



EBRC Policy Papers in Response to the 2022 Bioeconomy Executive Order

Engineering Biology Research Consortium

December 1, 2022

www.ebrc.org

Table of Contents

1. [Moonshots for the 21st-Century Bioeconomy.](#)
2. [Standards and Metrics to Accelerate the Global Bioeconomy.](#)
3. [Regulatory Clarity, Communication, and Nimbleness.](#)
4. [Platform vulnerabilities and security in the bioeconomy.](#)
5. [A Biosafety & Biosecurity Innovation Initiative to coordinate the incorporation of safety and security into engineering biology research and bioeconomic growth.](#)
6. [Development of a Workforce to Support a Distributed, Equitable Bioeconomy.](#)
7. [Educating the Next-Generation Bioeconomy Workforce.](#)
8. [Revising legacy approaches to biology education.](#)
9. [US Leadership in a Global Bioeconomy.](#)

Moonshots for the 21st-Century Bioeconomy

A Policy Paper by the Engineering Biology Research Consortium

Compiled and edited by Emily R. Aurand, EBRC Director of Roadmapping and Education

December 2022

Engineering biology has the immense potential to revolutionize our economy, further our societal goals, and ensure products, technologies, and solutions that benefit all Americans. A number of consumer products and solutions that we see everyday integrate engineering biology-based technologies, helping Americans and people worldwide to live healthier and happier lives. For example, in the healthcare sector, many biologics, like insulin, have been produced via biomanufacturing for over 40 years and more recently, CAR T-cell immunotherapy is being used to treat complex cancers with improved effectiveness. Engineering biology was also responsible for the rapid development of the vaccines to fight the COVID-19 pandemic. Engineering biology has the potential to make these healthcare solutions more equitable and accessible, and to treat many of the diseases and illnesses that impact hundreds of thousands of lives. Engineering biology will also be pivotal to tackling the climate crisis and global sustainability challenges. Over the last 50 years, ethanol, biofuels, and sustainable chemicals have been successfully produced through the engineering of biology and expanding the use of these technologies will be critical for energy and supply chain security. Innovations in engineering biology are making possible carbon-negative manufacturing using microbes to convert carbon from the atmosphere into the products we use every day, from packaging materials to clothing and laundry detergent. The agriculture sector has long employed engineering biology tools and technologies to accelerate breeding and develop agronomically valuable traits, and is gaining steam with sustainable, climate-friendly fertilizers and crops resilient to drought and pests. And for the dinner table, numerous companies are providing alternative and plant-based meats, dairy, and other sustainable foods developed with engineering biology to consumers, helping to secure the food sector and combat climate change.

Commercial Products and Solutions	Engineering Biology Technology
COVID-19 vaccines (e.g., Pfizer, Moderna)	mRNA designed to trigger an immune response to the SARS-CoV-2 spike protein.
Alternative meats (e.g., Beyond Meat, Impossible Foods)	Engineered proteins and enzymes to look, taste, and feel like meat.
Sustainable, climate-friendly fertilizers (e.g., Pivot Bio)	Engineered microbes designed to increase nitrogen availability for crops.
Bio-based, renewable chemicals and materials (e.g., BASF, LanzaTech)	Biobased chemicals, enzymes, and proteins for nutrition, personal and home care, medical and dietary nutrition, and cleaning detergents.
Synthetic DNA (e.g., Twist Bioscience)	Customized synthesis of genes and genomes at various scales for use in research and industry.

Looking forward, engineering biology will enable new products and technologies that catalyze the transition from fossil fuels into renewable and sustainable materials and solutions for nearly every sector and industry. The federal government has already shown a dedication to bio-based manufacturing through the establishment of the biology-centric Manufacturing Innovation Institutes BioMADE, BioFabUSA, and NIIMBL. But to make the bioeconomy a reality, the field needs funding, infrastructure, and policies that support the development of foundational tools, the transition of technologies, and processing and scaling to commercialization.

Here we envision moonshots for achievements in engineering biology across five sectors, highlighting the promise and potential of biotechnology. We also link to our interactive EBRC roadmaps, which provide more expansive visions of the innovations that are possible through engineering biology research and application.

Health care and medicine

Short-term Moonshot - New, decentralized manufacturing that does not rely on billion dollar manufacturing facilities, thereby reducing the costs of drugs, accelerating treatments, and benefiting patients across the board. This distributed infrastructure would enable on-demand production of therapeutics and biopharmaceuticals (including seasonal development and manufacturing, such as vaccines against flu), increasing the availability of treatments and therapies for rare diseases and hardening domestic defense against emerging biothreats. Requires capacity for rapid design, discovery, generation, and/or manufacturing in multiple bio-platforms (nucleic acids, proteins, and cells) and incentives (policy and financial) for physical infrastructure and workforce development.

Long-term Moonshot - Commercial deployment of smart, programmable biotechnologies. This will include therapeutic cells, probiotics for detecting and curing diseases, devices at scale for personalized medicine, and platforms or organisms for disease control or eradication. Such technologies leverage the dynamic and unique properties of biology (e.g. innate biosensing and actuation and output of biological circuits) within the therapeutic or device to treat diseases like auto-immune disorders or cancer, for wound healing or countering persistent environmental damage, or for combatting vector-borne diseases like malaria or West Nile virus.

EBRC roadmap resources - [Engineering Biology \(2019\)](#), see [Health & Medicine](#); [Engineering Biology & Materials Science \(2021\)](#), see [Health & Medicine](#)

Climate and energy

Short-term Moonshot - Domestic capacity to accelerate year-by-year declines in atmospheric greenhouse gas (GHG) emissions from agriculture, transportation and industrial sources. Biotechnologies can enable carbon capture from the highest GHG emitting industries (cement, steel) to produce value added chemicals and materials. Federal policies and incentives can accelerate and expand current technologies in practice that enable carbon capture and conversion with engineered microbes and plants.

Medium-term Moonshot - Displacement of today's commodity chemicals produced from fossil resources that have the largest GHG footprint (ammonia, ethylene, propylene, etc.) with biomanufacturing using engineered organisms and renewable feedstocks. Large-scale bioconversion of atmospheric carbon dioxide (gigatons per year) into value-added chemicals (bio-oil) and agricultural supplements (bio-char).

Long-term Moonshot - Eliminate the need for fossil resources for energy, chemicals, fuel through use of engineered organisms and biosystems, providing every consumer – regardless of where they are from or how much they earn – with a sustainable choice of products.

EBRC Roadmap Resources - [Engineering Biology for Climate & Sustainability \(2022\)](#); [Engineering Biology & Materials Science \(2021\)](#), see [Energy](#), [Environmental Biotechnology](#), and [Industrial Biotechnology](#); [Engineering Biology \(2019\)](#), see [Environmental Biotechnology](#), [Industrial Biotechnology](#), and [Energy](#); [Microbiome Engineering \(2020\)](#), see [Energy](#), [Environmental Biotechnology](#), and [Industrial Biotechnology](#).

Food and agriculture

Short-term Moonshot - Consumer-scale production of sustainable protein and meat alternatives through cellular agriculture technologies to meet the needs of a growing population while maintaining a smaller ecological and physical footprint. This level of production will rely on our ability to scale-up processes cost effectively and on the development of clear and effective standards and product regulation.

Short-term Moonshot - U.S. agriculture producers' widespread adoption of enzyme- and cell-based sustainable fertilizers for more efficient nutrient cycling in agriculture. This will help reduce waste and run-off that cause environmental damage.

Short-term Moonshot - Deployment of engineered crops with higher nutrient density. Such crops can improve food security and human and animal nutrition, particularly in regions with resource scarcity. One of the key challenges in achieving this is the translation of foundational knowledge into diverse crop systems.

Medium-term Moonshot - Implementation of alternative crops and methods for biomass generation for use in chemical and energy production, without competing with food production. This includes strategies like the use of marginal lands and fallow season to sustainably increase biomass production.

Long-term Moonshot - Agriculture that is resilient to climate change and disease. By engineering crops and soil systems to respond to and withstand stress from climate extremes and threats posed by pathogens, we can increase the availability and capacity of agricultural yields around the world.

EBRC Roadmap Resources - [Engineering Biology for Climate & Sustainability \(2022\)](#), see [Food & Agriculture](#); [Engineering Biology \(2019\)](#), see [Food & Agriculture](#); [Microbiome Engineering \(2020\)](#), see [Food & Agriculture](#)

Industrial biomanufacturing and supply chain security

Short-term Moonshot - Reuse and upcycling of wastes, including plastics, agricultural wastes and GHG emissions across the U.S. through controlled application of engineered microbes and consortia. The biotechnologies to recycle and upcycle waste materials are becoming increasingly mature, including strategies to ensure their biocontainment, enabling a circular bioeconomy. Adoption into municipal waste management systems would help to eliminate bottlenecks in recycling and, perhaps more importantly, can help to recover valuable commodity chemicals and materials that can be transitioned back into the supply chain.

Medium-term Moonshot - Transition/adaptation of current petroleum infrastructure to accommodate production and processing of biobased fuels and chemical manufacturing. This includes establishing an expanded network of biorefineries specifically designed to process regional sources of biobased and/or GHG feedstocks. These biorefineries will need to address the specifications for either the subsequent bioprocess including fermentation and down-stream processing or meet the specification as a feedstock for chemical conversion at existing chemical manufacturing facilities.

Long-term Moonshot - Net exportation of renewable chemicals, fuels, and materials. Biobased production, extraction, recycling, and upcycling of supply chain staples is not only possible with engineering biology, but necessary for a sustainable future and healthy planet. Investment in biomanufacturing could make the U.S. a forerunner in producing, and exporting, these commodities.

EBRC Roadmap Resources - [Engineering Biology for Climate & Sustainability \(2022\)](#), [Engineering Biology & Materials Science \(2021\)](#), [Engineering Biology \(2019\)](#)

Foundational research to support biotechnology advancements

Short-term Moonshot - Widespread capacity across research and development enterprises to produce designed genomes, biomolecules, and cells. Technologies have advanced such that most laboratories can routinely engineer genes and genomes, proteins, and (non-natural) biomolecular circuits, and to customize cells, organisms, and cell-free systems, all bolstered by the integration of advanced data analysis, computational design, and data modeling. These advancements highlight the transformative potential of integrated biological data models, design frameworks for biomolecules, hosts, and organismal communities, and the promise of automating the design-build-test-learn process; however, bottlenecks exist in risk assessment and translation of fundamental tools to economically-viable technologies.

Medium-term Moonshot - Frameworks for FAIR (findable, accessible, interoperable, and re-usable) data. Engineering biology and biomanufacturing are increasingly model and data driven. To ensure a robust bioeconomy, widely accessible, quality data about biological systems, as well as scalable approaches to generate such complex data, are necessary. For biomanufacturing, creation of a publicly-available database of model and non-model production host organisms, their growth characteristics, genomics and other -omics data, predictive models of gene regulation, and genetic tools and protocols for each organism is necessary to enable growth and scale-up of the industry. Incentives are needed to encourage research and industry to develop and leverage FAIR data.

Medium-term Moonshot - Design, predict, evolve, and generate genetically-encodable biomolecules, such as proteins and RNAs, with user-specified complex molecular structures and functions. Genetically encoded macromolecules such as proteins and RNAs carry out myriad molecular functions at the heart of life. Understanding how a macromolecule's sequence maps to its function and developing new abilities for navigating the high-dimensional sequence space controlling macromolecular function will allow us to generate custom macromolecular sequences with custom functions. This will vastly expand the range of structural and material properties, catalysis, and molecular recognition that we can routinely engineer into biology, which will drive innovations across all sectors of the bioeconomy.

Medium-term Moonshot - Design, predict, and construct microbial consortia for specific niche environments and/or complex functions. Robust communities of organisms exist everywhere on Earth and are responsible for the health and wellbeing of entire ecosystems. Understanding the interplay between organisms in nature, and being able to capitalize on how different components of the system generate different reactions and responses, will help researchers to innovate on biotechnologies for all sectors across the bioeconomy. While developing engineered organisms, biocontainment strategies should be considered and developed to ensure their safe deployment.

Long-term Moonshot - Harness the tools and capacity to engineer any biomolecular, organismal, or cell-free system on Earth. While engineering biology should proceed with an inclusive depth of engagement from the research community, other science and engineering disciplines, government leadership, and the general public, the ability to understand, and the tools to safely, securely, and ethically engineer biology could have monumental advantages for the planet and would ensure continued success and growth for the bioeconomy.

EBRC Roadmap Resources - [Engineering Biology \(2019\)](#)

Standards and Metrics to Accelerate the Global Bioeconomy

A Policy Paper by the Engineering Biology Research Consortium

*Compiled and edited by Cynthia Ni, EBRC Postdoctoral Scholar and Emily R. Aurand, EBRC Director of Roadmapping and Education
December 2022*

The need for standards and metrics to advance the bioeconomy

The rapid emergence of biotechnologies has the potential to transform our current economy into a sustainable and secure bio-based economy. However, this emergence is happening largely in the absence of the standards and metrics needed to assess and sustain a successful bioeconomy through useful data, and to promote innovation. As an example, metrics are foundational for establishing useful benchmarks to assess performance within the bioeconomy. Such benchmarking would benefit startups and established companies alike by making it simpler to compare their new or alternative bio-based products to what already exists. Trusted standards and metrics also play a key role in securing investments in new technologies and commercialization in more established industries, but do not yet exist for bio-based processes. Common language, measurements, and widely adopted standards are critical for many activities within the bioeconomy, including:

- benchmarking to demonstrate the value-proposition of advancements in biotechnology developed in research laboratories to be translated to at-scale, industrial use;
- encouraging investment in commercialization;
- successful consumer and business-to-business transactions;
- and forming clear regulations to achieve a safe and secure bioeconomy, that spur rather than sacrifice innovation.

Establishing standards and metrics will not only accelerate U.S. bioeconomy development, it has important biosecurity implications. Standards and metrics will underpin the [regulations](#) and [biosecurity assessments](#) that will be critical to promote and protect the bioeconomy. The U.S. can demonstrate leadership in the global bioeconomy by recognizing and acting on the importance of clear, effective standards and metrics.

Challenges in developing standards and metrics

Though there have been previous attempts to establish standards within engineering biology – including the inactive NIST Synthetic Biology Standards Consortium, the NSF-funded Nuts and Bolts of Bioengineered Systems: A Workshop on Standards in Synthetic Biology, the EU-funded project BioRoboost, and an early British Standards Institute advisory paper, among others – with the exception of the International Gene Synthesis Consortium’s standards of screening for DNA synthesis, none of these initiatives have had lasting impact on the industry. Many of those efforts were focused on research applications, rather than commercialization. While standards for research may have been more relevant for the nascent field, the low rate of adoption has led to a weakened value proposition for further development and use. Additionally, previous efforts in standardization were narrow in scope, and in many cases siloed, neither addressing the diversity and complexity of biological processes and data, nor being able to keep pace with the rapid advances in engineering biology development and translation. In addition, the overall breadth of standards needed to support various aspects of the evolving engineering biology field and the broader bioeconomy has led to a lack

of consensus amongst stakeholders on what standards are needed and when they should be developed. The lack of consensus extends to the definitions of the bioeconomy and how it should be measured. Spheres of biotechnology approach the development and use of standards with different incentives and priorities, necessitating consensus building to identify standards and metrics that would be useful across the industry. As the engineering biology industry matures, and its products have the potential to bolster the bioeconomy, there is an apparent and timely need for standards and metrics in the commercial space that are agreed upon and coordinated across the engineering biology community.

Next steps in establishing standards and metrics to promote a secure bioeconomy

While the standards landscape for the bioeconomy is as vast as the biotechnologies and biomanufacturing that it supports, a critical initial step is a common lexicon. Clear, generally agreed-upon, definitions for vocabulary related to the bioeconomy underpin all activities related to technology development, commercialization, and regulation. This makes the lexicon that NIST was directed to develop for the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy a prerequisite for all other activities. Under the current [Executive Order](#), NIST has 90 days to develop and release an initial list of terms and definitions. To support the growing bioeconomy, a more advanced, comprehensive, and maintained taxonomy would be needed. It is critical that the lexicon and taxonomy are developed by NIST in collaboration with a broader coalition of stakeholders from government agencies, academia, industry, and international partners.

Using the lexicon, stakeholders across the bioeconomy should be consulted and convened to determine what standards would be useful and relevant for advancing their industries continuously. The development of standards and metrics should then follow, guided by industry and community consensus, with the support of NIST resources and capabilities. NIST is thus poised to take a leadership role in facilitation, coordination, and promotion of these activities to ensure widespread adoption and use, thereby avoiding the pitfalls of previous standards setting attempts. Additionally, NIST laboratory programs should be expanded to support benchmark innovative engineering biology products and processes, while supporting the development and adoption of best practices.

The resulting standards and metrics will help enable risk assessment and more streamlined regulatory processes that lower barriers to commercialization and keep the bioeconomy and its consumers safe. These efforts will drive innovation by making it clear what startups and companies need to do to bring their products and services to market and to shift more of their manufacturing to bio-based processes.

Recommendations

1. Direct no less than 50% of the anticipated \$14M increases in Biotechnology and Biomanufacturing in FY23 budget to support the development of standards related to engineering biology, including lexicon, technical standards, support and coordinate evolving engineering biology metrics and benchmarking development, and the underpinning laboratory program in microbial systems.
2. Implement a long-term public-private partnership program, helmed by NIST together with research and industry organizations (e.g., EBRC), to convene stakeholders and maintain ongoing dialogue for advancement of biometrology, engineering biology tools, capabilities and standards. Initial information gathering activities will need a budget of approximately \$5M.

3. Appropriate \$50M currently authorized for NIST in the CHIPS and Science Act to expand NIST engineering biology programs in support of the bioeconomy.
4. Provide funding to improve and/or expand laboratory infrastructure, including state-of-the-art laboratory spaces, to enable the development of engineering biology metrology and bioeconomy standards, and develop pre-competitive technologies.
5. Provide support for the Departments of Commerce, Energy, Defense, and other federal agencies involved in biomanufacturing, to further develop their respective infrastructures (including Manufacturing Innovation Institutes) to support and implement bioeconomy standards, and to coordinate their implementation of standards and metrics.
6. Coordinate the development of standards and metrics for engineering biology with updates and clarifications to biotechnology regulatory frameworks, ensuring that NIST is represented among agencies tasked with biotechnology regulations.

Regulatory Clarity, Communication, and Nimbleness: Enabling the safe and secure deployment of biotechnologies to address global challenges

A Policy Paper by the Engineering Biology Research Consortium

*Compiled and edited by Becky Mackelprang, EBRC Associate Director for Security Programs
December 2022*

Technologies being developed today in academic, government, and industry laboratories are poised to usher in a biotechnology revolution that supports human, plant, and animal health and wellbeing; ensures global food security; and combats climate change. The United States is at the forefront of this revolution, and its [regulatory agencies are and will continue to be tasked with establishing and enforcing rules and regulations](#) that ensure the commercialization of biotechnologies that are viable and economically-sound solutions and do not present unacceptable risk. Stakeholders across the biotechnology ecosystem recognize and value the challenge of this role and respect the need for sensible regulation. However, real and perceived regulatory hurdles and uncertainty around future regulatory actions, can affect decisions by researchers and companies about which projects and products to pursue. Improved clarity, communication, and nimbleness of U.S. regulations will enhance innovation. The U.S. federal agencies responsible for regulating biotechnology need the resources and capacity to provide clear pathways to biotechnology regulation and effectively communicate them with stakeholders across the bioeconomy.

The modernization of regulations through the January 2017 [Update to the Coordinated Framework for the Regulation of Biotechnology](#) helped clarify the roles of Federal agencies, communication between agencies, and timelines for review of products of biotechnology. A [2019 Executive Order](#) that addressed the regulation of agricultural products was also an important step. Now, the Biden Administration Executive Order on the bioeconomy represents an opportunity to “identify areas of ambiguity, gaps, or uncertainties” in relevant regulation and policy, which may occur in the regulations themselves and/or in the way those regulations are communicated or understood by the private sector. If regulatory agencies are able to deliver on this directive, they will enable the development of products that deliver maximal benefits to society while minimizing associated risks. We herein articulate select areas of uncertainty and concern that have caused challenges in the development of biotechnologies.

Clarity of coordination and regulation among U.S. agencies

USDA, EPA, and FDA should be commended for the development of [The Unified Website for Biotechnology Regulation](#). This resource is a useful starting point for stakeholders who want to familiarize themselves with the Coordinated Framework and the [laws, legislation, and guidance](#) that are relevant to biotechnology innovation and regulation. However, it offers little in describing how the three agencies work together or the path that a given biotechnology might take through and between agencies. Visitors are instead directed to the websites of individual agencies and may lack clarity on which agency they might need to work with first, the types of data required by each, and/or how the timelines and coordination between agencies might work. The anecdotal reliance on consultants to help companies prepare for and navigate regulation highlights the lack of clarity within the system and represents another obstacle to the success of small-mid sized businesses.

To make the interagency regulatory process more transparent and accessible to stakeholders, the Unified Website could be expanded to provide: i) a summation of Section E of the 2017 Update to the Coordinated

Framework to describe *how* USDA, FDA, and EPA work together to regulate biotechnologies, strengthened with clarity and/or examples about how Working Groups and MOUs might, in practice, facilitate coordination around a single biotechnology product; and ii) information to help stakeholders determine which agencies a biotechnology may be regulated by. This could be as straight-forward as sharing Table 2 from the 2017 Update to the Coordinated Framework on the website. Alternatively, a decision tree could be useful, perhaps similar to that used to determine [disclosure requirements for bioengineered foods](#). At the end of the decision tree, or as an addition to an adapted form of Table 2, the user could be directed to the relevant areas of agency websites and linked to information about the documentation that may be required. To avoid confusion and keep the information current with respect to developing technologies, agencies will need to consistently review and periodically update the Coordinated Framework (and be afforded the adequate resources to do so), as they are called to do in Section F of the 2017 Update. To communicate that such a tool is meant to be a useful aid to stakeholders and not a definitive regulatory decision, users could be required to click a button acknowledging the non-binding nature of the decision tree before using it.

This enhanced communication and increased visibility into the regulatory process would inform researchers at all stages of development, from technology conceptualization to scaling and commercialization. This could also help early-stage entrepreneurs demonstrate to investors that the regulatory processes are not an insurmountable barrier.

EPA, USDA, and FDA: Communication of agency-specific regulatory approach and timelines

In addition to visibility into interagency regulatory processes, innovators would also benefit from greater visibility into the regulatory processes within EPA, USDA, and FDA. Each agency commendably provides extensive resources on their websites and point to the pieces of legislation that establish regulatory authority. It is less clear, however, which considerations might be wise for innovators to examine during development, which data and documentation are needed, what happens after paperwork is submitted, and how long review processes take. For example, EPA's website is incredibly useful for pointing to the rules and regulations that EPA uses to regulate products of biotechnology, however companies may struggle to understand how those rules and regulations *apply* to the products they are developing. It could be useful to develop a schematic or case study that represents the regulatory process with an example product. Such a schematic or case study would be most useful if it described or exemplified the ideal time to reach out to regulators, timelines, important considerations, and the data and documentation required. Minimally, the website might point readers to (and link directly to) specific sections of TSCA, FIFRA, and other relevant guidance documents. PDFs of rules and regulations might also be enhanced with links to referenced statutes. Any clarity that can be provided on these topics will be incredibly useful, particularly for small to mid-sized organizations taking their first products to market.

Regulatory officials have publicly indicated their availability and willingness to speak with individuals and companies at any stage of the development of new biotechnologies. This is a tremendous benefit for stakeholders, and could be better emphasized on their websites, particularly with regards to early-stage development. Agencies could individually—or even better, jointly—establish a formalized portal through which developers could request virtual appointments with agency staff whose job it is to guide developers with early-stage questions. An agency staff member could then act as an early-stage regulatory point-person. Crucial

decisions are made early in the development of an engineered organism to optimize its biological activity or function. Developers may find out after expending significant resources to develop a given strain that a few differences, such as the use or removal of a given antibiotic, make a significant difference in the regulatory process. Expressing this openness to communication early in product development could help minimize confusion within industry and enable developers to make informed decisions early in development. The success of a regulatory approach that relies on early and often communication between regulators and developers hinges upon the dissemination of that approach to stakeholders and on the capacity of regulators to work with stakeholders in a timely manner. Thus, it is crucial that regulatory agencies have sufficient funding, staffing, and resources to meet this need.

Horizon scanning to promote a nimble regulatory system

Engineering biology research and advancements in scaling and manufacturing processes leave the bioeconomy poised for massive innovation and expansion. Recognizing that many products will need regulatory review, the U.S. Government should support technically-based horizon scanning in coordination with regulatory agencies. This will enable these agencies to anticipate policy and regulatory clarifications and developments that will be needed. While the agencies cannot be bogged down by developing clear policy for technologies that may not exist for years to come, they can use the information generated through horizon scanning to identify where current policies, guidance, and regulations are insufficient or where there might be ambiguity in which agencies have regulatory purview. They might also recognize areas where current strategies for assessing biological risk are insufficient. That information can be incorporated into policy review and clarification efforts as opportunities arise and will enable a more nimble, risk-based response when the biotechnology products of the future near commercialization. (See [Preparing for Future Products of Biotechnology](#).)

Conclusion

As regulatory agencies identify ambiguities, gaps, or uncertainties in biotechnology regulation and undertake the important work of providing clarity, communicating standards with stakeholders, and building agility into their processes, they will enable bioeconomy stakeholders to develop products with greater confidence in their understanding of the pathways to commercialization. If regulatory agencies are appropriately funded, staffed, and resourced, the U.S. Government can maintain and build upon its position of leadership in the global bioeconomy and address major societal challenges.

Platform vulnerabilities and security in the bioeconomy

A Policy Paper by the Engineering Biology Research Consortium

Compiled and edited by Becky Mackelprang, EBRC Associate Director for Security Programs

December 2022

The foundational tools and technologies of engineering biology developed over the past 20 years are enabling the development of commercial products for a rapidly expanding bioeconomy. Many developing applications of engineering biology rely on platforms such as gene editing. Platform technologies “typically are highly shared, have multiple purposes and uses, and offer tremendous benefits through their scalability and adaptability.”¹ However, because they can underpin products and systems across applications, they can “introduce new and shared vulnerabilities that can be exploited to misuse any technology on the platform.” It is thus important to recognize the platform technologies and systems that underpin the bioeconomy, understand their vulnerabilities, and identify steps the US Government can take to prevent or mitigate their exploitation. Crucially, in the identification of such steps, USG must also recognize that security measures that prohibit areas of research, sharing of information, and collaboration across national boundaries can undercut the bioeconomy and cause real loss to the development of [life- and planet-saving biotechnologies](#). Thus, decisions to implement security measures should account both for security benefits and lost opportunities.

Below, a non-comprehensive view of platform technologies, their vulnerabilities, and potential exploits of those vulnerabilities is described. Platforms are divided into three sections—biology-based platforms, automation platforms, and computation and data-based platforms—with an additional section to consider vulnerabilities and exploits that are relevant across platforms. [Much of this information is also available in the linked table](#), which includes segments of the bioeconomy that particularly rely on given platforms.

Platform technologies, vulnerabilities, and exploits specific to the bioeconomy

All platforms

- An overarching vulnerability across platforms is their very existence and the potential for another nation to develop new or improved platforms that are widely adopted. If another nation is able to offer superior, cost-competitive DNA synthesis or sequencing capabilities, lab automation systems, or computational tools, that nation could achieve platform dominance. This would come at an economic loss to the U.S. That economic loss could be amplified many fold if the competitor nation uses the data from platform users to bolster their own research and innovation efforts.
- Insufficient regulatory capacity for a complex [regulatory landscape](#): If regulatory agencies do not have the necessary staffing and resources to handle the coming tidal wave of products developed on biotechnology platforms, the U.S. may miss seeing the return on its investments in research and development. If a product lacked sufficient review and caused damage to a consumer because of an insufficient or overburdened regulatory process, entire segments of the bioeconomy could be shut down. And, when regulations are too complex and/or stringent, we forfeit US competitive advantage and leadership across the global bioeconomy.

¹ National Academies of Sciences, Engineering, and Medicine 2022. Protecting U.S. Technological Advantage. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26647>.

Analytical and biology-based platforms

The research and development required for innovative biotechnologies is enabled by biologically-based platforms and the analytical platforms that enable measurement and analysis of biological activity and outputs. For example, gene sequencing, gene editing, and DNA synthesis are biological-based platforms while proteomic and metabolomic platforms enable the measurement of biological systems. These platform technologies enable the development of commercializable products across segments of the bioeconomy from medicine to agriculture to consumer cosmetics and fashion. Many of these platforms share common vulnerabilities, including:

- **Disinformation:** With many consumers still carrying a negative view of the products of bio-innovation, such as genetically engineered foods, bio-based platforms such as gene editing are vulnerable to disinformation. This could be exploited by adversarial groups or nations seeding and/or amplifying disinformation that destroys trust in products of the bioeconomy.
- **Introduction of contaminating or counterfeit chemicals or infectious agents to source materials for the bioeconomy:** Biology-based platforms depend on high-quality, consistent reagents and feedstocks. The interception and tampering of a shipment e.g. of nucleotides en route to a DNA synthesis company—or worse yet tampering by an insider post quality control measures—could impact tens of thousands of orders and researchers, perhaps resulting in a lack of primers for medical diagnostic PCR tests, halting research, and delaying the biological parts and services supply chain. Such exploits should be viewed with acknowledgement that accidental contamination and supply chain issues caused by natural disasters, pandemics, and global political realities are more likely and may have broader impacts.

Automation and scale-up platforms

Engineering biology researchers often employ a design - build - test - learn (DBTL) cycle to develop systems and organisms that are optimized for a given function or outcome. It is not uncommon for institutions to invest in automation platforms, which enable more samples or experiments (and thus DBTL cycles) to be run in a given time, enhance reproducibility, and save on labor costs. And, as biological systems are optimized, they must be scaled up to commercial levels. Scaling and manufacturing facilities and platforms are key nodes whose vulnerabilities may be ideal targets for nefarious actors.

- The code that runs automation platforms or pieces of automation equipment may be vulnerable to hacking. Vendors may or may not commit the resources required to penetration-test their own code. Furthermore, users may buy pieces of equipment from different vendors and develop their own code to enable communication between instruments. Such users generally focus their code development on functionality without dedicating sufficient resources to security. Thus, vulnerabilities in the code driving a single piece of equipment or connecting several pieces of equipment could be exploited by an outsider (or insider) gaining access and, for example, undetectably changing the automated process to give inaccurate results.
- Scale-up platforms are susceptible to contamination and physical infrastructure damage. Microorganisms could be introduced to massive bioreactors, inhibiting the production of or contaminating desired products. Physical infrastructure damage could cause leaks of engineered organisms or toxic by-products.

Computation and data-based platforms

Biotechnology innovation is enabled and informed by advanced computational capabilities and platforms. Huge searchable databases such as GenBank[®], which contained 240,539,282 sequences and 1,562,963,366,851 bases as of Oct 2022,² provide up to date, comprehensive DNA sequence information across the scientific community. Computing platforms enable researchers across application areas to process “big data” rapidly, hastening discovery and shortening the DBTL cycle. Machine learning and large scale modeling are improving significantly each year and are close to reliably predicting protein structure and function from sequence. Furthermore, researchers are working on an even bigger challenge — generating sequences based on the input of a desired function, which could drastically reduce research timelines. Vulnerabilities of these computation and data-based platforms include:

- Imperfect taxonomic labeling in searchable databases: When researchers deposit a synthetic sequence in a database—for example, a single sequence containing DNA from both Ebola and benign Green Fluorescent Protein—that sequence has to ultimately be given a single taxonomic label. That taxonomic label has implications for other researchers and for security processes that reference these databases, such as DNA synthesis screening. One can imagine purposely feeding such databases inaccurate information which could enable concerning sequences to escape screening by DNA synthesis providers or, more broadly, result in experiments premised on inaccurate data. This would require significant knowledge of how these databases employ quality control and would not be a trivial pursuit.
- Lack of adequate code security:
 - Advances across life sciences have made it more common for researchers to collect gigabytes, or even terabytes, of experimental data. Because not all researchers are competent in handling and processing such large swaths of data, individual researchers and companies may use computational analytic platforms. Developers of such platforms—whether commercial or academic—may not have the funding, awareness, and/or motivation to implement appropriate cybersecurity measures, potentially leaving the platform and its users susceptible to attacks that compromise system fidelity and result in inaccurate experimental results and analysis.
 - The ability to generate sequence information for a desired protein function (e.g., conversion of a common metabolite to a therapeutic metabolite) would be a powerful platform technology. It could be exploited to develop methods for biologically producing chemical compounds with high human toxicity. This exploit would be very challenging, requiring significant time, expertise, infrastructure, and trial and error. Compounds with high human toxicity also often kill the microbial cells one may try to produce them in (see Urbina et al, 2022³).

Addressing vulnerabilities

Some of these vulnerabilities arise from the same characteristics that enable innovation in the bioeconomy, such as the sharing of tools and information. Thus, those making efforts to address vulnerabilities should be cognizant that regulatory interventions may present significant risk of ceding [global leadership of the](#)

² NIH National Library of Medicine, National Center for Biotechnology Information. GenBank and WGS Statistics (Accessed Nov 17, 2022). <https://www.ncbi.nlm.nih.gov/genbank/statistics/>

³ Urbina, F., Lentzos, F., Invernizzi, C. et al. Dual use of artificial-intelligence-powered drug discovery. Nat Mach Intell 4, 189–191 (2022). <https://doi.org/10.1038/s42256-022-00465-9>.

[bioeconomy](#), which is a vulnerability itself. The United States Government can minimize platform vulnerabilities across the bioeconomy through steps such as:

- Conducting outreach to large and growing bioeconomy platform and equipment vendors to educate companies on the importance of cyber- and physical security practices, insider threat programs, and process-monitoring to detect intrusion and sabotage attempts.
- Supporting public/private partnerships that work with platform companies to detect vulnerabilities through tabletop exercises, red-teaming, etc., and are trusted to rapidly disseminate warning messages and patch/mitigation strategies to user communities.
- Encouraging platform companies to develop and implement continuity of operations plans and capabilities to ensure robustness in the face of significant temporary supply chain disruption, natural disaster, etc., and to be capable of delivering when surge production is necessary.
- Dedicating resources to the [characterization of these vulnerabilities](#) so that i) those that carry the greatest risk can receive the greatest attention and ii) mitigation strategies can be developed with stakeholder input that do not compromise U.S. leadership of the global bioeconomy.
- Supporting [workforce development](#) so that the workforce operating these platforms are well-trained, which will make them better able to understand and implement safety and security measures.
- Supporting the incorporation of [safety and security into education and workforce training](#) so that participants in the bioeconomy understand why safety and security are important and how to implement best practices.
- [Developing and perpetuating standards](#) for interoperability, accountability, measurability, safety, and security in engineering biology and the bioeconomy. For example, the United States is the only nation to provide screening guidance to providers of synthetic DNA. Some international companies adhere to screening standards in compliance with their nation's export laws or as required for membership in the International Gene Synthesis Consortium, but efforts that encourage and support the global adoption of screening practices would support the continued productivity of that platform for peaceful research and innovation. Similarly, the US might consider [establishing leadership](#) in efforts such as the development of [metrics and standards](#) around the bioeconomy or a unified standard for obtaining, storing, and disseminating genetic information.

Many platform technologies underpin the bioeconomy and enable incredible discovery and innovation across its segments. However, these platforms can also present vulnerabilities, and the USG must place these vulnerabilities in context and estimate the [risk of their exploitation](#). The measures suggested above, meant to secure and safeguard the bioeconomy and biotechnology without compromising innovation, will help us ensure that platform technologies in engineering biology can continue to help us address our nation's and planet's most significant challenges.

A Biosafety & Biosecurity Innovation Initiative to coordinate the incorporation of safety and security into engineering biology research and bioeconomic growth

A Policy Paper by the Engineering Biology Research Consortium

Compiled and edited by Wilson Sinclair, EBRC Postdoctoral Scholar, and Becky Mackelprang, EBRC Associate Director for Security Programs

December 2022

Safety and security play a critical role in maintaining a strong and resilient bioeconomy. Failure to recognize vulnerabilities and counter threats before they cause significant harm could severely hamper the progress already made within the US bioeconomy, adversely impact public trust, and jeopardize our collective future safety and security from extant threats. There are currently limited incentives or fora for bioeconomy stakeholders to discuss, share, analyze, and learn from issues that arise relating to biosafety and biosecurity across the research, development, scale-up, and manufacturing lifecycle. There are also limited efforts to encourage and support innovation around best safety and security practices. When best practices are identified, they may not be encouraged, shared, and/or tailored to an individual organization's practice. There is an urgent need for government coordination of a federal strategy, in partnership with leading experts across academia and industry, for biosafety and biosecurity issues that have and will continue to emerge from innovative engineering biology research and a robust bioeconomy.

The recent Executive Order (EO) on [Advancing Biotechnology and Biomanufacturing Innovation](#) recognizes the importance of enhancing safety and security at all stages of biotechnology development and commercialization and directs the Federal Government to meet this imperative. The Secretary of HHS, in coordination with the heads of other relevant agencies, is tasked with launching the Biosafety & Biosecurity Innovation Initiative (BBII) to reduce biological risks associated with a growing bioeconomy. In the spirit of the EO, the BBII should be structured as an interagency working group or panel, supported by full-time staff. Its operations should draw on the integral participation of federal partners, including Departments of Homeland Security, Commerce, Agriculture, Defense, and Energy, in addition to NIH, NSF, EPA, and others to incorporate broad expertise linking information from various sources to develop a more clear picture of the biosafety and the biosecurity landscapes in the United States. As its three core functions, detailed below, the BBII should serve to coordinate i) on-going assessments of current and prospective vulnerabilities of the bioeconomy and the effectiveness of current mitigation measures to identify emerging threats and best practices; ii) the funding of biosafety and biosecurity research; and iii) incentivization of safe and secure best practices. To fulfill these functions, the BBII should regularly communicate with research practitioners and other stakeholders across academia and industry, hosting fora to discuss approaches, challenges, and areas in need of clarity from the federal government. Building and sustaining such dialogue will position the BBII to take a holistic, forward-thinking approach to protecting human, plant, animal, and environmental safety and security.

Core Functions of the Biosafety and Biosecurity Innovation Initiative

Identify emerging vulnerabilities and best practices in coordination with stakeholders throughout the bioeconomy enterprise

Safety and security concerns, incidents, and near-misses can arise from across the expansive academic and industry landscape. So too can best practices to counter such threats. The BBII should identify these issues and coordinate and/or perform the continual evaluation and assessment of vulnerabilities, weaknesses, or threats to a safe and secure bioeconomy. It should identify and communicate best practices that minimize and mitigate the impacts of bioincidents. To do so, the BBII should engage in dialogue and assemble fora that bring together and leverage the expertise within agencies like DHS and FBI and the expertise of research practitioners, funders, and other relevant partners such as Institutional Review Boards and Institutional Biosafety Committees. With a broader view of the threat landscape across the bioeconomy, the BBII can deliver targeted communications of concerns and best practices across segments. It may also identify regulatory gaps or unclear policy that might be strengthened or clarified. These activities of the BBII directly support the execution of Goals 1-3 of the 2022 [National Biodefense Strategy and Implementation Plan](#),¹ as required by [National Security Memorandum-15](#).

As the BBII considers the maturing and evolving nature of the biorisk landscape, it should consider alternatives to list-based approaches to safety and security. Biology is challenging to bound and fit into lists because of its expansive variation. An analogy may be drawn to cybersecurity prediction models as an alternative to list-based approaches. Early models of risk assessment in cybersecurity began by naming and searching for a set of known bad threats, such as computer viruses, akin to today's list of controlled pathogens. However, enumerating specific threats was deeply insufficient because it tempted bad actors to modify attacks just enough to evade detection. List-based approaches for biosafety and biosecurity offer that same temptation. Instead, risk assessments based on the enumeration of [known biological vulnerabilities](#) built with tools to predict potential harms in novel constructs, sequences, etc., may provide a more complete picture.

The BBII should further be cognizant that industry leaders may seek to discuss biosafety and biosecurity incidents or near-misses and improvements to their processes in a non-attributable manner. We suggest that the BBII establish or contract with an independent public-private partnership to enable data sharing and open discussions of issues of concern while protecting industry partners' privacy and interests. This partnership could be modeled after the Aviation Safety Information Analysis and Sharing (ASIAS) program where a company can report an incident or unsafe practices or conditions to a third party who investigates and helps the company or institution improve their systems. The third party is trusted to confidentially document incidents, analyze them for any patterns of commonalities, and communicate trends, emerging concerns, and best practices to community stakeholders and/or federal partners, as appropriate, to prevent similar future threats from emerging. In this way, the BBII could serve as a central hub to continuously identify, describe, catalog, and communicate the safety and security landscape across the bioeconomy. Importantly, this hub should be open to academia and others with federal grants or contracts, but should not supplant other required reporting.

The BBII and agency partners should recognize that, as biotechnology rapidly advances, additional biosafety and biosecurity research needs will emerge, requiring continual risk assessment. This core function is essential

¹ Goal 1: Enable risk awareness and detection to inform decision-making across the biodefense enterprise.

Goal 2: Ensure biodefense enterprise capabilities to prevent bioincidents.

Goal 3: Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents.

to ensure efficient investment in needed areas of safety and security innovation and that the most recent best practices are upheld, shared, and incentivized.

Fund applied biosafety research and biosecurity innovation

As discovery and innovation open new doors of opportunity throughout the bioeconomy, new biosafety and biosecurity challenges will emerge. Through communication efforts described above, the BBII can have awareness of those challenges and, as directed in the EO, “support, as a priority, investments in applied biosafety research and innovations in biosecurity to reduce biological risk throughout the biotechnology R&D and biomanufacturing lifecycles.” These investments should be made both in technical developments (e.g., biocontainment, DNA synthesis screening) and in nontechnical research, partnerships, and practices (e.g., identifying and promoting best practices) that, together prevent or reduce the impacts of bioincidents (see National Biodefense Strategy Goals 1 & 2). Both types of activities require consistent funding that allows for the continuous refinement of objectives and approach through the assessment and evaluation of findings and outcomes.

The BBII might consider funding [efforts such as](#): the development of technical biosecurity technologies that can be embedded in bioenabled products (e.g., kill switches and other biocontainment methods); machine learning tools that predict the function of an engineered sequence or organism in an operational context; risk estimation tools at multiple scales and cellular contexts; furthering our understanding of current biosafety and biosecurity practices and their results from early research through operational biomanufacturing production; identification of gaps in biosafety and biosecurity and development of technical and policy recommendations to close such gaps; social science research on strategies for fostering innovation and overcoming obstacles to the adoption of new biosafety and biosecurity tools and practices by stakeholders.

When possible, the funding of these efforts should be collaborative, including both technical and social science researchers. Such efforts could be modeled on the NIH [bioethics supplement program](#). Similarly, there could be “technical supplement programs” where social scientists lead and receive supplemental funds to work directly with technical researchers. These collaborations are challenging to develop, maintain, and adequately fund, but could play a key role in identifying and solving security problems in emerging biotechnology research and open new areas for funding and building best practices.

Incentivize best practice adoption by integrating safety and security into the research lifecycle

Funding research to develop and identify best safety and security practices is important but does not ensure the adoption of those practices. The BBII could consider the following incentive-based approaches to encourage adoption across the bioeconomy and promote a culture of attentiveness to safety and security throughout the research and biomanufacturing lifecycle:

Funding incentives - i) Funders could incentivize researchers in relevant fields to incorporate safety and security activities and consideration into their work by directing them to do so in requests for proposals, incorporating engagement with these topics into scoring criteria, and requiring grantees to report on security and safety activities through grant reporting mechanisms. Funders should include information to grantees on what this engagement looks like and be wary of building a “compliance culture” with boilerplate answers. Rather, funders should communicate to researchers that, for best proposal reviews, they should demonstrate a [generative safety and security culture](#) within their labs or organizations that values proactive discussion across disciplines to better understand the far-reaching impacts and risks of ongoing, cutting-edge biotechnology research, scale-up, and production; ii) Additionally, the BBII could request that government agencies awarding

contracts to the private sector in relevant fields place greater emphasis on the demonstration of safety and security practices by contractors.

Certificate program - The BBII could also develop or fund the development of [efforts such as](#) course curricula and a certification program or credential geared at i) recognizing the comprehensive incorporation of safety and security practices into an organization; ii) recognizing the training and competency of a researcher or student in biosafety and biosecurity; iii) training opportunities for future biosafety and/or biosecurity leaders; and/or, iv) training opportunities for early-stage (undergraduate or graduate) technical researchers. To incentivize participation, relevant government career track positions could require certification. As the value of such training becomes recognized across research and the bioeconomy, individuals with such a certificate might receive higher pay or be permitted to work on certain projects.

Conclusions

The Biosafety and Biosecurity Innovation Initiative represents an exciting opportunity to ensure that scientific progress delivers on its promise. The BBII can serve to harmonize USG's assessment of biorisks and support for best practices by bringing stakeholders across the government together to develop coordinated practices and community engagement. Those who work for and with the BBII should also recognize that others around the world are watching its activities and strive to be [helpful international partners](#). We recommend that it provide iterative, ongoing assessments of the biorisk landscape, fund biosafety and biosecurity research, and incentivize safe and secure best practices. As it does so, the BBII should remain as transparent as possible and seek to involve diverse stakeholders.

Biosecurity and biosafety touch all parts of the bioeconomy and biomanufacturing. With the collective efforts set forth by the Biden Administration's Executive Order, coupled with legislation such as CHIPS + Science, it is a pivotal moment to deliver broad coordination with lasting impacts. By collectively working to minimize a significant safety or security breach, we can ensure a healthy and productive bioeconomy, protect national interests, and enable human, environmental, plant, and animal health and well-being.

Development of a Workforce to Support a Distributed, Equitable Bioeconomy

A Policy Paper by the Engineering Biology Research Consortium

*Compiled and edited by Emily R. Aurand, EBRC Director of Roadmapping and Education
December 2022*

The development of [biotechnologies that will usher in a more sustainable and healthier future](#) require a talented, trained workforce that reflects the diversity of America. The bioeconomy will rely on the distribution of opportunity geographically, demographically, and across the workforce spectrum. To support the growth of talent in all 50 states and reach all Americans—including people of color, people with disabilities, and people from economically disadvantaged backgrounds—federal agencies must advance [biotechnology education](#) and workforce development policies and programs that meet potential trainees where they are. The U.S. Government can establish and incentivize programs, infrastructure, and funding for regional education and training, direct assistance to those with traditionally fewer opportunities, and to make sure that there are entry and access points into the bioeconomy workforce throughout the pipeline.

Opportunity should be geographically distributed

Challenge - The bioeconomy is growing in a distributed fashion across the country; however, the US still needs to rapidly onshore and expand capacity if we are to meet the demands of the growing bioeconomy. While biomanufacturing capacity is distributed more broadly, major research and innovation is currently centered in a few regions, creating an opportunity for greater geographic distribution of education and workforce development.

Recommendation - The federal government can:

- Incentivize and establish educational institutions, programs, and training centers that are geographically distributed to meet regional needs and opportunities in biomanufacturing and the bioeconomy and ensure that students in rural areas have access. Congress and agencies can earmark funding for educational programs (secondary, post-secondary, and graduate) and workforce training (CTE, apprenticeships, informal educational programs, portable training materials) that can reliably meet the future workforce where they are.
- Establish and invest in biotechnology and biomanufacturing infrastructure across the U.S. This can include identifying existing fermentation and manufacturing capacity that can be repurposed for bioproduction and developing a strategy for adding new biomanufacturing facilities in regions near key resources and where costs are low. The federal government can also provide financial incentives for states and companies to build and use domestic facilities and then draw their labor pool from the region in which the facilities are located.

The future workforce should be demographically diverse

Challenge - Education is the surest, shortest path to economic prosperity, but long-standing inequities limit the diversity of our nation's skilled workforce. Some institutions do not yet appreciate the inherent and practical value of diversity, equity, inclusion, and accessibility (DEIA) as important drivers not just for the scientific

research enterprise, but for sustainable and sound workforce development. While organizations like the NSF have placed an emphasis on broadening participation of traditionally underrepresented groups in STEM, institutions serving those groups (MSI, HBCU, etc.) are generally under-resourced for providing educational and training opportunities in STEM, and even more so for providing education and training in emerging areas like the bioeconomy. Similarly, to engage a broader demographic of individuals in the fast-growing bioeconomy, education and training needs to extend beyond traditional educational institutions to all points of entry, with programs and resources for non-traditional communities and those outside of the educational pipeline.

Recommendation - To attract a diverse workforce into the bioeconomy, the federal government must ensure abundant opportunities for education and technical training. Effective education and training for bioeconomy jobs requires access to expertise, instructional capacity and materials, and tools and technologies that are foundational to the sector. The federal government should:

- Provide direct support to minority-serving institutions, including the infrastructure and physical resources to introduce students to engineering biology and biomanufacturing skills, encouraging the development of interdisciplinary programs in bioeconomy-allied fields of science and engineering, and incentivizing the establishment of programs and activities that expose students to career opportunities in biotechnology.
- Catalyze the training of talent throughout the country, for individuals at all levels of educational attainment. This includes establishing skills-oriented training programs that serve teenagers in poor and/or immigrant communities and that offer a high school credential or certificate, veteran-serving community programs that provide after-hours training with wrap-around support for active service military spouses and under-employed service-men and -women, and informal education centers with coordinated public programming that can familiarize residents of non-traditional STEM hubs with the career opportunities and required technical skills to meet regional needs in biomanufacturing.
- Incentivize programs and action for research-intensive institutions and industry to engage and hire individuals with various disabilities that can thrive in the bioeconomy with certain workplace accommodations.

Opportunities should exist to consistently retrain and upskill

Challenge - There are both economic and social imperatives for investing in workforce training specific to the bioeconomy. Bioeconomy opportunities are starting to arise in areas that are seeing losses in other sectors. Today's incumbent workers who see their expertise as either insufficiently up to date or focused on a narrow and perhaps shrinking area of the economy, must not be allowed to fall behind but should, instead, be supported with federally-funded professional development opportunities.

Recommendation - The federal government should

- Expand the availability of existing retraining programs and events, to ensure that talent will persist in or transfer to jobs in biotechnology and biomanufacturing.
- Provide formal and informal opportunities tailored to those from sunseting industries to develop skills and abilities that align with regional bioeconomy jobs.
- Catalog and provide incentives for companies to enroll their employees in short, effective programs that are specific for current and potential bioeconomy workers.

Educating the Next-Generation Bioeconomy Workforce

A Policy Paper by the Engineering Biology Research Consortium

Compiled and edited by Emily R. Aurand, EBRC Director of Roadmapping and Education

December 2022

The US is poised to be a [global leader](#) in the bioeconomy in the coming age of biotechnology based on its intellectual and human resources. Since a robust and distributed bioeconomy is still emerging, forging and maintaining leadership requires a [skilled, diverse workforce](#) to (1) create new technologies and materials that spawn new companies and entire industries, and (2) execute the manufacturing and development tasks created by those companies and industries. These two components of the workforce comprise cohorts with different education levels that are each critical to US bioeconomy excellence, and across the cohorts there is serious need of programmatic and financial support to enable their training and expansion. The innovation workforce (the former above) for creating new technologies is predominantly scientists and engineers with doctoral and other advanced degrees to push the boundaries of technology and to advance the frontiers of scientific knowledge to enable new technical innovations. The execution workforce (the latter above) comprises workers with a variety of educational and professional experiences, ranging from apprenticeships to training certificates to associates and bachelors degrees, who all have unique and valuable roles within the bioeconomy. The following opportunities and recommendations focus primarily on education and training in engineering biology at educational levels where EBRC is best-positioned to provide remarks; we point to publications and commentary from other organizations (including BioMADE and BioBuilder) for further guidance and recommendations.

High School level:

There is currently no coordinated federal strategy to help secondary school students understand the way engineered biology can meet society's needs, or a roadmap that shows students how they can pursue successful careers in the field. Indeed, despite decades of calls from biotechnology practitioners to modernize the way life science is taught in our public high schools, biology is not a graduation requirement in all states and fewer than 30% of public school [biology classes incorporate molecular biology](#)-related activities, foundational to most current biotechnology innovations.

It is imperative that **federal agencies advance strategic and coordinated educational initiatives** that integrate biotechnology and engineering biology education and opportunities into public education for high school students. Foremost, the federal government must articulate national and state-level goals that require the adoption of effective biotechnology curricula, spotlighting its importance for sustainability, a robust economy, and national security. The Departments of Education, Labor, and Commerce can support teacher training and umbrella organizations that advance industry-relevant pedagogy and incentivize commercial and industrial partners to work directly with schools to establish and hire candidates who can secure a meaningful profession in the bioeconomy without post-secondary schooling. The federal government can also invest in regional infrastructure and opportunities such that access to high quality learning laboratories exists in all zip codes and students are exposed to biotechnology and bioeconomy careers through creative experiences including internships, innovation competitions, and out-of-school programs.

Undergraduate level:

At the undergraduate level, the Federal agencies can support the future bioeconomy workforce by **facilitating interdisciplinary programs and curriculum** at more US colleges and universities. Large US colleges and universities often already integrate programs that can be leveraged to make strong interdisciplinary education programs; we need to make these programs more widely available and accessible. Interdisciplinary education enables the cross-training of concepts and teaches students how to apply engineering tools to biology and to incorporate social, economic, and other concepts to their understanding of science.

The US Government can expand **direct funding and access to undergraduate research opportunities**. This can include support for formal institutional programs, student and institution participation in iGEM and similar experiences, and for internships and other experiential learning opportunities. For example, agencies including NSF, NIH, DOE, and DoD can offer federal support for innovation competitions, such as iGEM, to develop the next generation of bioeconomy workers; these competitions develop skills in creativity, entrepreneurship, and communication, with occasional tangible benefits of new IP, scientific advances, and startups. The Federal government, through the Department of Education and Department of Labor, can support and offer programs for undergraduate student internships and experiential learning within industry and other sectors connected to the growing bioeconomy. Additionally, enabling more institutions, particularly those without existing or sizable research capacity, access to tools and technologies associated with engineering biology will increase equity and participation in the future bioeconomy workforce.

In addition to undergraduate education and research opportunities, post-baccalaureate programs provide a bridge to success in graduate school for students who are underprepared due to lack of research opportunities during their undergraduate education. Post-baccalaureate participants contribute to the research enterprise while gaining experience and professional development skills that improve outcomes when they enter graduate school. A new program through NSF provides supplemental funding for career investigators to support post-baccalaureate student research and may serve as a reference point for the creation of additional opportunities.

Masters level:

There is an opportunity to **expand funding for and access to professional masters degrees, particularly those that emphasize project-based learning and training**. The Federal government can provide incentives for institutions to create masters degrees that enable undergraduate students to develop skills in another discipline after their undergraduate degree (e.g., an undergraduate physics major followed by a 1-year masters degree in bioengineering with a hands-on emphasis). The US government can support schools and students by providing fellowships for professional masters degrees in engineering biology and related disciplines. One avenue for this might be to match funding provided by companies and corporations to send their current and future employees to full- or part-time programs (which would also give colleges an incentive to expand into part-time programs).

Doctorate and Postdoctoral level:

Stipends for graduate students and salaries for postdoctoral fellows are below a living wage in much of the country. State wage laws are increasingly mismatched with minimums (for example, in the state of Washington, the salary threshold below which workers are overtime eligible is above the salary of many postdocs). At many institutions, the NSF Graduate Research Fellowship (GRFP) stipend and NIH minimum funding level for postdocs (NRSA stipend) is the de facto standard for wages, which can be out of sync with

costs of living. Because of this, there is an important opportunity for the federal government to **set a minimum standard wage for graduate students and postdoctoral fellows** that is pegged to region-specific cost of living (c.f. GSA region-specific per diem rates), independent of these particular funding mechanisms. Notably, research grant award amounts, especially for junior faculty, should increase accordingly to support students and postdoctoral fellows at or above a living wage. Adequately supporting graduate student and postdoctoral researchers ensures that the U.S. academic enterprise can sustain the scientific productivity and innovation that the bioeconomy relies upon.

In addition to increases in (and standards set for) graduate student and postdoctoral fellow stipends and salaries, a **greater number of fellowship opportunities** would supplement grant support for universities and also give individual students and postdocs independent funding that gives them more flexibility and agency. Fellowship allocation allows funding institutions to influence student population composition by incentivizing certain research areas and values like racial and gender equity. However, it is also important that the government advocate (if not require) that students and postdocs have access to the same benefits that an institution's employees have, as fellowship recipients are often not considered employees of their host university and thus are not eligible for basic benefits.

Revising legacy approaches to biology education

A Policy Paper by the Engineering Biology Research Consortium

*By Natalie Kuldell, Founder and Executive Director of BioBuilder and member of EBRC; Edited by Emily R. Aurand, EBRC Director of Roadmapping and Education
December 2022*

The pace of discovery and innovation in life science is fast and getting faster. DNA sequencing technology, for example, is 10 million times cheaper than it was twenty years ago and became an indispensable tool in the global fight against COVID. Yet, approaches to teaching biology, especially in high schools, have not kept pace. Too often biology is taught as a collection of facts to be memorized rather than as a tool for solving global challenges and securing quality jobs in the future.

As a nation, we must rethink how we teach biology. To remain globally competitive and prepare our citizens for the jobs of the future, federal agencies must prioritize programs that bring a modern mindset to life science education. A pedagogical change is needed for biology to be perceived as an engineerable solution to meet persistent global challenges, and an attractive career for all. There is an important role for the federal government to improve the way educational programs are designed, the way companies manage their hiring processes, and the way current and future employees find training throughout their careers. Federal agencies should incentivize the use of existing, free, and/or low-cost resources to creatively reimagine how and where biology is taught.

Specifically, federal funding should be appropriated to:

Launch an interagency Biology Career Pathways initiative that helps connect biology learning to real-world opportunities. Coordinated by the Department of Labor, Department of Education, and the National Science Foundation, this initiative would support paid high-school internships, technical training pathways, and first jobs in the bioeconomy. Existing models that are proven and ready to scale include the [BioMADE-funded Innovation Pathway](#) and [Digital Ready](#).

Move to establish biotechnology training as a core competency. In particular, the federal government should allocate persistent funding for relevant teacher training and high-quality instructional materials at the high-school level. Existing educational resources that could be scaled nationwide include the [BioBuilder Educational Foundation](#) that provides standards-aligned problem-based curriculum and out-of-school programming. A good goal would be to introduce at least one million high school students each year to a modern mindset in life science by the year 2030.

To equitably advance our country's residents into bioeconomy opportunities,¹ funding should:

Create bioeconomy-specific certificates and credentials that are used by industry and are attainable through secondary education. This effort should be administered by the National Science Foundation, with guidance from the Department of Labor, the Department of Health and Human Services, the National Institute of Standards and Technology, and the White House Office of Science and Technology Policy. With a modest allocation of \$5 million, federal agencies could create such a credential and

¹ <https://www.dayoneproject.org/ideas/meeting-biology-s-sputnik-moment/>

develop a digital platform that connects certificate-seekers to training providers and certificate-holders to companies.

Promote regional alliances of academic, philanthropic, and business entities in rural communities and communities of color. Funding from the Department of Commerce and others could support entrepreneurship workshops and grants, subsidize construction of shared lab space for startups, or provide incentives for faculty at local academic institutions to further develop their research discoveries into pilot programs, patents, and products. Over time, flourishing regional bioeconomy hubs will enable local students to pursue technical careers close to home, wherever home may be, thereby distributing the benefits of the growing bioeconomy throughout the country.

Invest in public-private partnerships so high-quality Learning Labs are open to the public in all zip codes. More than a century ago, public-private partnerships established the nation's public library system. Thirty years ago, Bill and Melinda Gates helped democratize digital technologies by providing PCs and training in 5,800 libraries for low income communities. Today, the federal government has an opportunity to re-deploy schools, libraries, and community spaces into bioeconomy tinker-spaces and training facilities. A nationwide system of ["Lab-raries" \(or "Libra-tories"\)](#) has the potential to support regional talent growth in all 50 states, reaching all Americans—including people of color, people with disabilities, and people from economically disadvantaged backgrounds.

US Leadership in a Global Bioeconomy

A Policy Paper by the Engineering Biology Research Consortium

*Compiled and edited by Cynthia Ni, EBRC Postdoctoral Scholar, and Becky Mackelprang, EBRC Associate
Director for Security Programs
December 2022*

The emergence and growth of bioeconomies around the world is marking the beginning of a global transition to a sustainable, bio-based future built on engineering biology. In this early stage, there is an opportunity to establish international norms, standards, and regulations in the bioeconomy, as countries will look at precedents set by each other when making their own policies. The US should seize this leadership opportunity. It should develop and promote standards and regulations to simultaneously i) ensure the future of a secure domestic bioeconomy and ii) lead and steer the development of an equitable, healthy, and sustainable global bioeconomy through international coordination and cooperation. Herein, we describe four key focus areas where international best practices, norms, and/or standards are nascent or underdeveloped, and thus where there is real need and opportunity for US leadership: 1) Standards, Metrics, and Norms, 2) Regulations, 3) Biosecurity and Biosafety, and 4) Horizon Scanning. Development of these four areas have significant benefits to creating a robust bioeconomy both domestically and internationally. Leveraging action in these focus areas, the US can also demonstrate its international leadership by supporting the advancement of engineering biology in countries with less developed bioeconomic plans and infrastructure, thereby accelerating the formation of a well-integrated global bioeconomy. If the US does not provide such support, other nations likely will, and the US will cede leadership to them.

1) Ensure that US standards, metrics, and norms become de facto global standards for industry

Widely adopted standards and metrics are the foundation for commercialization, transactions, and regulations that spur innovation in a secure bioeconomy. As examples, bioindustrial products may need to meet certain purity standards. Reference genomes and naturally-occurring variants may need to be established to ensure safety and security of products (see [Genome in a bottle—a human DNA standard](#)). [Globally-recognized standards and metrics are needed](#) to enable products that are exempt from regulation in the US but not in other countries to be assessed and traded. The absence of such standards and metrics needs to be addressed the world over. If the US is able to fulfill the policy of the Biden Administration to “promote standards, establish metrics, and develop systems to grow and assess the state of the bioeconomy,” it will be well-positioned to lead efforts to establish universal standards for the global bioeconomy. Operating from shared standards would enable easier trans-national trade, thus adding value to and enhancing connections in the global bioeconomy.

In addition to technical standards, there is an opportunity to develop standards and guidelines on ethical and behavioral norms within the bioeconomy. As advancements in engineering biology blur the line between natural and synthetic biological systems, global norms could ensure ethical development and deployment of biotechnology. The US can coordinate these efforts by building off existing domestic examples, such as the [EBRC Statement of Ethics in Engineering Biology Research](#). This approach, in tandem with horizon scanning,

would strengthen the security of the bioeconomy by preempting misuses of engineering biology, rather than relying on ad hoc responses to incidents that arise.

2) Enable a global bioeconomy despite varied regulatory approaches

The US has demonstrated regulatory coordination across agencies through the [Coordinated Framework for Regulation of Biotechnology](#). [These efforts are commendable and must be continued](#) for the success of the domestic bioeconomy. In a global landscape, challenges arise due to the product-based regulatory approach of the US compared to the process-based approach used by most other nations. As a result, biotechnology products that are exempt from regulation in the US might be regulated in other countries. The US then needs to understand which types of products are regulated differently between countries, work to develop mutual recognition agreements and/or coordinate the sharing of regulatory approvals and/or dossiers, and provide information to US companies on how to approach an international stage with widely variable regulatory approaches. Any such understandings or arrangements will necessarily be informed by commonly defined and accepted standards and metrics. The USDA Foreign Agricultural Service plays an important role in linking the US agricultural system to the rest of the world. An interagency working group with counterparts at EPA and FDA may be useful as the more and different engineered products become ready to potentially enter global markets, and global coordination with regulatory bodies outside the US a necessity. This approach will strengthen the US bioeconomy and better enable bio-based products to be used for a more sustainable future.

3) Maintain global leadership for biosecurity and biosafety standards

As the bioeconomy advances on a global scale, it would be prudent to coordinate efforts to address biosecurity and biosafety. New research breakthroughs can not only be used to develop exciting new bio-based products, but also to inadvertently or deliberately create products or tools that could be used in ways that harm people, animals, plants, or the planet. The US can work with international partners to establish and share frameworks for risk assessment at all stages of the research, development, and commercialization lifecycle. In so doing, the US should recognize the importance of considering both the biosafety risks and the biosecurity risks associated with developing technologies, and seek to provide international leadership for each.

To demonstrate global biosafety leadership, the US could foster international recognition and agreements around safety standards for high-containment laboratories; partner to develop shared standards for recognizing the safety of engineered enzymes or products in food, cosmetics, or other consumer products; and pursue and share advanced approaches to biocontainment to preserve environmental integrity. Such activities would ensure that the deployment and consumption of technologies within the bioeconomy are safe for users and the environment.

To demonstrate global biosecurity leadership, the US should promulgate currently-developed best practices and guidance, such as the existing [guidance for providers of synthetic DNA](#). The US government should [fund innovative, collaborative international research to develop tools that reduce biosecurity risk](#). The US should also continue to identify [the vulnerabilities of our domestic bioeconomy](#) and, as appropriate, exchange information about these vulnerabilities with allies, working together to reduce risk and promote stability across the global bioeconomy. Crucially, in the face of real security concerns, the US must maintain focus on the benefits of an interconnected, collaborative global bioeconomy and avoid measures that lock down information or technologies.

4) Ensure that horizon scanning activities under the EO are global and widely shared

The US should undertake horizon scanning activities both internally and with international partners to better position itself to anticipate both the positive outcomes and negative consequences that could stem from biotechnology developments. The importance of horizon scanning for new developments in biotechnology has been recognized by countries such as [Australia](#) and by Parties to the Convention on Biological Diversity. Global issues, such as the impact of the bioeconomy on climate and the environment, require the perspectives inherent in multilateral collaboration. Global horizon scanning for engineering biology capabilities and for the applications of those capabilities would enable the US to identify areas for technical and/or [regulatory partnership](#) and break down international silos. [Horizon scanning also enables biosafety and biosecurity preparedness](#), enabling preparation for coming dual use technologies and informing US funding decisions for research that minimizes or mitigates potential negative consequences (e.g., research on biocontainment).

Currently, the US has a few mechanisms for horizon scanning. EBRC produces [technical research roadmaps](#) that identify technical innovations and their applications that may be attainable over the short-, medium-, and long-term. The roadmaps have a US focus but are intended for global use. Products on the horizon, but drawing closer as companies actively work on them, are tracked by [Future Bioengineered Products](#). The existence of these roadmaps and resources demonstrates horizon-scanning capabilities amongst US biotechnology stakeholders that could be leveraged on a global stage; international horizon scanning activities would enable people and the planet to reap the benefits of biological advancements while mitigating associated negative outcomes.