

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

*A Policy Paper by the Engineering Biology Research Consortium*

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

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

## Core Functions of the Biosafety and Biosecurity Innovation Initiative

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

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

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

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

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

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

Goal 2: Ensure biodefense enterprise capabilities to prevent bioincidents.

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

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

### **Fund applied biosafety research and biosecurity innovation**

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

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

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

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

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

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

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

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

## Conclusions

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

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