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Creating Clear Regulatory Pathways for Biotechnology

In brief…

The George Washington University Regulatory Studies Center, in partnership with the National Security Commission on Emerging Biotechnology (NSCEB), convened experts to discuss the modernization of U.S. biotechnology regulation. Participants broadly agreed on the need for clearer regulatory pathways, risk prioritization, and greater predictability, while emphasizing that progress will depend on leadership, accountability, and disciplined execution across agencies.

By: Matias Vesperoni | February 25, 2026

On January 28, 2026, the George Washington University Regulatory Studies Center, in partnership with the National Security Commission on Emerging Biotechnology (NSCEB), convened former government officials with crosscutting regulatory expertise to consider how the U.S. can revise its biotechnology regulatory system to improve the industry's competitiveness and accelerate commercialization of new products, all while maintaining safety and public trust for the general public. This discussion was structured around the NSCEB's recent discussion paper, *Creating Clear Regulatory Pathways for Biotechnology*, and the Commission's recommendation that Congress enact the National Biotechnology Initiative Act, which, among other things, would establish the National Biotechnology Coordination Office (NBCO) within the Executive Office of the President (EOP).

In 2022, Congress charged the NSCEB with conducting a thorough review of how advancements in emerging biotechnology and related technologies will shape current and future activities of the Department of Defense. The Commission submitted an interim report in December 2023 and released its final report to Congress in April 2025. Its work continues through 2026, seeking expert feedback on regulatory modernization, whole-of-government coordination, and near-term implementation priorities.

This discussion built on the Commission's previous work and consultation, and was structured around three topics: (1) Establishing a whole-of-government strategy for biotechnology, (2) Priorities for biotechnology regulation, and (3) Identifying near term implementation strategies and NSCEB's role in that implementation.

Establishing a Whole-of-Government Biotechnology Strategy

Based on your experience, what are the biggest obstacles to implementing a whole-of-government strategy for biotechnology, and how can they be overcome?

The proposal to create the NBCO garnered general agreement that improved federal coordination is necessary given the number of agencies with overlapping responsibilities for biotechnology research, regulation, commercialization, and national security.[1] Participants supported coordination that would clarify lead agency roles, align regulatory timelines, facilitate the sharing of data and risk assessments, and resolve jurisdictional conflicts. However, they emphasized that coordination failures rarely result from insufficient meetings or lack of formal structure, but instead from unclear national strategy, and lack of sustained leadership and tangible implementation authority. Drawing on prior interagency experience, discussants noted that coordination efforts tend to succeed when agencies are aligned around a shared national strategy and a concrete set of implementation priorities. These efforts tend to fail when coordination becomes the end goal. In this context, participants viewed the proposal for a new coordinating office as potentially useful, but stressed its effectiveness would depend on clear authority and a focus on execution rather than process.

Participants illustrated this point with a recent EOP-led "bioeconomy" coordination effort focused on a "segment of the total economy utilizing or derived from biological resources, and includes manufacturing processes, technologies, products and services." Presidential Executive Order (EO) 14081 directed the Assistant to the President for Economic Policy and the Director of the Office of Science and Technology Policy (OSTP) to coordinate executive branch actions with senior officials from economic, regulatory, and national security agencies.[2] Participants said the effort was effective because it was anchored in a clear mandate from the EOP, supported by regular senior-level engagement, and focused on implementing a defined set of priorities. OSTP set up a National Bioeconomy Board to which agencies were willing to commit staff time, share information, and resolve jurisdictional disagreements because the coordination effort was presidentially directed and led by senior policy officials.

However, when the EO was rescinded and senior-level engagement declined, the effort lost momentum and influence, even though the coordinating structure remained in place. Congressional authority and dedicated funding for coordination and implementation of priorities could make the NBCO more durable. This involvement would establish a clearer statutory mandate, enable congressional oversight, and

[1] The NBCO would create an interagency committee including departments and agencies with roles in biotechnology research, regulation, national security and commercialization, such as the Department of Defense, Health and Human Services, Agriculture, Energy, Commerce, Homeland Security, and State; the Environmental Protection Agency; The National Science Foundation; The Office of the Director of National Intelligence; and the Office of the U.S. Trade Representative.

[2] Executive Order 14081 involved coordination by the Assistant to the President for National Security Affairs, in consultation with the Assistant to the President for Economic Policy and the Director of the Office of Science and Technology Policy, reporting and implementation responsibilities assigned to the Secretary of Health and Human Services, Secretary of Agriculture, Secretary of Commerce, Secretary of Energy, Director of the National Science Foundation, Director of the Office of Management and Budget, the Secretary of State (in coordination with the U.S. Trade Representative), and regulatory implementation involving the Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture.

indicate to agencies that coordination is a sustained national responsibility rather than a temporary executive initiative.

This experience suggests that the creation of a new coordinating office does not, by itself, change the incentives of agencies. Coordination bodies that lack a budget, clear dispute resolution authority, or consistent senior-level engagement may gravitate toward convening meetings and producing process-oriented outputs rather than measurable outcomes. Historically, OSTP had the authority and resources to convene agencies under the 1986 Coordinated Framework for Regulating Biotechnology. Working with the Office of Information and Regulatory Affairs (OIRA), which reviews all agency regulations, they were able to identify issues and engage appropriate agencies. As another example, participants noted that engagement in international discussions can incentivize coordination among U.S. agencies to present a unified policy to other jurisdictions.

Priorities for Biotechnology Regulation

What regulatory challenges do you hear about most often from industry, academia, government, or international partners?

Participants agree that many of the challenges facing biotechnology regulation are longstanding and well understood. Reforms should focus on creating clearer pathways for approving products and research by reducing uncertainty, improving predictability, and addressing the most persistent sources of delays for developers.

Not only is there ambiguity regarding authority between agencies, but within agencies. Developers often face uncertainty about which agency has lead authority, what data will be required in the process, and how long review will take. For established products, agencies typically rely on existing statutory categories, prior approvals, and established review templates, providing clear expectations and predictable timelines. In contrast, novel products may trigger review by multiple agencies, and require case specific data requirements and uncertain timelines. This uncertainty is particularly concerning for small firms as they often lack the resources to navigate overlapping or sequential review processes.

Participants offered several possible reforms focused on clarifying pathways for approval. To address regulatory inefficiencies associated with burdening new products that are familiar or present low risk with extensive review without significant safety gains, discussants strongly supported more widespread use of exemptions, tiered review pathways, and risk proportionate oversight. They argued that these approaches would allow agencies to concentrate resources on genuinely novel or high-risk products while also accelerating the review process for well known technologies.

Several participants suggested mechanisms for streamlining the regulatory process to improve coordination and reduce redundancy. Using prior regulatory decisions and accumulated scientific knowledge across agencies through a shared database could reduce regulatory burden, shorten timelines, and improve consistency across agencies while maintaining safety standards. Formal interagency agreements, such as Memoranda of Understanding (MOU), could help clarify agency roles and expectations. MOUs between the agencies could clarify the steps involved for approval and how agencies

would coordinate, providing a clearer map for developers to follow. Or, they might offer what one participant referred to as an asylum approach, where a developer could approach the regulatory agency with which it was most comfortable, without risking subsequent challenge from other agencies with potential authority. A commitment to reviewing submissions and providing a science-based decision within fixed time periods (e.g., six months) would go a long way to reducing uncertainty.

For all these reforms, MOUs, as well as guidance documents, have the benefit of being implemented more quickly than regulations or statutes, but they are less durable. Nevertheless, to the extent such pathways prove effective, they are more likely to be retained across administrations.

While supporting legislative action, discussants were less optimistic about the likelihood of new statutory authorities soon. Instead, they thought executive branch policy options that clarify expectations, formalize existing best practices, and improve coordination within current legal frameworks might be more achievable in the short run. Participants emphasized that these incremental reforms in transparency and predictability could yield competitive benefits, as regulatory uncertainty and delays increasingly influence where firms choose to invest, seek approval, and scale production.

Near Term Implementation and the NSCEB's Role

Of the many policy options in NSCEB's discussion papers, which should be prioritized through 2026 to deliver the greatest near-term impact?

The final topic of discussion was what to prioritize for near-term implementation, especially since the NSCEB has one year left in its remit. Participants encouraged the Commission to identify actions that are easy to do, urgent, and important. Several identified product areas where reforms might meet these criteria, including agricultural products and microbes. They generally agreed that legislative action was not likely to move quickly, but thought MOUs between agencies with overlapping authority could go a long way toward clarifying pathways and expediting approvals. MOUs could help clarify the roles of leading agencies, establish expectations for data sharing, and reduce duplicative reviews across agencies. When used effectively, MOUs were seen as being capable of improving regulatory predictability and providing clearer points of entry into the regulatory process for developers.

Conclusion

Overall, the discussion reinforced the view that improving the regulation of biotechnology will require sustained attention to coordination, prioritization, and implementation rather than the creation of new structures alone. Participants broadly agreed on the need for clearer regulatory pathways, risk prioritization, and greater predictability, while emphasizing that progress will depend on leadership, accountability, and disciplined execution across agencies. While tools such as interagency agreements and coordination mechanisms are essential for short-term reform, lasting impact will likely require input from Congress. In this context, the NSCEB was seen as well positioned to identify legislative reforms, as well as to help guide near-term action by identifying practical priorities, facilitating coordination, and supporting implementation to translate policy intent into measurable improvements.