopher R. Isaac, 'Benchtop DNA Synthesis Devices: Capabilities, Biosecurity Implications, and Governance' (Nuclear Threat Initiative, May 2023), https://www.nti.org/wp-content/uploads/2023/05/NTIBIO_Benchtop-DNA-Report_FINAL.pdf.

Enhancing existing multilateral agreements

Existing multilateral fora and agreements related to biological weapons provide a starting foundation for expanding binding legal oversight. For example, the Biological Weapons Convention (BWC) prohibits the development and stockpiling of biological weapons globally but lacks strong enforcement and compliance mechanisms.[14] The treaty could be strengthened by establishing a formal verification regime through an oversight organization that conducts compliance inspections and investigations. This intergovernmental organisation could be modelled after the International Atomic Energy Agency, with a mandate to oversee and set standards for dual-use biotechnology research globally. It would coordinate and support national regulatory bodies while also serving as a direct oversight mechanism for international projects. With adequate funding and expert staff, it can develop biosecurity regulations, maintain risk databases, and ensure compliance through inspections and enforcement tools. This centralizes and harmonizes oversight at the global level to match the global nature of science.

Additionally, the United Nations Security Council Resolution 1540, which obligates states to prevent non-state actor access to biological weapons, could be broadened to encompass oversight of dual-use biological research.[15] Expanding the scope and tools of these international agreements addresses gaps by converting important biosecurity principles into concrete obligations backed by formal monitoring and accountability systems. This offers the benefits of striving for more oversight through binding global accords rather than relying purely on voluntary self-regulation by scientists and states.

Engaging the private biotech sector

Public-private partnerships (PPPs) have emerged as a powerful tool for bridging the gap between governmental regulation and private sector innovation, particularly in fields requiring high levels of technical expertise and rapid adaptation to new technologies. In biotechnology, PPPs offer a collaborative framework through which governments and biotech firms can work together to ensure that advancements in the field are realized in a manner that is safe and ethical.

A notable example of successful PPPs outside of biotech can be seen in the development and deployment of infrastructure projects, such as renewable energy initiatives. For instance, the partnership between the government and private entities in the construction of wind farms or solar energy plants often involves shared investments, risks, and rewards, with the government providing regulatory guidance and sometimes financial incentives, while private companies bring in technical expertise and innovative technologies. This model has accelerated the adoption of renewable energy technologies, demonstrating how PPPs can facilitate significant progress in complex, highly regulated sectors.

Translating this model to the biotech sector, PPPs could be structured around developing new therapeutic drugs, vaccines, or agricultural innovations. Governments could provide funding, regulatory guidance, and access to infrastructure, while biotech firms contribute their research and development capabilities. An example of this approach was seen in the rapid development and distribution of COVID-19 vaccines, where governments around the world partnered with pharmaceutical companies, providing financial support and regulatory fast-tracking in exchange for commitments to meet public health needs.

Global certification and auditing mechanisms serve as another critical strategy for regulating the private biotech sector, ensuring that companies worldwide adhere to internationally recognized standards for safety, biosecurity, and ethical practices. Drawing parallels from the field of information security, the International Organization for Standardization (ISO) offers certifications such as ISO/IEC 27001, which sets out the requirements for an information security management system (ISMS).

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[14] Nicholas R. Cropper et al., ‘A Modular-Incremental Approach to Improving Compliance Verification With the Biological Weapons Convention’, *Health Security*, 26 July 2023, https://doi.org/10.1089/hs.2023.0078.

[15] Elizabeth Rindskopf Parker and Bryan Pate, ‘Implementing UN Security Council Resolution 1540 to Combat the Proliferation of Biological Weapons’, *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 3, no. 2 (June 2005): 166–73, https://doi.org/10.1089/bsp.2005.3.166.

Companies across various sectors seek this certification to demonstrate their commitment to managing information security risks effectively.

Applying a similar framework to the biotech industry, a global certification program could be established, focusing on biosafety, biosecurity, and ethical research practices. Biotech companies would undergo regular audits by accredited third-party assessors to maintain their certification status. This process not only promotes transparency and accountability but also provides a competitive advantage to certified companies, reassuring investors, partners, and the public of their commitment to high standards.

The establishment of such a certification program in biotechnology could be overseen by an international body, perhaps under the auspices of an existing organization like the World Health Organization (WHO) or a new entity specifically created for this purpose. This body would develop the certification criteria, accredit auditors, and oversee the certification process, ensuring consistency and integrity across the globe.

Challenges in increasing oversight may be insurmountable

While enhancing existing multilateral agreements on biosecurity and engaging the private sector are strong approaches to increasing global oversight in biotechnological innovation, they may not be sufficient in ensuring that it proceeds ethically and safely. This is especially so when there are too many stakeholders spanning across borders and institutions, complicates the enforcement of uniform standards. Furthermore, it remains to be seen how feasible the two approaches are, given the limitations of multilateralism and given how unlikely the private sector would welcome increasingly stringent regulatory frameworks. Against this backdrop, a complementary promotion of a self-regulation model and internal oversight becomes not just appealing but necessary.

Thriving with Less: Rethinking Research Prioritization

Fostering a Culture of Ethical Responsibility

The cornerstone of thriving with less external oversight lies in fostering a deep-rooted culture of ethical responsibility within the biotech community. This entails embedding ethical considerations into the core of scientific education and professional development, ensuring that those involved in biotech research are not just aware of the ethical dimensions of their work but are also equipped with the tools and judgment to navigate these complexities. To this end, the Tianjin Biosecurity Guidelines for codes of conduct for life scientists are a positive example of promoting responsible innovation and strengthening biosecurity governance.[16] By prioritising ethical reflection at every stage of research and development, the sector can cultivate a self-regulating ethos that aligns innovation with societal values and norms, thereby mitigating the need for stringent regulatory intervention.

Promoting Self-Regulation through Industry Standards

Another pillar supporting the biotech sector's ability to self-govern involves the establishment of robust industry standards. Drawing inspiration from other fields that have successfully implemented self-regulatory models, the biotech industry can develop and enforce its own comprehensive set of best practices, safety protocols, and ethical guidelines. Such standards, developed through consensus among leading scientists, ethicists, and industry stakeholders, can serve as a benchmark for responsible research and innovation. The International Gene Synthesis Consortium, a trade industry organisation comprised of approximately 80% of global gene synthesis providers, was formed in order to commit to screening their orders and customers according to framework published by the United States Department of Health and Human Services.[17] By adhering to these self-imposed standards, the

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[16] Leifan Wang, Jie Song, and Weiwen Zhang, ‘Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists: Promoting Responsible Sciences and Strengthening Biosecurity Governance’, *Journal of Biosafety and Biosecurity* 3, no. 2 (1 December 2021): 82–83, https://doi.org/10.1016/j.jobb.2021.08.001.

[17] James Diggans and Emily Leproust, ‘Next Steps for Access to Safe, Secure DNA Synthesis’, *Frontiers in Bioengineering and Biotechnology* 7 (24 April 2019): 86, https://doi.org/10.3389/fbioe.2019.00086.

industry not only demonstrates its commitment to safety and ethics but also sets a clear expectation for what constitutes acceptable practice within the field.

Peer Review and Community Oversight

Peer review and community oversight represent a critical mechanism for maintaining high standards of research integrity and ethical conduct. This process, deeply embedded in the academic tradition, can be extended and adapted to the broader biotech sector, encompassing not just the review of scientific manuscripts but also the ongoing evaluation of research projects, biosecurity measures, and compliance with ethical standards. Through a system of mutual accountability, where researchers and companies hold each other to agreed-upon ethical and safety benchmarks, the biotech community can ensure that its collective pursuit of innovation does not come at the expense of public trust or societal welfare.

Conclusion

The rapid evolution of biotechnology presents significant challenges for existing oversight frameworks, which struggle to keep pace with the field's complexity, global scope, private sector dominance, and dual-use potential. To effectively bridge the gap between innovation and regulation, a holistic approach is essential, combining enhanced global regulatory frameworks with a fundamental shift towards embedding ethical responsibility within the research culture itself. Strengthening coordination among regulatory bodies and establishing binding international agreements are crucial steps for tightening oversight. Simultaneously, fostering a culture of ethical deliberation from the educational level and promoting self-regulation through community standards are imperative for ensuring that biotechnology's advancements are pursued responsibly. This integrated strategy offers a promising pathway to harness biotechnology's potential for societal benefit while proactively addressing the ethical and safety concerns inherent in its rapid development.

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