# Building Strong Biosafety and Biosecurity into the Expanding US Bioeconomy

Meeting report on a 10 January 2023 public-private roundtable organized by the Johns Hopkins Center for Health Security

February 28, 2023

JOHNS HOPKINS
BLOOMBERG SCHOOL
*of* PUBLIC HEALTH

Center for Health Security

## Johns Hopkins Center for Health Security Project Team

Aurelia Attal-Juncqua, MSc
Fellow, Johns Hopkins Center for Health Security

Thomas V. Inglesby, MD
Director, Johns Hopkins Center for Health Security

Matthew E. Walsh
PhD Student, Johns Hopkins Bloomberg School of Public Health

Gigi Kwik Gronvall, PhD
Senior Scholar, Johns Hopkins Center for Health Security

## Acknowledgements

We would like to express our gratitude to all the participants in the meeting. The authors would like to thank Alyson Browett, Julia Cizek, Cagla Giray, and Prarthana Vasudevan for their editing, design, and publication support; and Andrea Lapp and Rachael Brown for organization and logistics support of the meeting.

The views expressed in this publication and/or made by meeting attendees do not necessarily reflect the official views of the US Government or the Johns Hopkins Center for Health Security.

Suggested citation: Attal-Juncqua A, Inglesby TV, Walsh ME, Gronvall GK. Roundtable on the Biosafety and Biosecurity Aspects of the Bioeconomy. Baltimore, MD: Johns Hopkins Center for Health Security; 2023.

# Contents

## Summary

On January 10, 2023, the Johns Hopkins Center for Health Security at the Bloomberg School of Public Health convened an in-person, not-for-attribution meeting of experts and practitioners from government, academia, and the private sector to discuss the US Biosafety & Biosecurity Innovation Initiative launched as part of a September 2022 Executive Order titled, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy." The meeting focused on priority actions and efforts needed to enhance biosafety and biosecurity throughout the biotechnology research and development (R&D) and biomanufacturing lifecycles, while maximizing potential societal benefits, as well as safeguarding and boosting US national competitiveness. This report describes discussion on these topics undertaken by the experts who attended the meeting.

## Introduction

On September 12, 2022, President Joe Biden issued Executive Order (EO) 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," which launched a National Biotechnology and Biomanufacturing Initiative involving a "whole-of-government approach to advance biotechnology and biomanufacturing towards innovative solutions in health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security."[1] The bioeconomy previously has been defined as any "economic activity that is driven by research and innovation in the life sciences and biotechnology, and that is enabled by technological advances in engineering and in computing and information sciences."[2]

EO 14081 also launched the new Biosafety and Biosecurity Innovation Initiative, which requires agencies funding, conducting, or sponsoring life sciences research to "prioritize investments in applied biosafety research and innovations in biosecurity to reduce biological risk during the biotechnology R&D and biomanufacturing lifecycles, as well as incentivize and improve biosafety and biosecurity best practices." As part of the Biosafety and Biosecurity Innovation Initiative, the Secretary of the Department of Health & Human Services (HHS) and the Secretary of the Department of Homeland Security (DHS), in coordination with agencies that fund, conduct, or sponsor life sciences research, must produce an implementation plan for biosafety and biosecurity for the bioeconomy within 180 days of the EO's issuance. In December 2022, the White House issued a public Request For Information (RFI) pertaining to the broader EO that included specific questions on how to reduce risks to the bioeconomy by advancing biosafety and biosecurity.[3]

On January 10, 2023, the Johns Hopkins Center for Health Security convened an in-person, not-for-attribution meeting to discuss the Biosafety and Biosecurity Innovation Initiative. The meeting focused on priority actions and efforts needed to enhance biosafety and biosecurity throughout the biotechnology R&D and biomanufacturing

lifecycles, while maximizing potential societal benefits as well as safeguarding and boosting US national competitiveness. The purpose of the meeting was to respond to many critical questions posed by the RFI and to provide the National Institutes of Health (NIH), the National Security Council (NSC), the Office of Science and Technology (OSTP), and other US government (USG) stakeholders an opportunity to obtain information and viewpoints from subject matter experts on the development of the Biosafety and Biosecurity Innovation Initiative implementation plan.

The meeting also was an opportunity for USG stakeholders to describe the context and scope of the Biosafety and Biosecurity Innovation Initiative. During discussions in the morning session, experts shared their insights on several questions pertaining to supporting applied biosafety research, incentivizing biosafety practices, and supporting biosecurity innovation, while afternoon discussions focused on assessing and mitigating other potential threats to the bioeconomy, as well as future bioeconomy planning.

The meeting featured participation from members of government, academia, and industry, including subject matter experts from a range of disciplines and sectors: biosafety, biosecurity, biodefense, biotechnology, synthetic biology, global health, and public health. A non-exhaustive list of meeting participants is included in Appendix A. The Johns Hopkins Center for Health Security did not attempt to reach expert consensus on the topics discussed. This document is a synthesis of insights presented by one or more experts during the meeting.

## Context and Scope of the Biosafety and Biosecurity Innovation Initiative

### The Biosafety and Biosecurity Innovation Initiative

USG representatives opened the meeting by framing the Biosafety and Biosecurity Innovation Initiative within current national bioeconomy policy and goals. The White House, through EO 14081, aims to drive federal investments that will define US biotechnology leadership, realize the promise of biology in transforming the US economy, and help tackle major societal challenges such as climate change, energy security, food security, future pandemics, and supply chain resiliency. USG stakeholders outlined how current efforts to expand the US bioeconomy are critical to safeguarding US leadership, economic competitiveness, and national security, and how these efforts are coming at a defining inflection point in the industry's trajectory. While currently valued at US$1 trillion dollars, the US bioeconomy is predicted to grow globally to more than US$30 trillion dollars over the next 20 years.[4] The new National Biotechnology and Biomanufacturing Initiative—along with legislative actions such as the recent CHIPS and Science Act of 2022—will help the US attain its goal of revolutionizing the manufacturing industry to advance biotechnology.[5]

Rapid advances in the fields of biotechnology and biomanufacturing bring new risks, as new advances challenge the regulatory and biosafety frameworks designed for earlier biotechnology products. USG stakeholders emphasized the importance of ensuring that new technologies be developed in tandem with new advances in biosecurity and biosafety to both ensure the safety and security of specific products and to safeguard public trust in the bioeconomy if a safety or security incident were to occur.

USG participants described the Biosafety and Biosecurity Innovation Initiative as a whole-of-government endeavor aimed at better understanding risks and vulnerabilities and helping to establish national norms and standards for biosafety and biosecurity, as well as promoting those norms at the international level. Coordinated by the NIH, the Biosafety and Biosecurity Innovation Initiative will focus comprehensively on the bioeconomy sector, including innovations in the fields of medicine, energy, environment, material sciences, and agriculture. Ultimately, the aim of the Biosafety and Biosecurity Innovation Initiative is to build upon existing biosafety and security systems, while identifying ways to further incentivize best practices in biotechnology and biomanufacturing domestically and internationally. USG stakeholders explained that the development of an implementation plan, as prescribed in the EO, is a critical next step in launching the Biosafety and Biosecurity Innovation Initiative.

## Defining Biosafety and Biosecurity

Meeting participants underscored the importance of defining biosecurity and biosafety in the context of the bioeconomy. One expert noted that the National Institute of Standards and Technology (NIST) published a bioeconomy lexicon that defines biosafety as "practices, controls, and containment infrastructure that reduce the risk of unintentional exposure to, contamination with, release of, or harm from pathogens, toxins, and biological materials," and biosecurity as "security measures designed to prevent the loss, theft, misuse, diversion, unauthorized possession or material introduction, or intentional release of pathogens, toxins, biological materials, and related information and/or technology."[6] There was general agreement among participants that these definitions need to be expanded to fully capture the breadth of risks associated with rapid advances in biotechnology R&D.

Applied biosafety research has focused on pathogens and laboratory containment techniques; however, participants recognized that the definition must be explicitly expanded to include environmental biosafety, such as upstream controls like DNA watermarking. Similarly, participants noted that biotech advances are occurring rapidly, with some companies and research teams already creating whole new organisms. They agreed it is critical to ensure that stakeholders think about biosecurity broadly, considering not only the context of dual use research in which the methodologies, materials, or results could be used to cause harm but all potential adversarial action intended to create harm using biological systems or data.

## Supporting Applied Biosafety Research and Incentivizing and Enhancing Biosafety Practices

Supporting applied biosafety research and developing and maintaining strong biosafety systems to reduce risks while maximizing societal benefits throughout the biotechnology and biomanufacturing lifecycle should be a strategic interest of the United States. Discussions during this session focused on identifying actions and priority investments for the US government to strengthen its support of applied biosafety research and to further incentivize and enhance biosafety practices at home and abroad. Participants were asked to discuss what role the US government should play in advancing biosafety practices, oversight, and coordination, beyond federally funded research. Experts were also asked to examine how industry and academia might best participate in this work and how other nations are investing in biosafety-related efforts.

### Funding for Applied Biosafety Research

Participants generally agreed that federal funding should be made available for applied biosafety research, both in the laboratory setting as well as in the development of biomanufacturing and biotechnology products. Several experts noted that federal funding mechanisms are not usually available for biosafety studies, in contrast to other occupational health risks, and without dedicated research studies and the systematic collection of data, determining principles for biosafety can rely too much on anecdote and past experiences, which do not necessarily take into consideration the development of new technologies. As the biotechnology products of the future pose new potential safety and security risks, research into how to characterize and mitigate concerns while allowing technology development to proceed requires dedicated funding.

There was general agreement that studies identifying opportunities for biosafety research regarding novel products should characterize the capital cost and ease of adoption of biosafety investments, including those that can be undertaken by nontraditional, noninstitutional actors, such as do-it-yourself (DIY) labs and small start-ups. For example, automation, like most biosafety investments, requires significant upfront financing; cost-benefit analyses that could justify these investments depend on biosafety data from analysis and study. Some participants suggested that the US government should fund research to better understand where, when, and how accidents happen to delineate the processes that would benefit from automation or other biosafety-enhancing practices.

Several experts highlighted this lack of data pertaining to biosafety incidents as a clear barrier toward the broader integration of biosafety practices in biotech and biomanufacturing processes. One participant suggested greater adoption of anonymous reporting systems to increase incident reporting rates by lowering the barriers that may be linked to fears of punitive cultures—admitting a mistake or being seen as incompetent—disclosure, litigation, or other legal concerns. Other participants noted these anonymous systems have been under consideration for many years,

but significant barriers to and concerns surrounding implementation and usage persist. Some experts posited that the US government should work with industry and academia to identify new ways of gathering biosafety data, including funding students to undertake graduate-level research comparing laboratory practices as a part of their degree program. Another participant suggested that the US Department of Commerce could use its legal authority to mandate that companies respond to biosafety incident surveys, under penalty of law, as one way to gather additional and systematic biosafety data.

Participants also noted that research into biosafety practices should incorporate behavioral, social, and organizational sciences studies that look at how to create and promote a biosafety culture across the life sciences industry. This was considered especially important by participants in the context of increasingly democratized access to biotechnology and growing biotechnological social movements, such as DIY biology or other individual- or community-led biotechnological work. Experts agreed that it is critical to ensure the inclusion of this broader network of biotech actors in efforts to expand biosafety practices to further mitigate the possible ripple effect a single incident in a limited DIY context may have on the entire biotech ecosystem—for example, an accident in that setting may prompt regulatory action that does not meaningfully improve biosafety but may negatively impact the US bioeconomy.

## Financial Incentives and Support

With the US government striving to increase investments in biotechnology and biomanufacturing, there was consensus among participants that it is increasingly critical for grant recipients to keep biosafety top of mind. Some experts suggested that federal agencies that fund or sponsor life science research could enhance biosafety and biosecurity practices by incorporating and requiring documentation of biosafety and biosecurity steps in research reporting for federal funding. Another expert noted that, as was done with the Human Genome Project, a specific percentage of federal funding could be dedicated for other important research goals, in this case biosafety, biosecurity, sustainability, and responsible conduct of research.

Another meeting participant suggested insurance companies could begin applying financial incentives to biosafety risk mitigation. Insurance industry assessment of biological risks could motivate both public and private sector stakeholders to develop and implement safety protocols in order to reduce their insurance premiums. There was general agreement, however, that the dearth of data on biosafety-related incidents and applied biosafety research was a hurdle to insurance companies in this field.

Finally, some meeting attendees noted that the upfront cost associated with both biosafety risk pattern identification research and biosafety infrastructure (eg, automation) may be financially punitive or unaffordable for many research laboratories, start-ups, and smaller private labs. One participant suggested that USG investments or grants could help industry bridge these financial gaps to help expand biosafety research and infrastructure on the scale necessary to render safer advances in the US bioeconomy.

### Risk Identification and Risk Assessment Frameworks

Some participants said USG regulators and partners should prioritize the development of biosafety and biosecurity risk assessment frameworks as they are developing bioeconomy R&D efforts. The pace at which biotechnology and biomanufacturing are evolving requires nimble risk assessment frameworks that can be adapted to entirely new classes of bioproducts and that can assess risks to humans, animals, and the environment. Meeting participants agreed that in the context of an expanding bioeconomy, the US must move away from a pathogen-based risk definition and toward contextual risk assessments that include the potential scale and impact (eg, environmental or laboratory spill, etc.). One participant stated that these new risk assessments should consider the capacities needed for implementation and how to tailor them to different needs and environments, if they are to become economically and culturally viable international standards.

### Biosafety Workforce Investments

Most participants agreed there is very little investment in the development of a biosafety-specific workforce. One expert emphasized that there are no graduate programs focused on biosafety research and practice and, to this day, biosafety has been more anecdotal with no sustained funding to fully develop biosafety as a viable professional field.[7]

There was general agreement that the US government should prioritize investments needed to kickstart the development of a well-trained and diverse domestic biosafety workforce. Some experts suggested the US government should consider investing in and/or providing tax credit incentives to help bring industry and learning institutions together to increase the number of biosafety professionals through the support of certification programs, degrees, graduate research grants, competitions (eg, iGEM or similar), and/or other training curricula in a variety of educational settings (eg, community colleges, Historically Black Colleges and Universities, Tribal Colleges and Universities, Hispanic Serving Institutions, 4-year institutions, and others).

Another participant noted that major investments in the field of synthetic biology have been made—fostering a growing new generation of leaders—and suggested that these efforts be captured and analyzed to inform playbooks that could be applied to supporting the development of a broader biosafety and biosecurity workforce.

## Supporting Biosecurity Innovation

Accelerating the identification, development, and implementation of innovative technologies and approaches that enhance the capacity of the national biosecurity system to manage biosecurity risks is critical to safeguard and boost US national security and competitiveness. Discussions during this session focused on identifying actions and priority investments the US government could make to strengthen its support of biosecurity innovation. Participants were also asked to explore how the

US government could enhance its collaboration with industry, universities, and other research entities and consider how other nations might be investing in this space.

## Risk Prioritization

Some experts noted that USG stakeholders could take an active role in defining both the type and scale of harms that are seen as most concerning by developing a biosecurity risks priorities list (eg, uncontrolled spread of biological agent in humans, animals, or the environment versus localized and contained incident; population level genetic data theft versus individual data theft). Such a list could help set priorities for current biosecurity innovation efforts.

## Risk Characterization and Quantification

There was general agreement among participants that certain innovative technologies under development—such as technologies that can be embedded in bio-enabled products, like kill switches or genetic controls—are engineering solutions for problems that are not yet characterized. Biotech and biomanufacturing applications are increasingly moving out of traditional laboratory settings, and several experts suggested the US government fund studies to measure the impact of these new bio-enabled products on individuals and the environment. Some experts suggested the US government partner with the private sector and academia to invest in infrastructure needed for environmental monitoring and surveillance systems to characterize "normal" background environments and pick up specific genetic signals. Such systems could help to determine how newly engineered biological products or organisms behave and interact with their environments. One expert stated that US policymakers should outline plans and timescales over which these monitoring systems ought to be built and streamline ways to set up the aggregation of reporting and surveillance data nationwide.

There are logistical and technical challenges to building such broad-ranging monitoring systems without fully knowing the type of signal to screen for, and past lessons should be identified and studied (eg, from wastewater surveillance systems). One expert suggested that policymakers use tabletop or simulation exercises to outline the steps to take if a concerning signal is identified during a surveillance activity and determine preparedness and response investments needed to mitigate new biosecurity risks.

## National Security Intelligence

The US Intelligence Community has deep experience analyzing and profiling potential malevolent actors and threats to the US and its economy. Some experts suggested USG stakeholders responsible for identifying biosecurity threats work to ensure they are utilizing this expertise to help outline possible malevolent actors who could threaten the bioeconomy and identify their capabilities. In addition, the US government can partner with academia to fund research programs that study national security threats to the bioeconomy. These types of investment would help safeguard US competitiveness and protect national security.

### Bioattribution Technology

Some participants singled out bioattribution—the ability to accurately determine who is responsible for a biological incident—as a critical biosecurity hurdle. Attribution could ensure that those responsible for actions that may cause harm are held accountable and deter future threats, including actions that harm the competitiveness of US life sciences programs within the government, private sector, or academia. Attribution depends on multiple tools and methods, which may include the use of leading scientific techniques and access to data sets, public health information, and law enforcement tools and approaches.

Tools to detect evidence of bioengineering are already under development, such as in the Intelligence Advanced Research Projects Activity (IARPA) Finding Engineering-Linked Indicators project, FELIX, which seeks to use experimental and computational tools to augment biodetection and biosurveillance capabilities.[8] Most experts agreed that the US government should play a more active role in expanding attribution-related programs like these.

### Mitigating Risks Associated with Biological Data and Intellectual Property Theft

Some participants recommended that the US government collaborate with private sector stakeholders to better understand the risks associated with the theft of biological data or intellectual property (IP) to industry, the environment, or the public, and to identify what role the government should play in mitigating such risks. IP theft and other cybersecurity concerns are critical risks to industry, but young companies and start-ups often lack the funds to build protective cybersecurity infrastructure. Federal agencies could partner with US-based companies to help protect materials, methods, algorithms, code base, and other trade secrets behind transformative modern biology.

## Assessing, Anticipating, and Mitigating Threats, Risks, and Potential Vulnerabilities to the US Bioeconomy

Safeguarding the US bioeconomy is critical to protecting US economic competitiveness and national security. In this session, discussions focused on how to anticipate and mitigate foreign adversaries and strategic competitors that use legal and illegal means to acquire US technologies and data, including biological data. Participants were asked to examine threats and risks to the US bioeconomy and explore approaches the US government should take to proactively assess, anticipate, and mitigate these potential vulnerabilities. Experts were also asked to consider how to leverage stakeholder capabilities during their discussion.

### Balancing Global Partnerships and US Economic Competitiveness

According to the White House, "global industry is on the cusp of an industrial revolution powered by biotechnology … and other countries are positioning themselves

to become the world's resource for biotechnology solutions and product."[9] Many other countries are investing in their bioeconomy—such as Singapore, Taiwan, South Korea, and Malaysia—and pouring significant effort and funding into new biotech and biomanufacturing programs. Certain biotechnologies have advanced rapidly in sub-Saharan Africa (eg, mRNA platforms, sequencing technologies), though in some cases these technologies come with service contracts that require the use of Chinese infrastructure. Some participants noted that the US government use its "soft biological power" and offer its expertise and support to countries that are in the process of developing systems and infrastructure to support their bioeconomies.

Several experts noted that USG stakeholders should continue to engage internationally and recognize the important issues of equitable access to technologies, equipment, and genetic materials. Some participants suggested the US and its nongovernmental partners collaborate on ways to strengthen international engagement mechanisms and bolster scientific and diplomatic relationships through international sample-sharing programs, scientific and academic exchanges, and other Track 2 diplomacy efforts. As part of furthering international engagement, one participant proposed that the US should reassess its stance pertaining to the Convention on Biological Diversity and the associated Nagoya Protocol, which provides a framework that helps researchers access genetic resources for biotechnology research, development, and other activities, in return for a fair share of any benefits from their use.

In addition, there was general agreement that the US should work toward international biosafety and biosecurity norms and federal agencies should enhance international collaboration on issues related to biotechnology, biomanufacturing, safety, and security. Specifically, most attendees recommended that USG stakeholders identify and collaborate with international leaders in biosafety and biosecurity and leverage these partnerships to create and disseminate shared international norms, reinforce unified messages countering mis/disinformation that threaten the industry, and protect the bioeconomy at home and abroad. Finding, recognizing, and crediting like-minded champions around the world was considered critical in the long term to foster and elevate emerging leaders, integrate and protect supply chains with allies, and ultimately develop a shared understanding of what it means to be a responsible actor in biotechnology and biomanufacturing.

## Protecting and Expanding Domestic Biomanufacturing Supply Chain and Infrastructure

Participants discussed how building up domestic biomanufacturing infrastructure could mitigate risks associated with supply chain vulnerabilities and the loss of critical or promising IP. One expert noted that the White House recently issued an executive order (EO 14083) elaborating on key US industries requiring heightened regulatory scrutiny from the Committee on Foreign Investment in the United States (CFIUS). Specifically, the EO issues guidance to CFIUS so that its review of international investments and acquisitions continues to be adaptable and responsive to new national

security demands.[10] Some participants suggested that CFIUS and other government stakeholders partner with industry to review biotech and biomanufacturing supply chain vulnerabilities and identify weak nodes that could be targeted by foreign adversaries.

Availability and affordability of feedstock, rare earth minerals, and active pharmaceutical ingredients were identified during the meeting as significant weak points in the present US biomanufacturing infrastructure. Several participants also noted that the US government should fund systematic studies across the entire biomanufacturing landscape to identify the critical bioreachable ingredients (ie, critical ingredients that can be made with biological processes) necessary to maintain functioning and resilient biotech supply chains and protect the US bioeconomy. There was general agreement that the US biomanufacturing complex must be able to manufacture biological products domestically and at commodity scale to remain competitive. Fragilities in the bio-based supply chain put companies and their assets at risk and ultimately threaten the US bioeconomy. Some experts recommended that federal agencies continue to fund and champion governmental initiatives, such as the Bioindustrial Manufacturing and Design Ecosystem (BioMADE), to fill that investment gap. Most participants agreed that, at this inflection point for the US bioeconomy, the US government should be more intentional with its industrial policy and how it prioritizes biotech and biomanufacturing. Importantly, experts noted that the US should avoid past mistakes, such as those made with semiconductors, and limit overreliance on foreign production for its critical industrial needs.

Other experts noted that, from a national security perspective, IP and academic brain trust loss via the acquisition of smaller start-ups by foreign companies or adversaries is also a major risk and vulnerability to the US bioeconomy. They suggested the White House consider issuing an additional EO with guidance to CFIUS that specifically focuses on the biotech and biomanufacturing industry and calls for the analysis and aggregation of data pertaining to these acquisitions to better understand and predict those that will pose a risk, what risks might be acceptable, and which technologies ought to be protected from a national security and competitiveness standpoint.

## Mitigating Adversarial Information Campaigns

Several meeting attendees acknowledged the security and economic risks associated with adversarial information campaigns that may sour public sentiment and threaten the overall promise of the bioeconomy. Some experts recommended that federal agencies fund additional research to better understand how to identify and combat viral information campaigns and how these impact the industry, for example by stifling investments and market opportunities for new biological products.

One participant suggested that the US government also fund studies aimed at better understanding the post-pandemic public's perceptions of scientists and healthcare professionals to tease out some lessons learned. This type of research could help document how public sentiment and government leaders align, or not, with science,

scientists, and the prospect of new biotechnology, and how negative perceptions might be used by US adversaries.

## Future Bioeconomy Planning

Discussions during the final session focused on identifying important issues not raised by the RFI but that USG stakeholders should consider as priority investments or actions in bioeconomy planning policy. Participants were also asked to identify current strengths and weaknesses of the US bioeconomy, and what policy, regulatory, and/or legislative instruments might need to be used to address challenges and gaps over the next decade.

### Data and Biobanks

Domestic biobanking capacity was identified as a key weakness of the US bioeconomy. Indeed, several participants noted that other countries were quickly outpacing the US with their investments in biobanking infrastructure for human, animal, plant, and microbial biological material. They suggested the US government increase investment aimed at enabling US-based storage of such materials, including genetic information. The evolution of diverse, comprehensive biobanks, and the associated sharing capabilities, could revolutionize biotech and biological research and enable the US to become the go-to public resource for reference genomes for the global bioeconomy.

### Public-Private Partnerships

There was general agreement among participants that the US's long history of effective public-private partnerships (PPPs) is a key strength of the US bioeconomy. Some experts suggested that lessons learned from previous PPPs be captured in order to identify how such partnerships help accelerate certain USG goals. Other participants noted that USG agencies should explore and expand new opportunities for biotech- or biomanufacturing-related PPPs, especially for projects pertaining to biosafety and biosecurity innovation and building more resilient biological supply chains. Existing programs and partnership that were singled out by experts as examples included:

- BioMADE: Department of Defense (DoD)–funded nonprofit created by the Engineering Biology Research Consortium (ERBC) to enable collaboration through memberships with non-USG partners to accelerate the DoD's biotechnology modernization goals via a new Manufacturing Innovation Institute (MII).
- Traveler Genomic Surveillance program (TGS): A partnership among the Centers for Disease Control and Prevention (CDC) and the companies Gingko BioWorks and XpresCheck that works to fill gaps in disease surveillance by testing travelers and airplane wastewater to detect SARS-CoV-2 variants. The program is unique in that the CDC is not merely subcontracting certain aspects of its work but truly partnering with the companies on day-to-day challenges, allowing for more flexible and fluid responses to real-time needs.

Several participants noted that while the US government may want to engage in PPPs to leverage private sector capabilities and speed up certain USG goals, this type of partnership can be hindered and slowed down by lengthy and bureaucratic government contracting processes. Other experts identified cost-sharing as another potential barrier to PPPs, specifically for smaller biotech start-ups that make up a significant portion of the bioeconomy.

## Academic Partnerships and Collaboration

Most participants agreed that the US bioeconomy is strong now because of decades of academic investments but that it risks falling behind other countries in terms of investment rates, a potential hurdle to continuing its growth at a similar historical pace. Several participants recommended USG agencies further boost their current investments and partnerships with universities and other academic centers.

Other experts suggested federal agencies also work to identify and outline capabilities available within the US academic network and find ways to effectively leverage such experience to achieve US bioeconomy and biomanufacturing goals. One participant noted that in the early days of the COVID-19 pandemic, the US experienced severe testing and diagnostic challenges and bottlenecks. By concentrating testing responsibility to a single national laboratory, the US government ignored academia's wealth of know-how. Universities throughout the US had diagnostics capabilities and assays, often developed with federal funding, that remained untapped until later in the crisis but that could have been used to more rapidly expand domestic testing capacity. Some experts agreed that US agencies responsible for funding academic research partners should identify ways to better maintain their networks of resources, experts, and university partnerships after grants conclude in order to facilitate and speed-up collaborations in times of necessity or crisis.

## Making MCM Programs More Sustainable

USG-funded medical countermeasure (MCM) research and development programs often suffer from sustainability challenges post-crisis. One participant suggested the government should act as a dependable market maker to ensure the continuity and maintenance of critical MCM infrastructure and research (eg, mRNA technology platforms and manufacturing capacities).

## Bioeconomy Coordinating Body

Several participants noted the challenges USG stakeholders face engaging on biosecurity issues with various agencies within the federal government, as they all have different cultures, missions, and incentives. One expert suggested that stakeholders create a single coordinating body across the government to streamline USG policy, lexicon, and overarching goals, which also could serve as an information resource to interested parties. This coordinating body could be used to improve external communication and provide transparency to non-USG stakeholders in the private sector and academia.

### Prioritization of Biosecurity and Biosafety in Federal Budgets

Participants generally agreed that biosafety and biosecurity historically have not been prioritized in government funding, both during legislative appropriations and within the Office of Management and Budget (OMB) processes. To help identify clear short- and long-term budget needs, a participant recommended USG stakeholders publicly define their biosecurity and biosafety goals for the next decade and outline key milestones and incremental steps necessary to achieve those goals. Examples included developing biosafety research and implementation plans for new biotechnologies that are meant to be used outside the laboratory; growing a biosafety workforce that can meet the demands of future biotechnologies; or preventing the theft of biological IP or life sciences infrastructure with negative consequences to the US bioeconomy.

Similarly, another participant suggested that USG officials and their partners come together to define the desired overarching goals for the entire US bioeconomy and create a matching priority list of biosafety and biosecurity harms that must be avoided or mitigated. The publication of these two lists as interconnected entities would elevate biosafety and biosecurity concerns in discussions with federal budget and appropriations administrators.

### Regulatory Landscape

Several participants noted that overreactive or inflexible regulatory measures may threaten the growth of the bioeconomy as well as US leadership and competitiveness in the field over the long term. To mitigate those risks, some experts suggested that USG stakeholders work closely with industry to build a deeper rapport, knowledge, and understanding of the products and technologies under development.

## Conclusion

This meeting was held by the Johns Hopkins Center for Health Security to solicit expert insights, summarized in this document, to inform the development of the USG-led Biosafety and Biosecurity Innovation Initiative implementation plan. The Initiative is an important step toward modernizing, streamlining, and strengthening the US biosafety and biosecurity policy apparatus at home and abroad. These efforts aim to enhance biosafety and biosecurity throughout the biotechnology R&D and biomanufacturing lifecycles, while maximizing potential societal benefits, as well as safeguarding and boosting US national competitiveness. Implementation of the recommendations of experts herein would realize meaningful reductions to the evolving biosafety and biosecurity risks in the context of rapidly advancing R&D.

## References


1. Executive Office of the President. Executive Order 14081 of September 12, 2022: Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy. *Federal Register*. Published September 15, 2022. Accessed January 31, 2023. https://www.federalregister.gov/d/2022-20167
2. National Academies of Sciences, Engineering, and Medicine. Safeguarding the Bioeconomy. Washington, DC: The National Academies Press; 2020. Accessed January 31, 2023. https://doi.org/10.17226/25525
3. Office of Science and Technology Policy. Request for Information; National Biotechnology and Biomanufacturing Initiative. *Federal Register*. Published December 20, 2022. Accessed January 31, 2023. https://www.federalregister.gov/d/2022-27600
4. Hodgson A, Alper J, Maxon ME. The US Bioeconomy: Charting a Course for a Resilient and Competitive Future. New York, New York: Schmidt Futures; 2022. Accessed January 31, 2023. https://doi.org/10.55879/d2hrs7zwc
5. The White House. FACT SHEET: CHIPS and Science Act Will Lower Costs, Create Jobs, Strengthen Supply Chains, and Counter China. Published August 9, 2022. Accessed January 31, 2023. https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/09/fact-sheet-chips-and-science-act-will-lower-costs-create-jobs-strengthen-supply-chains-and-counter-china/
6. National Institute of Standards and Technology. NIST Bioeconomy Lexicon. Updated December 9, 2022. Accessed January 31, 2023. https://www.nist.gov/bioscience/nist-bioeconomy-lexicon
7. Gronvall GK. A Biosafety Agenda to Spur Biotechnology Development and Prevent Accidents. *Health Secur*. February 1, 2017. doi:10.1089/hs.2016.0095
8. Intelligence Advanced Research Projects Activity. FELIX: Finding Engineering-Linked Indicators. Updated November 1, 2022. Accessed January 31, 2023. https://www.iarpa.gov/research-programs/felix
9. The White House. FACT SHEET: President Biden to Launch a National Biotechnology and Biomanufacturing Initiative. Published September 12, 2022. Accessed January 31, 2023. https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/12/fact-sheet-president-biden-to-launch-a-national-biotechnology-and-biomanufacturing-initiative/
10. Executive Office of the President. Executive Order 14083 of September 15, 2022: Ensuring Robust Consideration of Evolving National Security Risks by the Committee on Foreign Investment in the United States. *Federal Register*. Published September 10, 2022. Accessed January 31, 2023. https://www.federalregister.gov/d/2022-20450

## Appendix A: Participant List

**Adejare (Jay) Atanda, DMD, DrPH, MPH**
Policy Advisor and AAAS STPF Fellow
Strategy, Plans, and Policy (SPP) Directorate (CW-5)
Countering Weapons of Mass Destruction
US Department of Homeland Security
Adejare.Atanda@hq.dhs.gov

**Aurelia Attal-Juncqua, MSc**
Fellow
Johns Hopkins Center for Health Security
aattalj1@jhu.edu

**Andrew Bremer, PhD**
Program Officer
National Academies of Sciences, Engineering, and Medicine
abremer@nas.edu

**Michael Callahan, MD, DTM&H(UK), MSPH**
Director, Clinical Translation
Vaccine & Immunotherapy Center
Massachusetts General Hospital
MVCALLAHAN@mgh.harvard.edu

**Kitty Cardwell, PhD**
Professor
Institute of Biosecurity and Microbial Forensics, Oklahoma State University
kitty.cardwell@okstate.edu

**Genevieve Croft, PhD**
Program Scientist
Schmidt Futures
gcroft@schmidtfutures.com

**Ryan Donohue, PhD**
Health Science Policy Analyst
NIH
ryan.donohue@nih.gov

**Gerald Epstein, PhD**
Distinguished Fellow
National Defense University
gerald.l.epstein.civ@ndu.edu

**Amer Fayad, PhD**
National Program Leader
National Institute of Food and Agriculture
US Department of Agriculture
amer.fayad@usda.gov

**Amanda Field, PhD**
Health Science Policy Analyst
NIH
amanda.field@nih.gov

**Julie Fischer, PhD**
Technical Director for Global Health
CRDF Global
jfischer@crdfglobal.org

**Robert W. Fisher, PhD**
Senior Advisor for CBRN and Pandemic Influenza
Office of Counterterrorism and Emerging Threats (OCET)
Office of the Chief Scientist, Office of the Commissioner
US Food and Drug Administration
robert.fisher@fda.hhs.gov

**Katie Gibson, PhD**
Senior Biotechnology Advisor
Office of the Undersecretary of Defense (Research & Engineering)
kathleen.m.gibson4.ctr@mail.mil

**Gigi Gronvall, PhD**
Senior Scholar
Johns Hopkins Center for Health Security
ggronvall@jhu.edu

**Alessandra Holland**
International Trade Administration
alessandra.holland@trade.gov

**Lloyd P. Hough, PhD, PMP**
Lead, Hazard Awareness & Characterization Technology Center
DHS/S&T/OSE/TCD
Lloyd.Hough@hq.dhs.gov

**Michael Imperiale, PhD**
Arthur F. Thurnau Professor
University of Michigan
imperial@umich.edu

**Thomas V. Inglesby, MD**
Director
Johns Hopkins Center for Health Security
tinglesby@jhu.edu

**Mark Kazmierczak, PhD**
Director, Biosafety, Biosecurity & Emerging Technologies
Gryphon Scientific
mkazmierczak@gryphonscientific.com

**Yong-Bee Lim, PhD**
Deputy Director, Nolan Center on Strategic Weapons
The Council on Strategic Risks
ylim@csrisks.org

**Monique Mansoura, PhD**
Executive Director, Global Health Security
MITRE
mmansoura@mitre.org

**Jessica McCormick-Ell, PhD**
Director, Division of Occupational Health and Safety
NIH
jessica.mccormick-ell@nih.gov

**Michael Montague, PhD**
Senior Scholar
Johns Hopkins Center for Health Security
michael.montague@jhu.edu

**Kevin O'Connell, PhD**
Senior Vice President, Technology
In-Q-Tel
koconnell@iqt.org

**Megan Palmer, PhD**
Executive Director of Bio Policy & Leadership Initiatives, Adjunct Professor of Bioengineering
Stanford University
mjpalmer@stanford.edu

**Dana Perkins, PhD**
Senior Science Advisor
ASPR
US Department of Health and Human Services
dana.perkins@hhs.gov

**Brian Renda, PhD**
Associate Director, Business Development
Ginkgo Bioworks, Inc.
barenda@ginkgobioworks.com

**Michelle Rozo, PhD**
michelle.e.rozo@gmail.com

**Erin Sorrell, PhD**
Assistant Professor
Georgetown University (now with Johns Hopkins Center for Health Security)
esorrell@jhu.edu

**CDR Cody Thornton**
Director, Security and Assurance (soon to be Security and Intelligence)
HCORE, ASPR
US Department of Health and Human Services
Cody.Thornton@hhs.gov

**Alexander Titus, PhD**
Vice President of Strategy
Colossal Biosciences
alexander@bioeconomy.xyz

**Matthew E. Walsh**
PhD Student
Johns Hopkins Center for Health Security
mwalsh52@jhu.edu

**Matt Watson**
Lead Bioeconomy Analyst
MITRE
mwatson@mitre.org

**Cari Young, ScM**
Acting Director, Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
NIH
caroline.young@nih.gov

700 E. Pratt Street, Suite 900
Baltimore, MD 21202

Tel: 443-573-3304
Fax: 443-573-3305

centerhealthsecurity@jhu.edu
centerforhealthsecurity.org

JOHNS HOPKINS
BLOOMBERG SCHOOL
*of* PUBLIC HEALTH

**Center for Health Security**