Roadmap for Biosecurity and Biodefense Policy in the United States

Executive Summary

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ROADMAP FOR IMPEMENTING BIOSECURITY AND BIODEFENSE POLICY IN THE UNITED STATES

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Executive Summary

The U.S. policy landscape for countering biological threats is split into two main groups: 1) biosecurity, which specifically focuses on preventing theft, diversion, or deliberate malicious use of biological sciences knowledge, skills, materials, and technologies to cause harm; and 2) biodefense, which involves the development of capabilities and knowledge-based to assess, detect, monitor, respond to, and attribute biological threats. Policies in both groups often affect the same stakeholders, which may result in mutual benefits among defense-oriented policies or counteract (or limit achievement of) defense and/or security objectives. Complicating the system for countering biological threats is the rapidly changing biotechnology landscape, which simultaneously presents new opportunities for building technological capabilities for defending against biological threats and for enabling security risks and vulnerabilities. As the U.S. government finalizes its new National Biodefense Strategy and begins preparing its Global Health Security Strategy, understanding the current policy landscape and the potential ability or inability of policies to achieve biodefense objectives is crucial to ensuring that the new strategies address long-standing gaps. Despite all of this activity in biodefense and biosecurity policy, systematic evaluation of existing policy and implementation to identify gaps and policy solutions for addressing those gaps has not been conducted, until now.

This report presents a roadmap for implementing biosecurity and biodefense policy to leverage the capabilities of science and technology advances and minimize security risks. Supporting the conclusions and suggestions in the Roadmap chapter are detailed analyses of the overall system of U.S. biosecurity and biodefense policy, existing methodologies for evaluating successful implementation of policies, and historical case studies with which to develop an analytic framework for assessing potential opportunity costs of biosecurity policy requirements. This study presents two analytic frameworks, one for developing and evaluating policy implementation and a second for examining direct costs, indirect effects arising from those costs, and their downstream consequences.

Changing Biotechnology Landscape

Four primary changes have occurred during the past 10-15 years that have, and will continue to, alter the biotechnology landscape: 1) expansion of the funding landscape to include cross-over venture capital firms and public crowdsourcing in addition to private industry, philanthropic organizations, and government funders; 2) increasing convergence of physical, computational, materials, and life sciences; 3) broadening of practitioners of biology to include citizen scientists and non-life scientists and engineers; and 4) globalization of biotechnology capabilities. These changes are driven by many factors, including, but not limited to, social acceptance of health applications and increased agricultural needs. Together, these factors lead to transformative changes in biotechnology that enable new knowledge gain and new applications. Examples of biotechnologies that have altered current life science capabilities include precision medicine, systems-level analysis, bio-based systems for chemical production, synthetic biology, tissue printing, additive biomanufacturing, neural networks, and artificial

intelligence. Government and non-government funders have recognized the potential for these advances to improve health, agriculture, environmental monitoring, and energy.

Findings from Systems-based Evaluation of the Biosecurity and Biodefense Policy

The systems-based policy analysis conducted in this study revealed several limitations of the current policy landscape and highlighted gaps in capabilities, implementation, and infrastructure. Limitations were identified in scope and relevance of policies, consistency of policy development and implementation, and in stakeholder engagement.

Priority Gaps and Consequences of the Limitations

Gaps	Consequences of the Limitations
The need for greater investment, innovation, and workforce development for microbial forensics.	The decreasing ability of the U.S. government to be a leader in scientific and technological advancement and application.
The need to improve the input data for biosurveillance and early warning.	An inability to identify mutually-beneficial policies, such as worker protection and laboratory biosafety, and counteracting policies, such as biodefense research investments and the Biological Select Agents and Toxins (BSAT) regulations.
The need for greater attention to the security implications of scientific and technological advances beyond those associated with pathogens and toxins.	Difficulties of stakeholders to implement policies with many mandated activities and little, or no, financial support.
The lack of financial and technical resources to support local implementation of biosecurity policies.	Challenges of local stakeholders to understand their roles and responsibilities in implementing biosecurity and biodefense policies.
The continuously changing regulatory landscape for BSAT.	
Annual and inconsistent investments in nonproliferation activities, which can limit sustainability of activities.	
Effective measures for evaluating policy implementation and examining opportunity costs of new policies.	
The lack of programs for promoting resiliency within the research sector, including at the regional and national biocontainment laboratories, despite the key role it plays in preventing, detecting, and assisting with response to biological threats.	

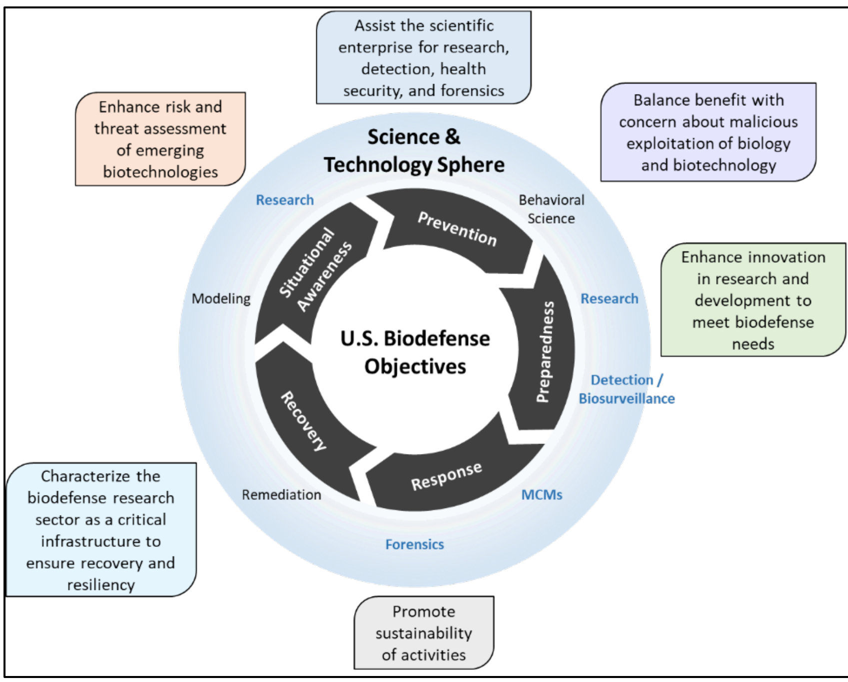
In addition to these limitations and gaps, several key *findings* were observed from the policy analysis:

- The U.S. biosecurity and biodefense policy landscape is a system of intersecting components, which can lead to mutually reinforcing policies or counteracting policies. Therefore, approaching U.S. policy development, analysis, and implementation in a systematic way enables more thorough understanding of the indirect costs, trade-offs, and feasibility of policies and their implementation.

- No single strategy describes the full range of biosecurity and biodefense objectives of the U.S. Therefore, the U.S. biosecurity and biodefense enterprise would benefit from the development of a comprehensive, inclusive strategy that recognizes the interconnectedness of existing policy, depth of implementing and affected stakeholders, and outstanding gaps.
- On occasion, local stakeholders voluntarily have developed and implemented policies and practices to address biosecurity and biosafety risks, and biodefense knowledge and technological gaps. These voluntary actions play a major role in risk reduction and capability building for the U.S.
- Several barriers may prevent policies from being fully or adequately implemented, limiting their abilities to meet U.S. biodefense objectives. These barriers include counteracting policies, lack of support for compliance with high-burden requirements, and lack of cross-sectoral and cross-disciplinary stakeholder involvement in the policy development process.

System-wide Roadmap

The roadmap for implementing biosecurity and biodefense policy addresses the identified limitations and gaps, builds on the key policy findings, and focuses on six primary actions that federal and local stakeholders have responsibility in implementing. The figure highlights the key elements of the roadmap.



U.S. Biodefense Objective	Policy Scope
Situational Awareness	Risk Assessment, Threat Assessment, Intelligence, Counterproliferation
Prevention	Nonproliferation, Export Control, Physical Security, Personnel Security, Cyber Security, Threat Reduction, Biosafety
Preparedness	Natural, Engineering, and Social Science Research; Detection and Biosurveillance; Diagnostics; Medical Countermeasure Research and Development; Forensic Capability Development; Community Engagement
Response	Medical Countermeasure Distribution, Microbial Forensics, Epidemiologic Response, Emergency Response
Recovery	Resuming Normal Conditions or Operations

Roadmap for implementing biosecurity and biodefense policy in the United States to leverage science and technology advances and simultaneously, minimize security risk.

Given the Department of Defense's role in implementing biodefense and biosecurity policies more broadly, several of these actions apply to DoD.