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Security Nexus Report

BIOTECHNOLOGY, GREAT POWER COMPETITION, AND SECURITY: AN OVERVIEW

By Ethan Allen - 10 Feb 2025

Summary

Threats from biotechnology fall into the areas of fundamental human health and safety, environmental risks, and ethical and social issues. Some of the threats from unconstrained biotech are clear, while others are unforeseeable. Such security challenges counterbalance the potential for broad human benefits from biotech and mandate transparent, enforceable, international regulation of its research, development, and implementation. The rising synergy between artificial intelligence and biotech presents a particularly troubling conundrum. A whole-of-society approach involving biotech companies, ethicists, and governments (including militaries) must recognize both the promise to do good and the power to do harm that biotech poses now and how both the promise and the power are growing at exponential rates. The situation urgently demands leadership in fostering guardrails that are strong, clear, and enforceable.

Key Words: science, society, risk, regulation

Abstract

At the intersection of biology and technology, biotechnology offers tremendous potential benefits and risks to regional and even global peace and stability. Biotech has impacts in the realms of fundamental human health and safety, environmental risks, and ethical and social issues. Biotech synergizes with other technological advances, especially Artificial Intelligence. As the field is growing explosively, with rapidly increasing possibilities of non-state actors entering the arena with nefarious intent, it is in the interests of both the United States and the People's Republic of China, along with other nations, to quickly build stronger and enforceable international regulations to ensure its safe and responsible application. The challenges to formulating such regulations are huge, as they involve aspects from basic laboratory procedures to legislative issues to national security concerns, and must confront significant issues in the realms of both transparency and trust. However, in spite of the difficulty of the challenge, it must be addressed. The costs of failing to do so will surely yield a world of unimaginable and widespread suffering, as unconstrained actors increasingly will use biotechnology as a convenient, accessible tool to advance their own ends, inflicting damage on ecosystems and human societies around the globe.

Introduction

Biotechnological advances offer immense, as-yet-untapped benefits to human security in fields such as agriculture, environmental protection, and medicine.[i, ii] Equally, however, biotechnology presents immeasurable threats to the lives and well-being of individuals and societies around the globe.[iii, iv] At present, little in the way of regulation limits the paths of biotechnological advances, and even less in terms of enforceable controls.[v] Particularly within the context of great power competition, the considerable and expanding resources that are being directed toward biotechnological advances by both the United States (US) and the People's Republic of China (PRC), as well as by other countries such as Russia, Iran, and North Korea, present a broad spectrum of security concerns. In order to maintain its historical advantages and leadership in the biotechnology field, the US must move quickly and decisively towards "greater investment in biotechnology research and infrastructure. This is especially the case in sectors beyond health and medicine; expanding the pipeline of biotalent; and leading globally to drive biotechnology norms, standards-setting, and responsible adoption," while simultaneously removing regulatory impediments and barriers, particularly in the realm of biomanufacturing. [vi]

Given the exponential growth in both the breadth and power of these biotech advances, an in-depth and up-to-date exploration of the possible dangers they pose to human security is beyond the scope of this report. Instead, with a focus on great power competition, this paper will briefly: (1) highlight some of the major types of hazards of the current technologies; (2) note some perils that future developments may raise; and (3) suggest some possible avenues for fostering productive directions in biotechnological research.

Beyond the context of great power competition, however, it should be recognized that many of the new biotech 'cookbooks' and off-the-shelf technologies that are appearing almost daily offer significant threats, now and in the near future, that may be created by individuals and small-scale operations with limited funds and little scientific expertise. In this sense, biotechnology represents a danger of equal magnitude but with a much larger potential instigator ‘work force’ than do nuclear weapons; yet, to date, few security professionals are seriously considering how to either mitigate or adapt to this multi-faceted threat. The divergent nature of these perils in terms of detection and responses constitutes a major challenge to security workforces around the globe, and will be discussed in a future paper.

Threats from biotech can be said to fall into three major areas – (i) fundamental human health and safety concerns, (ii) environmental risks, and (iii) ethical and social issues - while recognizing that these arenas overlap and may merge with one another and that other sorting rubrics exist. For each of the risk areas, the discussion will start by briefly outlining some of the major types of biotechnology dangers currently facing humanity before speculating on some of the directions the particular ‘brand’ may take in the future and considering both of these in terms of great power competition. A short section will examine the synergistic confluence of artificial intelligence (AI) and biotechnology. The article will conclude with some recommendations that have been proposed for the types of guardrails that might be created to optimize the good outcomes and reduce those less-desirable ones of this under-appreciated domain of the security impacts of biotechnology.

Fundamental Human Health and Safety Concerns

- **Bioweapons**: The same powerful, novel processes that allow, for example, scientists to make genetic modifications that can be passed down to offspring (*e.g.*, genetic engineering techniques like CRISPR) are often referred to as dual-use; many current and emerging biotechnological advancements can be applied either beneficially or harmfully. This makes such technologies serviceable for creating dangerous pathogens or enhancing the virulence or transmissivity of existing diseases, leading to their potential use as bioterror or biological warfare weapons. As the laboratory equipment, reagents, and processes are quite similar for either pathway, distinguishing between benign and malicious intent of such biotech work is problematic.
- **Synthetic Biology**: The ability to create synthetic organisms from scratch (or modify existing ones) could be exploited for harmful purposes, such as the creation of novel pathogens that are resistant to existing antibiotics or vaccines. Synthetic biology is an engineering approach where novel genetic sequences, not found in nature, are built into organisms so as to create chemical products, often proteins, that are not produced naturally. Here, too, the dual-use conundrum applies. Drugs that may be difficult or expensive to chemically synthesize might be more simply, plentifully, and cheaply generated by synthetic life forms. But equally, naturally harmless microbes might be modified to produce new toxins. Particularly in the context of the

ever-deepening civil-military fusion of the PRC's biotechnology enterprise, security concerns around its development in this arena are warranted.[vii]

- **Antimicrobial Resistance (AMR)**: AMR is already a significant problem; largely due to sporadic or insufficiently maintained treatment, strains of harmful bacteria have evolved mechanisms to avoid being impaired by antimicrobial agents designed to kill them. Methicillin-resistant *Staphylococcus aureus* (MRSA) infections, particularly in hospital settings, produce about 1.2 million devastating, even lethal, infections in the US alone each year. Advances in biotechnology, especially in the development of new antibiotics or agricultural practices, might inadvertently contribute to the rise of antimicrobial resistance. Overuse of genetically engineered organisms in agriculture, for example, could accelerate the development of resistant pathogens. The global MRSA outbreak illustrates how AMR might impact great power competition through the spread of resistant pathogens – human, veterinary, or agricultural.

The US has ratified the Biological and Toxin Weapons Convention (BWC), and the PRC has acceded to it (as have Iran, North Korea, and Russia), so both states ostensibly adhere to its prohibition against the development, production, acquisition, transfer, stockpiling, and use of any biological and toxin weapons. However, the BWC has been chronically under-resourced and lacks both transparency measures and an operational organization (*i.e*., means for verification and/or enforcement), so few have confidence that its terms are being fully implemented by its signatories.[viii]

The PRC reportedly has historically weaponized ricin, botulinum toxins, and the causative agents of anthrax, cholera, plague, and tularemia, among other agents.[ix] Moreover, it has explicitly engaged both military and civilian sectors in its ongoing, purposeful development to become a 'biotech superpower.'[x] In March of 2024, the Under Secretary of State for Arms Control and International Security Washington summarized:[xi]

> PRC military scientists and strategists have consistently emphasized that biotechnology advancements are one of the fields that could allow a country to dominate the next Revolution in Military Affairs (RMA). MCF, the national development strategy under which the PRC is working to adapt modern technologies to apply to the RMA, has identified biology as a research and development priority and key field for developing dual-use technologies. As the PRC targets advances in biotechnology, it has emphasized the importance of actively exploring new frontiers of biological cross-disciplinary technologies with potential military application, including prominent developments in CRISPR to bionic robotics, human enhancement technologies such as intelligent control exoskeletons, and techniques for human-machine collaboration. The PRC has demonstrated its commitment to advancing biotechnology capabilities for the military by funding projects on military brain science, advanced biomimetic systems, biological and biomimetic material, using biosynthesis for military production, and human performance enhancement. The People's Liberation Army (PLA) has further identified brain-machine interfaces and the resulting human-machine integration as a potential game changer for future combat platforms.

The US formally renounced the offensive use of biological weapons in 1969, followed by ratification of the BWC in 1974.[xii] The US runs a National Biodefense Analysis and Countermeasures Center (NBACC), a one-of-a-kind facility dedicated to defending the nation against biological threats. Its work supports intelligence assessments, preparedness planning, response, emerging threat characterization and bioforensic analyses. The NBACC hosts laboratories with biosafety levels (BSL) 2, 3, and 4, the last of which allows NBACC to work with pathogens for which no vaccine or treatment exists.[xiii] The US hosts seven BSL 4 laboratories, while the PRC has four.[xiv] While most of the remaining 25 countries that currently host BSL 4 labs are considered stable and well-governed, most of the nations now planning to build such facilities score low on governance and stability;[xv] the security concerns of such potentially dangerous technology in such situations are many and varied.

Environmental Risks

- **Genetically Modified Organisms (GMOs)**: GMOs are being engineered for resilience against pests, droughts, and diseases; as such, they can improve crop yields, reduce use of insecticides and fertilizers, and enhance food security. However, their release into the environment could disrupt ecosystems. For example, desirable plant species that have been genetically modified for resilience as noted above could crossbreed and share gene sequences with weed species, creating unintended ecological consequences, such as the spread of super-weeds better able to thrive and spread, and/or resistant to eradication methods. Despite these risks, since its introduction in the mid-1990s, a number of GMO species – such as corn, cotton, and soybean - are being propagated, with 75-90% of the current US yields of these now being from GMO seed.[xvi] Notably, natural GMOs exist; sweet potatoes, for example, incorporated and expressed bacterial genes prior to their domestication. Current capacities to 'mix and match' widely varying gene sequences into organisms only very distantly related to their original host have produced such oddities as glow-in-the-dark zebrafish; the broad applicability of this technique suggests numerous potential nefarious uses. Large-scale sabotaging of a favored food crop of an adversary, for example, could be used to destabilize a government.
- **Gene Drive Technology**: The capacity to introduce genetic elements into a sexually-reproducing species so as to produce its rapid spread – *i.e*., above the 50% inheritance of standard Mendelian genetics - through the target population offers a novel and extremely powerful way to potentially eradicate harmful species. The technique has great potential as a cost-effective, efficient approach to managing such long-standing health threats as malaria.[xvii] However, there is a risk of unintended ecological consequences if these gene drives spread uncontrollably.[xviii] Unlike the GMOs described above, this technique has not – yet - been applied outside of laboratory settings.

The application of GMO crops has impacted the environment in both positive and negative ways. Just two GM traits have been widely approved/adopted - herbicide tolerance and insect resistance - impacting crop losses, pesticide use, tillage, and crop diversity levels. These changes, in turn, affect agricultural expansion, deforestation, pollution, human health, greenhouse gas emissions, and biodiversity. The environmental impacts differ across geographic scales and GM traits, leading to both positive and negative effects, with, for example, both greater and lesser use of pesticides being reported among GMO-using farmers, depending on specific circumstances. The technology is in widespread use in the Americas, with more than 60% of the corn, cotton, canola, and soybean crops being GMO in the US and much of South America; much lower proportions (e.g., ~10%) of these main GMO crops are grown in the Indo-Pacific.[xix]

One great power competition impact of GMO technology lies in the PRC's being a net importer of soybeans and corn from the US, setting new records in recent years for both the volume and value of these crops.[xx] The differing demographic trends in the two states, differing impacts of climate change, and recent changes in the PRC's regulation of GMOs[xxi] are likely to affect this trade/economic balance in the long term, but trends since the early 2000s suggest continuing and increasing imports of GMO crops by the PRC for the foreseeable future.

Ethical and Social Concerns

- **Human Gene Editing**: CRISPR-Cas9 and related technologies enable genetic modifications, including, notably germline editing (altering DNA in eggs, sperm, or embryos). In 2018, a Chinese geneticist used this approach to modify the DNA of two human embryos so as to confer a heightened resistance to HIV infection, resulting in the world's first "designer babies;" the ethical shortcomings in the experiment led to the geneticist's jailing.[xxii] Potential issues around editing the genomes of human and the potential unintended consequences like unforeseen genetic mutations or eugenics practices that exacerbate social inequalities, raise a myriad of social and ethical questions; there is broad agreement among the scientific community that such issues must be explicitly addressed prior to any further application of the techniques to humans.
- **Loss of Genetic Diversity**: Selective breeding for agricultural crops has led to the homogenization of genetic traits in a number of plant lines. While the approach may produce more uniformity of product and greater efficiencies in raising, harvesting, and marketing, it makes populations more susceptible to disease outbreaks. This can be clearly seen in the current spread of Panama disease, which is devastating Cavendish bananas globally and may well result in their extinction.[xxiii] The enhanced ability to edit or select genes that current technologies now provide could lead more quickly to reduced biodiversity in plants or animals on which we depend, rendering large populations more susceptible to single pathogens and/or environmental changes, here again with considerable impact on great power competition.
- **Genetic Privacy**: Genetic data is being collected (and shared) at increasing rates around the world. While there is great value in gathering such information for diagnosis of individuals' diseases and disease predispositions, misuse of such data can result in discrimination in employment, insurance, or access to services based on genetic predispositions. In wealthy countries such as the US, much of the data handling is done via corporations and private entities,

while in authoritarian regimes such as the PRC, it is more often the State that is collating and analyzing the data. As recently noted by Caroline Schuerger and Anna Puglisi:[xxiv]

> China has made genomics a national priority and treats its genomic data as a strategic resource, which has several national security implications for the US The Chinese government has created an R&D ecosystem where genetic data fuels the development of biotechnology applications, including public health and biodefense, medicine, and agriculture and food security. The rapid development of artificial intelligence in genomics facilitates large-scale data processing and utilization. China's generation, accumulation, and utilization of genetic data is aided by central policy planning in health-specific and R&D policy areas and is translating into global leadership in genomics. China is amassing large amounts of genomic data by leveraging its collaborations with foreign entities while at the same time prohibiting external access to its genomic data.

- **Surveillance**: Given the preceding, it is not surprising that many are concerned that advances in biotechnology could lead to more invasive surveillance techniques, such as the use of DNA profiling for population control, monitoring of genetic conditions, or even social manipulation. In 2023, the US House Select Committee on the Chinese Communist Party reported:[xxv]

> Beijing Genomics Institute, now known as "BGI," is a PRC "national champion" biotechnology company that collects, stores, and analyzes DNA and other genomic information from people in the United States and around the world. BGI has engaged in the illicit collection of pregnant women's DNA and conducted research with the Chinese Communist Party's (CCP) People's Liberation Army. The US government has placed export control restrictions on BGI for its involvement in the genetic tracking of ethnic minorities in the Xinjiang region, where the CCP is conducting genocide against the Uyghur people. Beijing uses BGI as a strategic and diplomatic tool overseas, to recruit foreign talent, and to amass foreign genomic data. BGI is rapidly making inroads in the US market after gaining access in August 2022, after years of litigation over theft of US intellectual property.

- **Access to Technology**: In our increasingly unequal world, it seems certain that the unequal access to biotechnological advances is exacerbating existing global inequalities. Wealthier nations are benefiting disproportionately from innovations in medicine, agriculture, and genetic enhancement. These advances are slow to trickle down to poorer nations, furthering an unjust *status quo*. Relevant to the economic aspects of great power competition, the PRC's biotech industry has been expanding rapidly in recent years; this is particularly true in the realm of pharmaceuticals.[xxvi] PRC companies are no longer simply copying western drug formulations and producing them more inexpensively, but are quickly improving them, and developing, testing, and marketing new and better drugs globally. Coupled with growing around PRC intellectual property theft in the biotech arena, their increasing marketplace dominance is raising concerns among US politicians as well as biotech companies.[xxvii] The US BIOSCURE Act seeks to prohibit contracting with foreign adversary biotechnology providers.[xxviii] The Office of the Director of National Intelligence, in its February 2024 annual threat assessment, warned that Beijing is prioritizing biotech and is using IP theft and other means to fast-track its science and technology development for economic, political, and military advantage.[xxix]

Social and ethical concerns are, by their very nature, deeply interwoven into individual cultures and so will vary across societies. While the US values individualism, along with freedom of thought and expression, and concedes only limited powers to its central government, the PRC assesses a cooperative population with more uniform, consistent viewpoints as being more desirable, and allows a broader swath of powers to its government. These cultural biases play out in how biotechnology is viewed, regulated, and practiced in the two states.

Reflecting its individualistic, entrepreneurial perspective, the US government funds a decreasing proportion of research and development (R & D), including the field of biotechnology - from about 1% of its GDP in 1990 to about 0.6% today. In contrast, since 2000, the PRC has increased its governmental support of R & D from 0.3% to 0.45% of its GDP. In other respects, the nations are more similar; the US spends ~$900B per year now, while the PRC spends ~$800B per year. The two countries far outspend any others, with the E.U. being a distant third at ~$550B.[xxx]

While the PRC has employed internationally accepted and normal biotech innovation policies (e.g., investing in basic research, R & D infrastructure, and a skilled workforce), it has also used unfair and illegitimate practices, including:

- “Subsidies and regulations that strongly advantage domestic firms (including discriminatory review and approval processes, price controls, export financing, and procurement policies), distorting markets and pressuring foreign companies to enter into joint ventures if they wish to access China’s domestic consumer markets;
- Leveraging such pressured joint ventures to force technology transfer from the foreign partners, allowing PRC state enterprises to gain their assets, data, and IP;
- Investing in U.S. companies to procure and export their valuable biological and genetic data while strictly constraining access to PRC-controlled genetic data; and
- Supporting IP theft, from stealing data via espionage, cybertheft, or hacking to recruiting PRC citizens conducting research in U.S. universities or companies to return to China with their skills, knowledge, and, at least in some cases, stolen data or materials.”[xxxi; xxxii]

And while the US DoD is involved with biotech research among many other fields of investigation, the PRC’s People’s Liberation Army (PLA) views biotech as central to its mission:[xxxiii]

> PLA sources view the biological domain as an increasingly important consideration for China’s national security objectives. With China’s enhanced military capabilities and growing desire for great-power status, the PLA will likely emphasize biotechnology and health diplomacy in

its future military strategy. These PLA activities are also likely to support the Chinese Communist Party's broader efforts to become a more engaged actor in global health.

Here, too, we see the multi-faceted nature of biotech in terms of great power competition. Emphasizing the soft power aspects of such rivalry, both the PRC and the US wish to be seen as leading, positive figures in the global health arena.

Artificial Intelligence and Biotechnology Integration

AI is already widely integrated with biotechnology, serving to enhance biotech capabilities and expand horizons.[xxxiv] In concert with the closely related fields of Machine Learning and Deep Learning, AI allows faster, more efficient searching and analyses of ever-larger and more complex sets of data. Often more rapidly than could a human scientist, AI can suggest new lines of research, identify potentially useful compounds, and interface efficiently with a wide variety of sensors and cyber-physical systems (*i.e.*, robots). Advances in biotechnological knowledge, in turn, feed synergistically into data sets for AI analysis, enabling further progress in both realms.[xxxv]

Such synergies, however, also have downsides. These same features that are leading to exponential growth in fields such as medicine and agriculture equally facilitate the development of biological weapons.[xxxvi] AI systems, for example, trained on standard databases of toxic compounds, have rapidly 'discovered' or predicted thousands of novel toxins; "In less than 6 hours after starting on our in-house server, our model generated forty thousand molecules that scored within our desired threshold. In the process, the AI designed not only VX, but many other known chemical warfare agents that we identified through visual confirmation with structures in public chemistry databases. Many new molecules were also designed that looked equally plausible. These new molecules were predicted to be more toxic based on the predicted LD_{50} in comparison to publicly known chemical warfare agents."[xxxvii]

Moreover, as AI-driven systems may make decisions or conduct experiments without full human oversight, unpredictable consequences may well emerge, resulting in dangerous or unethical outcomes.

These threats highlight the need for stringent regulations, global cooperation, and ethical frameworks to ensure that the advancements in biotechnology are used responsibly and for the benefit of humanity while minimizing risks to health, security, and the environment.

Recommendations for Biotechnology Regulation to Enhance Security

Maximizing the potential positive potentials of biotechnology globally while minimizing the negative ones will require broad, inclusive, and carefully considered management of a sort the world neither knows nor seems inclined to adopt. As noted above, the dual-use nature of biotechnology makes distinguishing between legitimate, positive research and illicit, malicious development extremely difficult. Without regulations that are mutually agreed upon and adhered to, and that include full transparency, openness to on-site verification, and high levels of mutual trust, it will be virtually impossible to ensure that biotechnology research and development are being carried out to benefit to humanity.

The 2023 Global Biolabs Report suggests a set of concrete steps that laboratories, national authorities, nongovernmental entities, and international organizations should take to raise the chances of positive outcomes. These include providing complete, regular, and transparent reporting as required by the annual confidence-building measures of the BWC and under UN Security Council Resolution 1540, among other confidence-building actions.[xxxviii]

Beyond examining the laboratory context in which biotech R & D is carried out, in the context of the extant and growing great power competition, steps can and must be taken by the US government to minimize the chance of accidental or purposeful harm from biotechnology.

To start with, the US must attain a more comprehensive awareness of the biotechnology landscape and its potential impacts on security. Greater strides in developing biological intelligence, or BIOINT, must be taken.[xxxix]

To realize better BIOINT, greater collaboration among a diverse set of existing agencies must be enacted. Successfully facing the multi-faceted, emerging threats from the nefarious use of biotech will require multiple types of expertise. One model might be to build off of the collaborative evaluation of the risks of big data existing among the American Association for the Advancement of Science, the Federal Bureau of Investigation's Weapons of Mass Destruction Directorate, and the global security concentration of the United Nations Interregional Crime and Justice Research Institute. Along with risk assessment inputs from the National Academies of Science, Engineering, and Medicine (NASEM) and other groups, such a collaboration might create useful risk assessment analyses.[xl]

Certainly, the US Department of Defense (DoD) must play a role in any comprehensive national strategy to reduce security threats. The RAND Corporation published a set of recommendations including that the DoD:[xli]

- Enhance and build flexibility and redundancy, as appropriate, into its processes and capabilities to investigate and attribute biological incidents
- Continue to invest in biotechnology, including microbial forensic technology. Officials should develop, improve, and refine capabilities to model biological incidents.
- Maintain transparency about DoD efforts to work with international partners on biosecurity and biodefense efforts

Noting that building US resilience to biotech threats must necessarily be an international endeavor, the Stimson Center laid out a set of more globally-focused recommendations that include:[xlii]

- Prioritize good-faith participation in negotiations to finalize a new international pandemic preparedness instrument[xliii; xliv]
- Support implementation of the updated International Health Regulations[xlv]
- Affirm commitment to the Global Health Security Strategy[xlvi]

Finally, the US Department of State's International Security Advisory Board, noting the deeply interwoven nature of the global biotechnology enterprise, suggests the following in Figure 1: [xlvii]

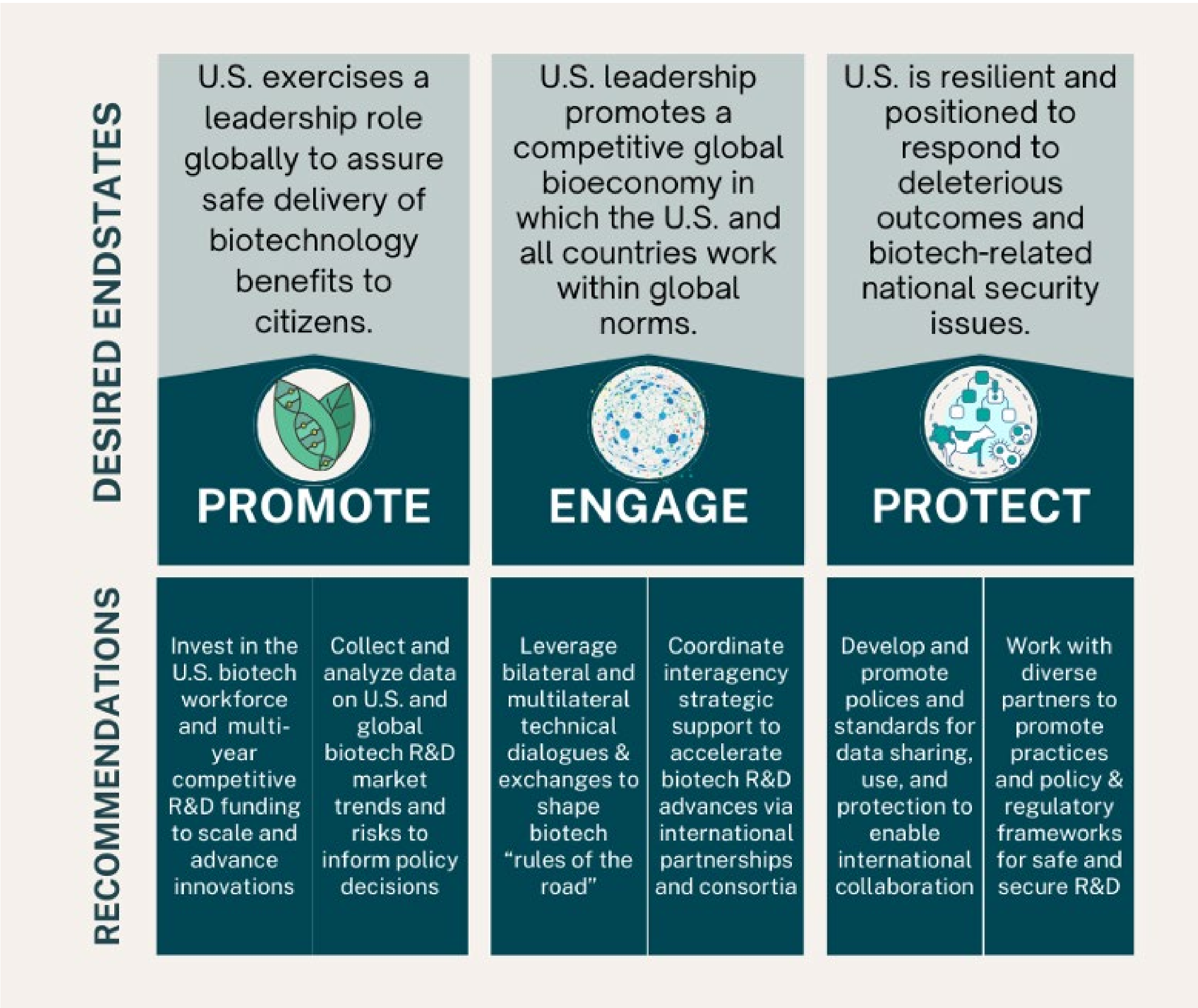

Figure 1: ISAD suggested courses of action to regulate biotech

This same group goes on to recommend that regulations for biotechnology specifically focus on four aspects of strategy:

- "Safety: A shared approach to biosafety would help the workplace, consumers, and the general public. Specific concerns for biosafety range from making sure that a worker in a poorly funded

clinical laboratory receives training and personal protective equipment, to developing the appropriate testing regimen before releasing a gene drive intended to reduce malaria transmission, or agreements on appropriate levels of containment for handling specific pathogens.
- Security: Potential biosecurity threats and loss due to theft, misuse, diversion, unauthorized possession of property, loss of intellectual property, and intentional use of a biological agent or product as a weapon are all biosecurity concerns that require shared approaches to deter, detect, and attribute.
- Sustainability: Nations have opportunities to maintain or improve the long-term viability of the environment and economy, including the impacts of biotechnology products and processes on the environment, supply chains, and consumer practices.
- Social Responsibility: The significant impact of biotechnology on stakeholders' benefits, risks, and consequences makes it a priority to maximize positive social outcomes and adherence to ethical standards. Outcomes may include shared perspectives on the importance for researchers to disclose conflicts via transparency measures, to understand research security guidelines, and to take training on scientific norms integrity."

Conclusion

Biotechnology presents a wide array of both tremendous potential benefits and equally immense risks to regional and even global peace and stability. Biotech has impacts in the realms of fundamental human health and safety concerns, environmental risks, and ethical and social issues. The field interacts synergistically with other technological advances, especially in the realm of AI. Particularly as the field is growing at an explosive pace, with rapidly increasing possibilities of non-state actors entering the arena with nefarious intent, it is in the interests of both the US and the PRC, along with other nations, to quickly build stronger, more concrete, enforceable mandatory international regulations to ensure its safe and responsible application. Great challenges exist to formulating such regulations, as they involve a broad spectrum of levels, from basic laboratory procedures to legislative issues, to national security concerns, and must confront significant issues in the realms of both transparency and trust. Despite the difficulty of the challenge, the cost of doing nothing to build a more secure biotechnology enterprise mandates a whole-of-society push to do so.

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February 2025

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