

BIOSAFETY AND BIOSECURITY INNOVATION INITIATIVE PLAN FOR THE BIOECONOMY

DECEMBER 2024

PREPARED BY

**The United States Government and Led by the
Departments of Health and Human Services and
Homeland Security**



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About This Document

This document fulfills Section 9(b) of Executive Order 14081 (E.O.) on *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*¹ that instructs the Departments of Health and Human Services (HHS) and Homeland Security (DHS) to lead development of a “plan for biosafety and biosecurity of the bioeconomy” (Plan). This Plan provides a framework for the mission of the U.S. government Biosafety and Biosecurity Innovation Initiative (BBII), including recommendations to: “(1) enhance applied biosafety research and bolster innovations in biosecurity to reduce risk throughout the biotechnology R&D and biomanufacturing lifecycles; and (2) use Federal investments in biological sciences, biotechnology, and biomanufacturing to enhance biosafety and biosecurity best practices throughout the bioeconomy R&D enterprise.”

BBII is hereby established by HHS in accordance with Sec 9(a) of the E.O., in coordination with other federal departments and agencies (referred to collectively as “agencies”) with missions to reduce biological risk (biorisk) associated with advances in biotechnology, biomanufacturing, and the bioeconomy. Through BBII, agencies that fund, conduct, or sponsor life sciences research will: “(1) 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; and (2) use Federal investments in biotechnology and biomanufacturing to incentivize and enhance biosafety and biosecurity practices and best practices throughout the United States and international research enterprises.”

This Plan was developed by the BBII Interagency Working Group, led by the National Institutes of Health (NIH) on behalf of HHS, which comprised over 50 federal experts in the bioeconomy, biosafety, and biosecurity. Co-led by DHS and NIH, this Plan was developed through interagency deliberation drawing on multiple sources including a public request for information² and a virtual listening session.

Biosafety and Biosecurity Innovation Initiative Interagency Working Group Agency Members

Department of Agriculture (USDA)	Department of Homeland Security (DHS)
Department of Commerce (DOC)	Department of State (State)
Department of Defense (DOD)	Executive Office of the President (EOP)
Department of Energy (DOE)	Federal Bureau of Investigation (FBI)
Department of Health and Human Services (HHS)	National Science Foundation (NSF)

¹ See: [Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy](#)

² See: [White House Office of Science and Technology Policy \(OSTP\) Request for Information - National Biotechnology and Biomanufacturing Initiative](#)

Executive Summary

Advances in biotechnology research and development (R&D) and biomanufacturing continue to have an immeasurable impact on American lives. These advances have enabled significant breakthroughs in life sciences and development of new innovative products and devices across every sector, supporting safety, security, health, and prosperity for Americans. This progress has benefitted from an open and collaborative U.S. bioeconomy rooted in scientific integrity, equity, ethics, safety, and security. Scientific and technological progress can, however, generate some new and unpredictable risks that can have the potential to cause harm to human health; animal or plant health or products; the environment; or economic or national security. Biotechnologies and their applications can produce new and occasionally unanticipated outputs. While biorisk management models may be similar to the nuclear or chemical sectors, risk management in the life sciences requires unique approaches due to the wide range of uses of biological organisms and products in laboratory, industrial, and real-world settings; the complex nature of biological systems; and the potential for replication, spread, and environmental persistence of organisms and other bio-based products. To reduce biorisks associated with advances in biotechnology and increased use of biology in new sectors, the U.S. government is taking concrete steps to strengthen our existing and robust biosafety and biosecurity programs, such as coordinating investment in biosafety and biosecurity research and promoting best practices. Toward this, the U.S. government establishes the Biosafety and Biosecurity Innovation Initiative (BBII).

This document presents *a plan for biosafety and biosecurity* investment to sustain and support the bioeconomy using BBII as a mechanism to coordinate federal government action and engagement with stakeholders supporting the bioeconomy (**Fig 1**). This Plan outlines three recommendations that target critical areas in the U.S. approach to biorisk management investment across all sectors supporting the bioeconomy: (1) strengthen the existing foundation for evidence-based biorisk management by increasing support in applied biosafety and biosecurity **research and risk assessment**; (2) bolster investment in and incentivize development and implementation of biorisk management **practices and proficiencies**, informed by the growing evidence base, including supporting a competent workforce; and (3) reinforce implementation through fostering improved biosafety and biosecurity **culture and coordination** by facilitating sharing of best practices and norms among communities to earn public trust. Implementation of these recommendations will require a whole-of-government and whole-of-society approach in collaboration with all partners supporting the bioeconomy to drive innovation. With these responsible investments, the U.S. can build a sustainable, safe, and secure bioeconomy, improving the lives of the American people through improved health, a cleaner and safer environment, and enhanced security.

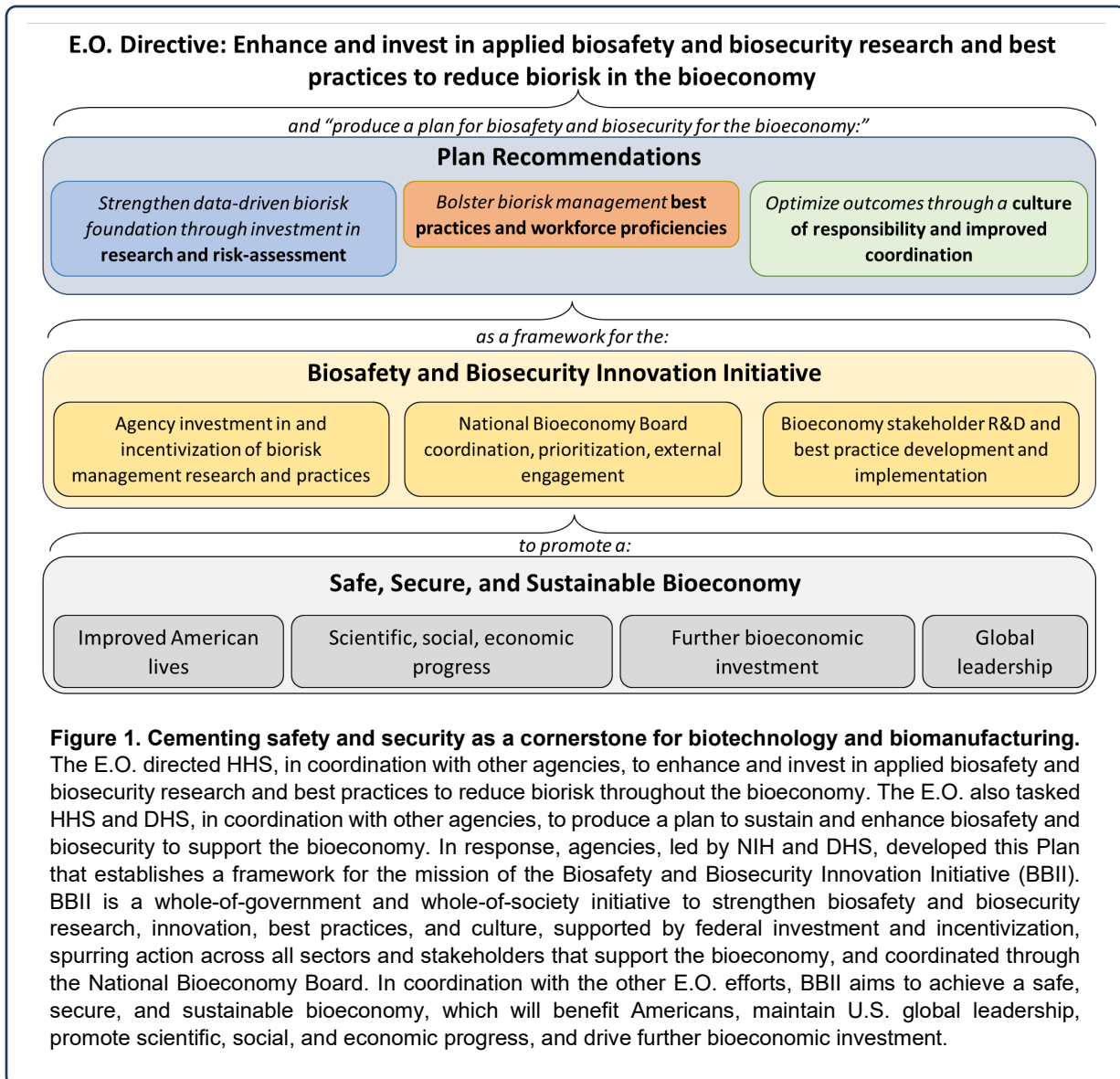


Figure 1. Cementing safety and security as a cornerstone for biotechnology and biomanufacturing. The E.O. directed HHS, in coordination with other agencies, to enhance and invest in applied biosafety and biosecurity research and best practices to reduce biorisk throughout the bioeconomy. The E.O. also tasked HHS and DHS, in coordination with other agencies, to produce a plan to sustain and enhance biosafety and biosecurity to support the bioeconomy. In response, agencies, led by NIH and DHS, developed this Plan that establishes a framework for the mission of the Biosafety and Biosecurity Innovation Initiative (BBII). BBII is a whole-of-government and whole-of-society initiative to strengthen biosafety and biosecurity research, innovation, best practices, and culture, supported by federal investment and incentivization, spurring action across all sectors and stakeholders that support the bioeconomy, and coordinated through the National Bioeconomy Board. In coordination with the other E.O. efforts, BBII aims to achieve a safe, secure, and sustainable bioeconomy, which will benefit Americans, maintain U.S. global leadership, promote scientific, social, and economic progress, and drive further bioeconomic investment.

Introduction

It is the policy of the U.S. government to protect the American people and the environment by reducing biosafety and biosecurity risks through the application of effective biorisk management and mitigation measures. The U.S. bioeconomy is vast and growing, with much of its activity outside of the U.S. government. Thus, preserving a safe and secure bioeconomy must be a shared responsibility among the U.S. government, industry, academia, private and non-profit research institutions, and other entities and individuals supporting the bioeconomy. Together, we all must do our part to integrate biosafety and biosecurity measures into all aspects of biotechnology and biomanufacturing innovation to protect public, animal, plant, and environmental health and safety.

To comprehensively mitigate biorisk throughout the bioeconomy, concepts of biorisk management must be applied across the lifecycle of biotechnology—including conception and application of biotechnology products, R&D, manufacturing, commercialization, and ultimate disposal—and keep pace with the rapidly advancing biotechnology landscape and increasing diversity and scale of biomanufacturing approaches. Biorisk management must also be implemented across all sectors of the bioeconomy with particular focus on new and emerging fields in life sciences.

The U.S. government has a robust biosafety and biosecurity oversight system that is founded on federal regulations, policies, guidelines, and science, and is predicated on identifying and assessing benefits and risks, and effectively mitigating these risks. This system is supported in part through federal investment in research in applied biosafety and biosecurity; training researchers and professionals on assessing and mitigating biorisk; and physical, technical, and social infrastructure that optimizes biosafety and biosecurity practices. With new sectors entering the bioeconomy and the advancements of biotechnology, now is the time to reinforce and expand investment in basic and applied biorisk management research and best practices.

BBII underscores the U.S. government's policy to elevate biorisk management as a cornerstone of the life cycle of biotechnology R&D and biomanufacturing innovation. Biorisk management strategies and practices must be based in evidence to ensure the safety and security of Americans, preserve critical discovery and innovation, and support the acceleration of the American bioeconomy.

BBII offers a mechanism to facilitate coordination across the U.S. government on biosafety and biosecurity research and biorisk management strategies for biotechnology R&D and biomanufacturing innovation. Each agency is called, through its unique mission, authorities, budgets, and policies, to elevate investment to meet the goals of BBII, and in turn spur action across all sectors and stakeholders supporting the bioeconomy. Leveraging this Plan's recommendations as its framework, BBII is designed to:

1. Improve understanding of the current spectrum of biorisk investment and mitigation efforts across the federal government;
2. Identify potential gaps in biosafety and biosecurity research, risk assessments, and best practices;
3. Institute iterative processes on best practices that keep safety and security prioritized in the bioeconomy;
4. Ensure coordination, effective prioritization, and encourage innovation in biorisk management;

5. Engage with and garner support and collaboration across government, academia, private industry, and civil society; and
6. Incentivize biosafety and biosecurity approaches and their implementation across all sectors that support the bioeconomy.

Recommendations to Strengthen Biosafety and Biosecurity While Maximizing Benefits for the Bioeconomy

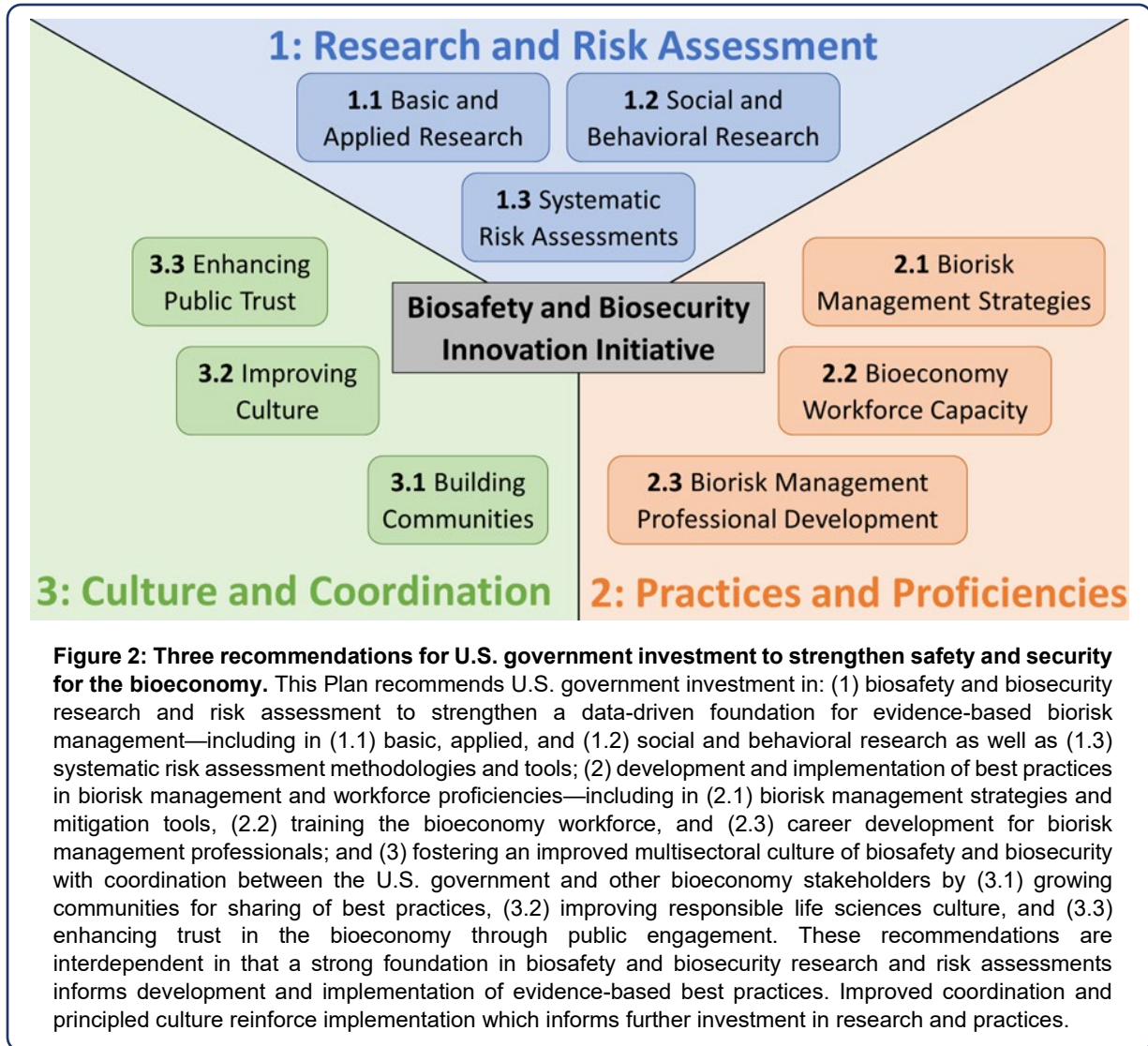
It is the intention of the U.S. government to support biosafety and biosecurity research and best practices throughout the bioeconomy while maximizing the benefits of discovery, innovation, and scientific progress. Toward this end, this Plan outlines three key recommendations that the U.S. government will pursue through BBII (**Fig 2**). Each recommendation includes three sub-recommendations supported by a non-exhaustive list of focus areas for suggested investment. The recommendations and focus areas build on ongoing federal efforts³, and are complementary, reinforcing, and designed to strengthen the culture of biosafety and biosecurity on which the bioeconomy should stand and grow.

Through BBII, the U.S. government will facilitate federal efforts to coordinate and implement this Plan's recommendations by leveraging expertise across sectors, reducing unnecessary duplication and burden, and identifying gaps. While not directly developing policy, BBII will provide guidance and information on areas of greatest risk and highest need to support agencies' decision-making processes for prioritization of funding.

This Plan's recommendations should be considered by all agencies that support, conduct, or sponsor life sciences research, development, manufacturing, or commercialization across the spectrum of sectors supporting the bioeconomy, and, when applicable, be implemented in coordination with academia, industry, and other relevant domestic and international partners. Full implementation of this Plan is subject to the annual President's Budget process and the availability of appropriations. The U.S. government will drive toward this Plan's recommendations synergizing implementation to the extent possible respecting the unique agency missions, authorities, and budgets. Long-term, centralized U.S. government coordination of BBII and prioritization of areas of greatest need and interest will be supported through mechanisms such as the National Bioeconomy Board.⁴

³ Several high-priority U.S. government initiatives that intersect with and complement BBII, include but are not limited to: the 2023 [Bold Goals for U.S. Biotechnology and Biomanufacturing](#) report, the 2022 [National Biodefense Strategy and Implementation Plan](#), the 2022 National Science and Technology Council (NSTC) [Evidence-Based Laboratory Biorisk Management Science & Technology Roadmap](#), the 2023 [National Cybersecurity Strategy](#), and the 2022 [CHIPS and Science Act](#). BBII reaffirms these initiatives and supports implementation of relevant activities using a coordinated and systematic approach.

⁴ See: [OSTP Blog "The White House Advances Biotechnology and Biomanufacturing Leadership with the Launch of the National Bioeconomy Board"](#)



Recommendation 1: Strengthen biosafety and biosecurity research and risk assessment to enable data-driven biorisk management for the bioeconomy

High-quality and comprehensive data are the foundation for discovery, innovation, and policymaking to enhance American lives and better protect the safety and security of both producers and consumers in the bioeconomy. To benefit from advances in biotechnology and biomanufacturing, we must have a strong scientific understanding of potential biosafety and biosecurity risks and impacts associated with scientific advancement and technological innovation. Supporting mechanistic, applied, and socio-behavioral biosafety and biosecurity research and systematic assessment of risks provides biorisk management professionals, researchers, policymakers, and other workers of the bioeconomy with the data necessary to

develop and strengthen evidence-based practices, tools, and policies to manage those risks effectively.

1.1: Support basic and applied biosafety and biosecurity research and innovation

There is a critical need to strengthen scientific understanding of the frequency, causes, and impacts of biosafety and biosecurity incidents to prevent and manage such incidents and the unsafe, improper, or illicit uses of emerging biotechnologies throughout the bioeconomy. Prioritizing funding for basic and applied biosafety and biosecurity research is essential to build a data-driven foundation for improving understanding of risks and developing evidence-based biorisk mitigation strategies and practices⁵. Agencies should invest in biosafety and biosecurity research to improve understanding of the principal elements of biorisks, the impacts of biosafety and biosecurity lapses, the effectiveness of established practices, and methods to improve identification, monitoring, and mitigation of biorisks. Integrating research opportunities into existing life sciences research portfolios will help ensure biosafety and biosecurity are duly considered as part of the development of biotechnologies and their applications and products, though new biosafety- and biosecurity-focused programs are also needed. Research conduct and funding should focus on the following areas:

Prevention Conduct studies to identify and improve preventative procedures, protocols, and controls needed for effective biosafety and biosecurity in field, laboratory, and biomanufacturing environments, such as inactivation or decontamination studies, including those supporting agricultural and environmental biosecurity.

Detection and exposure Fund research to bolster innovations to develop, test, and evaluate new sensors, tools, systems, and controls for detecting field, laboratory, and biomanufacturing incidents including but not limited to environmental releases, personnel occupational or animal exposures, and security breaches.

Biocontainment Evaluate existing primary and secondary containment approaches in various settings, including manufacturing and agricultural facilities; identify opportunities to innovate engineering controls, materials, and other containment or protective equipment to address risks; and test the efficacy of biocontainment controls more methodically.

Computational advances Leverage innovation in computational biology, such as artificial intelligence and machine learning (AI/ML), to, when feasible, predict biorisks in experimental and manufacturing settings, such as structure-to-function prediction of novel microorganisms, toxins, and proteins; detect nefarious activity; secure resilience of supply chains; and mitigate associated risks.

Environmental and human impact Support studies to mitigate the negative impacts of biotechnology and biomanufactured materials on workers, the public, animals, plants, and the environment. Studies should include identifying and characterizing 1) potential hazards that could result from exposure to organisms and biomaterials and 2) early indicators of exposure

⁵ BBII supports ongoing efforts to strengthen applied biosafety research, including those efforts outlined in the 2022 NSTC [Evidence-Based Laboratory Biorisk Management Science & Technology Roadmap](#), and the “Global Research Agenda for Evidence-Based Biosafety,” supported by the Department of State.

and harm through environmental monitoring and surveillance, to inform regulatory policy and best practices.

Risk mitigation Promote and incentivize development of innovative risk mitigation tools and approaches that address vulnerabilities and needs at all scales, including R&D, pilot, and manufacturing scale. Bolster innovations in areas such as: personal protective equipment (PPE); sensors and systems to detect and prevent laboratory and industrial incidents including to environmental releases, personnel occupational exposures, and security breaches; genetic controls, including kill switches; cybersecurity tools to protect biological data, automated control systems, or other aspects of the bioeconomy; and innovative methods for protecting intellectual property.

1.2: Support social science research to inform adoption of biorisk management practices

The bioeconomy is rapidly changing due to scientific discoveries and innovation, the convergence of biotechnology with other technologies, and the increasing application of biotechnology across the spectrum of sectors. Researchers, other workers, and organizations supporting the bioeconomy may not fully appreciate the safety and security implications of these developments. Understanding such implications and their effect on behavior can provide key insights toward improving risk evaluation and maximizing effectiveness and adoption of biosafety and biosecurity practices. The following considerations need to be addressed during both the design and application of biotechnology to enhance public trust in biotechnology and biomanufactured products:

Human factors and automation Support research to understand human factors that contribute to incidents and accidents involving biological agents and materials to better assess where the risks of exposure, release, or contamination occur. Such efforts could inform evidence-based biorisk assessment and development of preventative and mitigation practices, including in areas where automation could reduce risk.

Social science of biorisk management Invest in social and behavioral studies to foster responsible, innovative biorisk management practices. Social sciences research can also be used to identify the impediments and solutions to building a proactive biorisk management culture, including reasons for non-compliance such as barriers and facilitators for the consistent and correct use of PPE, metrics for successful biorisk management programs, and test strategies and tailored techniques to improve biorisk management programs.

Administrative and commercial impact Support research focused on assessing the costs, benefits, and ease of adoption of biorisk management measures for a variety of scientific, product test, and manufacturing settings.

Ethics and norms Support research on the ethics and norms surrounding advances in biotechnology, biomanufacturing, and expanded applications as a result of convergence of biology with other technologies. Research on ethics and norms can be leveraged to create a positive culture of biosafety and biosecurity, focused on elements such as management systems, behavior of leadership and personnel, guiding principles, and beliefs and attitudes.

1.3: Support systematic and streamlined risk assessment and characterization to inform biorisk management

New biosafety and biosecurity risks can arise through emerging or advancing biotechnologies, applications, and manufacturing practices. Existing risk assessment practices⁶ provide a robust starting point. However, expansion and enhancement through data-driven systematic assessments and characterizations of risk are needed to address emerging risks. These systematic analyses are essential to generate accessible and usable information for biorisk management professionals, researchers, and sector-specific workers to better understand and manage the landscape of potential risks. Through BBII, the U.S. government will support strengthening existing programs and initiating new efforts to systematically analyze and characterize the risks in the growing bioeconomy, such as:

Risk assessment indicators and methodologies Support research to develop context-appropriate biorisk assessment methodologies and frameworks across a range of bioeconomic industries and those in non-traditional settings, such as biomanufacturers, venture capitalists, nongovernmental organizations, and do-it-yourself practitioners. These should include the study and implementation of robust performance indicators. Such metrics should account for laboratory or facility outcomes and upstream practices such as management, oversight, budget allocations, and review criteria.

Biomanufacturing systems analysis Support the development of end-to-end systems-level risk assessment approaches—from biomanufacturing inputs to product end use—to identify equipment and process safety and security vulnerabilities that inform the development of actionable risk management frameworks based on priorities and needs. This work should be scoped to account for process innovations, such as integrating automation, at R&D, pilot, and manufacturing scales.

Supply chain assessment Evaluate safety and security of bioeconomic supply chains, including feedstock, raw and bioprocessed materials, and intermediate- and end-products.⁷ Supply chain assessment efforts should encompass the whole bioeconomy, including reliance on foreign materials or processes, to ensure development and maintenance of resilient and sustainable supply chains during both steady-state operations and emergencies where demands may exceed capacities.

Horizon scanning Support technological horizon scanning activities to understand the implications of advancing and utilizing biotechnologies and biomanufacturing processes and develop resources to bolster risk assessment and risk mitigation tools. These assessments can help inform the development of norms and governance approaches and should be ongoing due to the rapidly advancing nature of the bioeconomy.

⁶ For example, DHS Science and Technology Directorate's Probabilistic Analysis of National Threats Hazards and Risks ([PANTHR](#)) program is conducting preliminary analysis of scenarios for bioeconomy risk. DOE biomanufacturing and ecosystem test bed platforms seek to identify and evaluate risks and vulnerabilities and mitigation strategies. These platforms include the [Advanced Biofuels and Bioproducts Process Development Unit](#). E.O. sections 4, 5, and 11 include risk assessment and mitigation related to data-, cyber-, and physical- security, respectively.

⁷ For example, the USDA [Center for Veterinary Biologics](#) ensures that veterinary biologics are pure, safe, potent, and effective. DOE established the [Biopreparedness Research Virtual Environment \(BRaVE\)](#) to understand threats to a broader bioeconomy and ensure resiliency and sustainability in bioenergy crops.

Recommendation 2: Bolster biorisk management practices and workforce proficiencies to advance a safe and secure U.S. bioeconomy

Biorisk management across the bioeconomy requires a coordinated approach due to the wide range of uses of biological organisms and products, the complex nature of biology, and the potential for replication, spread, and environmental persistence of organisms and other bioproducts. A strong bioeconomy is best supported through incorporation of evidence-based risk management practices that are implemented by a well-informed workforce and reinforced by trained biorisk management professionals. Agencies should continue to support development of sector-specific and broadly applicable biorisk management practices, working with relevant stakeholders whenever possible,⁸ and continue to recruit and retain a well-trained workforce capable of implementing them. Building on the foundation established through biosafety and biosecurity research and risk assessment outlined in Recommendation 1, and with an informed and trained bioeconomy workforce, each of the specialists in sectors across the bioeconomy will be well poised to anticipate, identify, and manage risks associated with a growing bioeconomy.

2.1: Enhance biorisk management strategies and mitigation tools

Through the systematic and iterative assessments of risks, practices, and incidents associated with the bioeconomy, agencies should bolster support for the development and implementation of both cross-cutting and sector-specific strategies and tools to manage and mitigate those risks. Such preparation includes the development of best practices, technical resources, and tools to facilitate forward-thinking policy frameworks, with the following concentrations:

Resilient and nimble infrastructure and practices Support efforts to design and establish adaptive biotechnology and biomanufacturing infrastructure and implement practices that can prevent and recover from natural, accidental, or intentional events, and improve facilities and supply chains as needed. Within each bioeconomy sector, create reliably funded mechanisms to enable immediate assessment, characterization, and mitigation of unforeseen biological incidents to minimize high consequence impacts.⁹

Technical resources Support and incentivize the development of biosafety and biosecurity technical resources that incorporate findings from risk and vulnerability assessments in different settings to fill knowledge gaps. For example, create and maintain online libraries of biosafety and biosecurity resources and best practices that can be used to share knowledge among stakeholders in areas such as inactivation protocols, manufacturing facility decontamination methods, and containment air filter integrity testing.

Policymaking and implementation resources Consistently invest in resources, tools, and data collection so policymakers can assess effectiveness of policy and regulation implementation as biotechnology and biomanufacturing evolve. Continue to support the offices, mechanisms, and oversight systems that provide critical assessment, development,

⁸ For example, the National Institute for Occupational Safety and Health (NIOSH) conducts free [nanotechnology on-site workplace evaluations](#). NIOSH has used information from assessments to develop best practices for nanotechnology workforce protections.

⁹ The mechanisms could be structured to enable decision-makers to rapidly respond similar to that for hurricanes, tornadoes, forest fires, and floods. Mechanisms should explicitly enable the U.S. government to proactively investigate, identify, and rule out potential harmful effects to human or animal health; animal or plant products; and the environment.

monitoring, and implementation of biosafety and biosecurity policies, regulations, and guidelines.^{10, 11}

Critical infrastructure Establish, maintain, and improve federal physical infrastructure, such as biocontainment facilities and PPE, to ensure effective implementation of laboratory and manufacturing biosafety and biosecurity programs. This may include plans to mitigate risks and potential damage associated with natural or human-caused disasters. Continue to promote similar infrastructure resiliency efforts in non-federal facilities to the extent feasible.

Safe and secure design Incentivize the integration of biosafety and biosecurity risk mitigation measures at all stages of the R&D pipeline, including design of biotechnologies, development of applications and products, and generation of biomanufacturing protocols. Disincentivize the use of high-risk technologies and processes when not necessary. Establish better aftermarket quality control assessments to identify potential risk after commercialization and improve design and utility of biotechnologies, their applications and products.

Digital biosecurity Fund the development of tools and approaches to strengthen cybersecurity practices for biological systems and applications (digital biosecurity), emphasizing mitigation strategies for potential adverse biosecurity events involving biotechnology and biomanufacturing data, automated control systems, AI/ML, or other aspects of digital infrastructure.

2.2: Incorporate biosafety and biosecurity tenets in workforce training curricula

As the industries within the bioeconomy grow, competition will increase, and each sector will need trained workers at all educational levels with the appropriate skill sets, knowledge base, and proficiencies in biosafety and biosecurity to fulfill bioeconomy workforce positions. Bioeconomy training programs incorporating tenets of biosafety and biosecurity are critical for recruiting and retaining a responsible and competent workforce and for building a culture of biosafety and biosecurity. Federal efforts to assess and promote biosafety and biosecurity tenets in curricula for secondary, technical, associate, undergraduate, graduate, advanced, and professional degrees in the life sciences and allied fields should include:

Core competencies curricula Support the identification and development of biosafety and biosecurity core competencies and skill domains relevant for the professional development of all workers across the bioeconomy sectors. Published core competencies¹² can be leveraged by academic institutions, professional societies, and industry employers to develop training programs and curricula for certificate, degree, and other training programs that would be recognized across the bioeconomy.

Standardized education Support the development of standardized biosafety and biosecurity training core curriculums¹³ through comprehensive assessments of training practices currently available to workers in key sectors of the bioeconomy. Training should be incentivized for

¹⁰ Such as the CDC's [Office of Laboratory Science and Safety, Federal Select Agent Program](#), and [Import Permit Program](#).

¹¹ For instance, the 6th edition of [Biosafety in Microbiological and Biomedical Laboratories](#) (BMBL) was developed by >200 scientific and professional colleagues, who served as reviewers, guest editors, and subject matter experts.

¹² Such as the CDC and the Association of Public Health Laboratories' 2011 [Guidelines for Biosafety Laboratory Competency](#).

¹³ Such as the [Global Biorisk Management Curriculum](#) (GBRMC) and NIH's [National Biosafety and Biocontainment Training Program](#) (NBBTP). The American Biological Safety Association International's (ABSA) [Training Tools & Resources](#) also serves as a good model.

organizations, agencies, and entities receiving federal funding, and be made publicly available to the benefit of domestic and international partners. Supporting a biosafety- and biosecurity-minded culture necessitates the training, professional development, and engagement for key program and senior leadership personnel.

Sector-specific training Expand engagement in the planning and execution of biorisk trainings, workshops, symposia, and conferences with focus areas supporting each sector of the bioeconomy, in partnership with academic institutions, professional societies, industry, and international partners.¹⁴ Support outreach and training targeting post-secondary and post-baccalaureate students and continue to include or add training on biosafety and biosecurity tenets as part of these programs. Existing programs can serve as models for expansion to other institutions to increase awareness of potential biosecurity risks and available best practices to mitigate those risks,¹⁵ and include approaches to allow rapid adaptation of training as the understanding of biorisk management evolves with advances in life sciences and technology.

Scientist training/fellowships Continue to support and existing training and fellowship programs that incorporate the development of biosafety and biosecurity competencies.¹⁶

2.3: Expand training and incentivize career paths for biorisk management professionals

The U.S. is a global leader in public investments in the life sciences. As such, talent development and retention of biorisk management professionals should remain a high priority for federal efforts to help sustain and grow the U.S. bioeconomy safely and securely. A professional workforce with expertise in biosafety and biosecurity principles and practices drives effective implementation of biorisk management at the institutional level and keeps the bioeconomy thriving. The U.S. government should partner with industry, nonprofits, academic institutions, and professional associations to provide career development opportunities to workers in various sectors to ensure acquisition of biosafety and biosecurity competencies, such as the following:

Recruit and retain talent Provide incentives to recruit and retain a highly qualified biorisk management workforce. Increase federal support for science, technology, engineering, and mathematics (STEM) education and partnerships between under-resourced schools and industries aimed at growing a technically competent and skilled workforce in biosafety and biosecurity. Incentivize the creation of employment opportunities at industrial biomanufacturing facilities located across diverse geographic regions of the U.S.

Educational programs and network centers Expand established educational programs¹⁷ and training centers to incorporate flexible, evidence-based biosafety and biosecurity training

¹⁴ Current examples include the USDA Agricultural Research Service (ARS) [International Biosafety and Biocontainment Symposium](#) series, CDC's [International Biosafety Symposium](#), the [Biosafety Level 4 Zoonotic Laboratory Network \(BSL-4Znet\)](#) conference series, NIH's [Regional Biocontainment Laboratory](#) training opportunities, ABSA's [International Biosafety and Biosecurity Conference](#), and ABSA's [Biosecurity Symposium](#).

¹⁵ Such as the U.S.-government supported [Biosafety Cabinet Certifier Training School](#) in partnership with Muhimbili University of Health and Allied Sciences.

¹⁶ Such as USDA APHIS's [National Bio and Agro-Defense Facility \(NBAF\) Scientist Training Program Fellowship](#), NIH's [Responsible Conduct of Research Training](#), and the Oak Ridge Institute for Science and Education (ORISE) [STEM internships and fellowships](#).

¹⁷ Such as NIH's [National Biosafety and Biocontainment Training Program](#) (NBBTP).

modules and methodologies to measure training outcomes. Build and expand support networks¹⁸ where scientific and technical staff can share lessons learned and best practices to coordinate efforts to enhance biosafety and biosecurity across the bioeconomy. Prioritize identifying training gaps and exploring public-private domestic and international partnerships and capacity building efforts to enhance the availability of domestic and international biosafety and biosecurity training options.

Professional development Develop and support new and existing training programs, apprenticeships, and certificate and credentialing programs for biorisk management professionals to meet biosafety and biosecurity competency requirements.¹⁹ Partner with industry, nonprofits, and academic institutions to provide career development opportunities to workers in various sectors to ensure access and acquisition of biosafety and biosecurity competencies. Provide incentives to those organizations that assist workforce credentialing at all levels.

Career path opportunities Promote and incentivize career trajectories with increasing responsibilities for biorisk management professionals, including opportunities to attend biorisk mitigation conferences. For instance, many federally funded entities with high-containment laboratories²⁰, large-scale biological production facilities, or pilot plants are required to have biorisk management professionals lead their biosafety and biosecurity programs. This requirement should be established as a best practice across all sectors.

Recommendation 3: Foster a multisectoral culture of

Best biorisk management practice includes regular assessment and optimization of practices as the bioeconomy grows and lessons are learned. This can be facilitated through strong multisectoral coordination and sharing of biosafety and biosecurity research findings and best practices, reinforced through an improved culture of biosafety and biosecurity, and bolstered with proactive approaches to bridge trust with the public—the ultimate consumer and beneficiary of the bioeconomy. Such measures would help ensure that principled behavior and awareness continue to be integrated into responsible innovation and real-world implementation, across all sectors and organizational structures. Expanding coordination of biosafety and biosecurity best practices and information sharing beyond the federal government to include U.S. industry, academia, and international organizations, as appropriate, would improve biorisk management. Engaging, in particular, non-traditional participants such as very small or non-academic laboratories, manufacturing facilities, and startup companies using or manufacturing biomaterials for the first time, will be vital to ensuring comprehensive coordination for biorisk management. Likewise, open and transparent bi-directional communication with the public will foster trust in the safety and security of the bioeconomy and drive innovation through investment in both R&D and the marketplace.

¹⁸ Such as the USDA-sponsored [Research Alliance for Veterinary Science and Biodefense BSL-3 Network](#) (RAV3N).

¹⁹ ABSA offers the [professional credentials in biosafety](#), a Registered Biosafety Professional (RBP) and certification Certified Biosafety Professional (CBSP) program. The International Federation of Biosafety Associations (IFBA) offers [task specific certifications](#) and credentials on biorisk management for several life sciences fields. USDA Agricultural Research Service [supports](#) establishment of the Indiana University of Pennsylvania's [Biorisk Management Certificate](#).

²⁰ Inclusive of biosafety level-3 and biosafety level-4 laboratories.

3.1: Grow domestic and international communities to help identify, share, and mitigate risks

All participants in the bioeconomy are critical partners to help identify and mitigate potential biosafety and biosecurity risks to the public and bioeconomy workers. Public-private engagements, communities of practice, and other collaboration mechanisms, both domestically and internationally, offer a critical platform to share biosafety and biosecurity research results and best practices, and in turn identify and mitigate risks and vulnerabilities. Agencies should foster growth of these partnerships in several forms, including:

Communities of practice Invest in groups focused on promoting a broad culture of biorisk management across the bioeconomy.²¹ Establish and maintain partnerships between industrial, environmental safety and health, physical, and cybersecurity professionals and bioeconomy partners to build facility resilience and biosafety and biosecurity minded workplace cultures. Expand engagement with the private sector to enhance awareness of biorisks and to identify and report risks and vulnerabilities.

Consortia and public-private partnerships Leverage ongoing consortia that provide forums for public-private engagement to help identify and mitigate risks and vulnerabilities. Encourage industry groups to expand sector-specific partnerships to optimize biosafety and biosecurity practices²². These sector-specific partnerships can help collect and propagate information to individuals and institutions about lessons learned to integrate biosafety and biosecurity best practices.

Security partnerships Partner with and provide resources to security-focused and other professional societies to develop credentials or programs in aspects of security that are relevant to the life sciences, such as physical, information, and cyber-security. This will promote a professional workforce with requisite knowledge and experience to support all sectors of the bioeconomy.

International coordination Enhance international coordination of biosafety and biosecurity best practices²³, including those related to biocontainment, personnel protection, responsible life sciences research, and product transition. Involve, inform, and collaborate with relevant international partners to identify and mitigate biorisks in the emerging bioeconomy.

3.2: Improve a culture of safe and responsible conduct in life sciences

The U.S. government should engage and incentivize domestic and international entities to improve the global culture of biosafety and biosecurity practice throughout the bioeconomy. Attitudes and cultural norms regarding safety and security influence all aspects of biorisk management, including willingness to report concerns, response to incidents, and awareness and communication of risk, and can ultimately influence effectiveness and impact desired outcomes. Approaches to improving biosafety and biosecurity culture could include:

²¹ For example, the International Working Group on [Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences](#), convened by HHS and USDA.

²² For example, DHS collaborations with the [National Council of International Sharing and Analysis Centers](#) and the Engineering Biology Research Consortium (EBRC) on [Malice Analysis](#).

²³ Similar to the Nuclear Threat Initiative (NTI) [International Biosecurity and Biosafety Initiative for Science](#).

Adoption of best practices Promote adoption of existing biosafety and biosecurity policies²⁴ and accepted best practices²⁵ for both federally-funded entities and those not receiving federal funds. Explore possible mechanisms for incentivizing adoption such as establishing biosafety or biosecurity certificates²⁶ for facilities or individuals, tying adoption to funding opportunities, or accreditation of biorisk management programs.²⁷

Leadership Although a vibrant biosafety and biosecurity culture relies on collective individual action from all participants of the bioeconomy, leaders have the responsibility and authority to shape behavior and influence norms, awareness, and practices that support and advance biosafety and biosecurity. Support and develop mid- and late-career training to teach leaders how to invest in and improve industry standards in biorisk management, build competent staff with the appropriate expertise, support professional development, and lead by example by acting in alignment with biosafety and biosecurity best practices.

Academic study Incentivize researchers to expand biosafety and biosecurity research through academic awards ancillary to their primary research.²⁸ Work with academic publishers to incentivize dissemination of methods, results, references, and best practices related to biosafety and biosecurity. Dissemination of biosafety and biosecurity measures may help build and promote further understanding and interest in applied biosafety and biosecurity by reinforcing its recognition as a valued field of scientific research.

Bioincident reporting Support and incentivize a global environment where bioincident reporting, including reporting of near accidents, is not just culturally acceptable, but desirable, including by exploring non-punitive approaches and/or empowering institutional responsibility, as appropriate. Support standardization of input, collection, interoperability, analysis, and usability of bioincident data where possible. Support systems that balance transparency with security of personally identifiable and proprietary information.

3.3: Strengthen public trust in science through biosafety and biosecurity outreach and engagement

Trust in the integrity of the bioeconomy is essential to drive innovation and promote the public good. Garnering trust requires multi-directional communication and collaboration between government, sectors supporting the bioeconomy, and the public. The organizations and workforce supporting the bioeconomy must also understand the needs and concerns of the public regarding biosafety, biosecurity, and the safety of biotechnology and biomanufactured products. Solutions to alleviate the public's concerns and provide them with understanding and confidence in the benefits of the bioeconomy must be developed with their active participation. Likewise, the public should be provided with information needed to understand and have confidence in the purpose and benefits of life science exploration and discovery and develop an appreciation for how biosafety and biosecurity practices help to mitigate potential risks, improve

²⁴ For example, the [NIH Guidelines](#), the [U.S. Government Policy for Oversight for Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential](#), or the OSTP [Framework on Synthetic Nucleic Acid Synthesis Screening](#).

²⁵ For example, the [BMBL](#).

²⁶ Model after CDC's [Clinical Lab Improvement Credentials](#) amendments.

²⁷ Akin to the accreditation systems that exist for research with human participants and animal subjects.

²⁸ Similar to NIH's 2024 notice of special interest on [Administrative Supplement for Research and Capacity Building Efforts Related to Bioethical Issues](#).

quality of life, and secure the bioeconomy. Toward this end, the following efforts should be implemented:

Public engagement strategies Develop new and innovative engagement opportunities with the public, including newcomers to bioeconomic sectors (e.g., computer scientists, teachers, journalists, and community-engaged researchers), such as research proposal input opportunities that include both community members and scientists or industry leaders, and participatory technology assessments. Outreach should include opportunities for equitable participation, such as hosting events at times and places available to diverse populations and using varied means of communication, and should provide opportunities for public feedback to be incorporated in substantial and meaningful ways.

Counter mis- and dis-information Engage with mainstream press and diverse communities to demystify science, scientific jargon, and novel discoveries pertaining to the bioeconomy. Use plain language to communicate the goals, benefits, and risks of scientific discoveries and innovations and the established mechanisms to conduct R&D in a safe and secure manner. These efforts will educate and build confidence within the public sector, especially those societies that are new to aspects of the bioeconomy.

Disseminate educational materials Invest in educational materials geared toward public consumption and promote learning from those materials. Share educational materials among stakeholders and the public by providing open communication platforms online²⁹. Use crowdsourcing as one approach to develop educational materials, promote understanding, and drive interest.

Challenge prizes Incentivize innovation solutions that could mitigate potential biosafety and biosecurity risks by publishing challenge prize competitions through challenge.gov or similar mediums³⁰.

Next Steps to Institutionalize Biosafety, Biosecurity, and the Biosafety and Biosecurity Innovation Initiative

The U.S. government is committed to strengthening biorisk management across the spectrum of sectors and stages of the bioeconomy. Launch of BBII affirms biosafety and biosecurity as a priority for the U.S. government in protecting the American public, the environment, and global security while developing a strong bioeconomy. This Plan provides a framework for expanding biorisk management throughout the bioeconomy by leveraging the launch of BBII through three recommendations for U.S. government investment to bolster biosafety and biosecurity in: research and risk assessment, biorisk management practices and proficiencies, and culture and coordination. Partnership between agencies and non-governmental entities will further strengthen and modernize biorisk management to protect Americans and enable the continual evolution of a strong, innovative, safe, and secure bioeconomy.

Agency Next Steps

Each agency should adapt the Plan's recommendations as appropriate to meet specific needs based on funding levels, mission, relevance, and statutory and regulatory authorities. Agencies

²⁹ For example, ABSA's [Training Tools and Resources](#). The European BioSafety Association (EBSA) and IFBA also share these materials with their members and member organizations, respectively.

³⁰ The [International Genetically Engineered Machine](#) (iGEM) competitions and responsibility programs, and NTI's [Next Generation for Biosecurity](#) can serve a good models.

should consider whether further investment and prioritization is feasible, and if so, develop steps, in coordination with BBII as necessary, to implement these recommendations. Individual agencies' next steps may include an assessment of funding, infrastructure, and labor needed to implement the Plan's recommendations; inclusion of this Plan's recommendations in budget requests; development of implementation plans or policies; and development of evaluation methods to regularly assess and inform ongoing implementation. Commitment from agency leadership will be important for success.

BBII Coordination through the National Bioeconomy Board

Implementing the Plan's recommendations will require significant coordination and resources, among other efforts, across the U.S. government, as well as actions from the private sector; state, local, tribal, and territorial governments; academic and non-governmental organizations; and international partners. Improving coordination between the U.S. government and external stakeholders can identify investment gaps, increase resource-use efficiency, and enable a fuller assessment of the state of biosafety and biosecurity, all in the context of an expansive bioeconomy lens.

To ensure BBII has sufficient coordination, the establishment of the National Bioeconomy Board (NBB) provides a mechanism to institutionalize BBII, streamline agency implementation, and interface with non-governmental partners. NBB seeks to advance the U.S. bioeconomy by harmonizing disparate federal efforts and working with partners across the public and private sectors. Leveraging NBB to coordinate BBII will ensure biosafety and biosecurity investments are not considered in isolation, but rather as a whole for broader bioeconomic progress.

Coordination of this Plan's recommendations through NBB will ensure that prioritization of biosafety and biosecurity investment and incentivization efforts are prioritized across the federal government so areas of greatest risk are effectively addressed; best practices, lessons learned, and strengths and weaknesses are shared between sectors; a central community of practice is established; and non-governmental and international partners are engaged. NBB will also facilitate coordination of progress reporting and updating the Plan as appropriate. Because biosafety and biosecurity coordination with the broader bioeconomy is vital for cultural change, NBB will streamline and institutionalize engagement with government partners supporting the bioeconomy.

Appendix: Abbreviations and Definitions

Abbreviations

Agencies – federal departments and agencies

AI/ML – artificial intelligence and machine learning

BBII – Biosafety and Biosecurity Innovation Initiative

E.O. – Executive Order 14081 on *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*

NBB – National Bioeconomy Board

PPE – personal protective equipment

R&D – research and development; inclusive of research, development, testing, and evaluation, as appropriate

STEM – science, technology, engineering, and mathematics

Definitions

Definitions are derived from the NIST Bioeconomy Lexicon,³¹ the 2022 *National Biodefense Strategy and Implementation Plan*³, and the *National Security Memorandum on Strengthening the Security and Resilience of United States Food and Agriculture*.³²

Biocontainment: the combination of physical design parameters and operational practices that protect personnel, the immediate work environment, and the community from exposure to biological agents. It includes the combination of physical design parameters and operational practices that protect plants, animals, and the environment from exposure to biological agents.

Bioeconomy: economic activity derived from the life sciences, particularly in the areas of biotechnology and biomanufacturing, including industries, products, services, and the workforce.

Bioincident: any natural or accidental occurrence in which a biothreat harms humans, animals, plants, or the environment, a crime involving a biothreat consistent with the scope of the 2022 *National Biodefense Strategy*; or any act of biological warfare or terrorism.

Biomanufacturing: the use of biological systems to produce goods and services at commercial scale.

Biomaterial: any substance in whole or in part, derived or obtained, from a human, animal, plant, or other organism(s) or cell(s).

Biorisk: the effect of uncertainty expressed by the combination of the consequences and the associated likelihood of occurrence that a biological event will adversely affect the health of humans, nonhuman animals, and/or the environment. A biological event may include naturally occurring disease, accidental infection or release, unexpected discovery, loss, theft, misuse, diversion, or intentional unauthorized release of a biological agent or biological material.

³¹ See: [NIST Bioeconomy Lexicon](#)

³² See: [National Security Memorandum on Strengthening the Security and Resilience of United States Food and Agriculture](#)

Biorisk management: For the purposes of this Plan, biorisk management is used to describe the practice of both biosafety and biosecurity, including both risk assessment and mitigation.

Biorisk management professionals: For the purposes of the Plan, biorisk management professionals are inclusive of biological safety, biosafety, or biosecurity officers, officials, or professionals.

Biosafety: 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.

Biosecurity: 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.