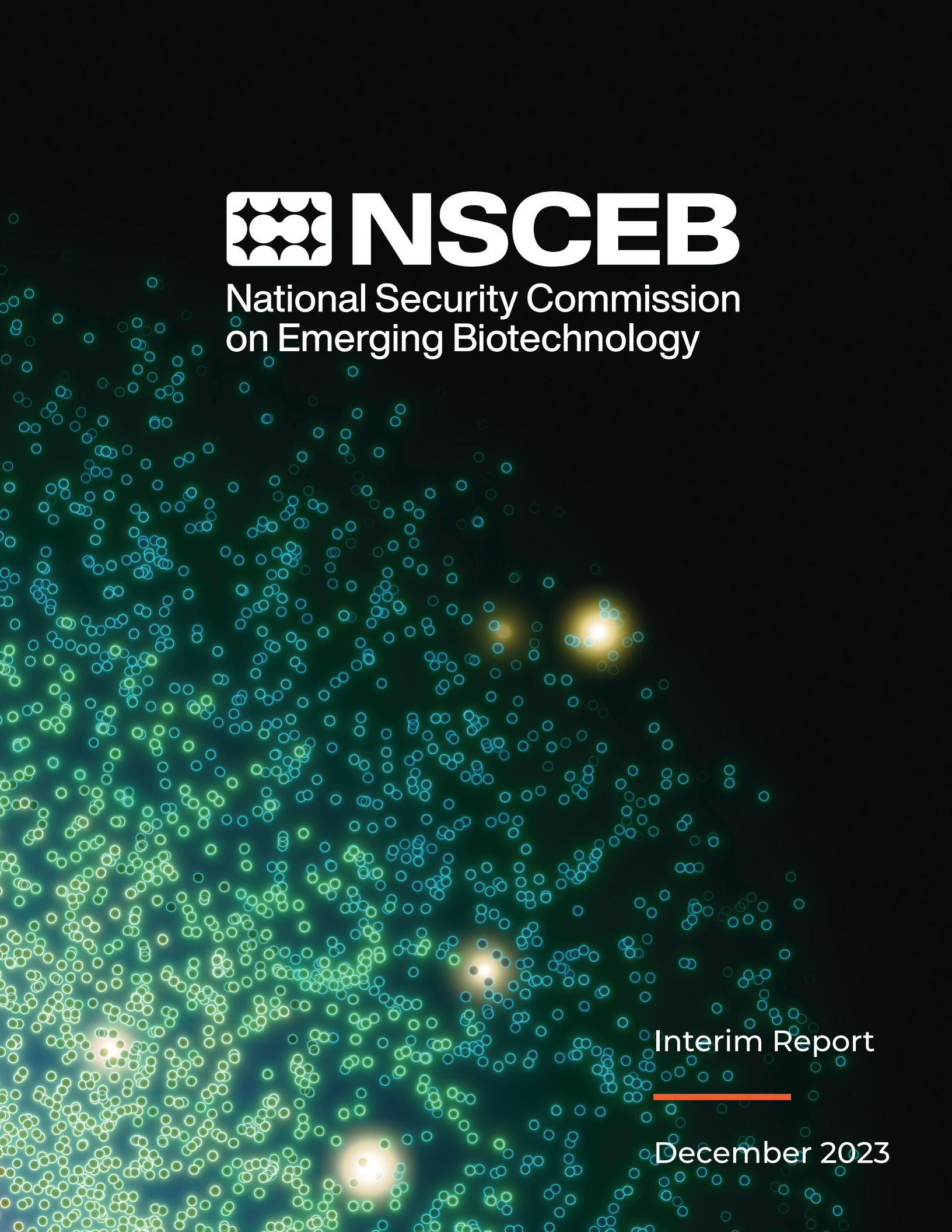
NSCEB

National Security Commission on Emerging Biotechnology



Interim Report

December 2023

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About the Commission

Message from the Chair and Vice-Chair

The United States has led biotechnology innovation for half a century. In 1978, a small American company called Genentech changed hundreds of millions of lives by producing synthetic human insulin, now one of the world's most widely used medications. This discovery and development of tools to "program" biology at the level of its underlying DNA code marked the birth of biotechnology. Forty-five years later, the United States is still the global biotechnology leader. But today we are facing challenges from countries like China that are investing billions of dollars into domestic biotechnologies with the intent of surpassing the United States. The stakes are high and time is short to secure American leadership.

Biotechnology already supports our society through providing medicines, food, materials, and much more. But this is just the beginning – advances in biotechnology could transform the economy and provide solutions to global challenges like pandemics, food insecurity, supply chain vulnerability, and environmental issues. As the speed of innovation increases, supercharged by convergence with AI and other technologies, we cannot afford to forget the lessons of semiconductors and 5G while we wait to act. Biotechnology could be more powerful and consequential than these technologies, both to benefit society as well as to cause great harm. America's leadership in advancing and safeguarding biotechnologies can uniquely create a future that serves not just our country but the world. In contrast, our strategic competitors have shown they are willing to wield technical power to suppress and control rather than empower.

Now is the time for us as a nation to unify across government, industry, academia and with our global allies and partners to drive biotechnology foward. Our Commission's goal is simple but ambitious: to strengthen America's longstanding leadership in biotechnology and take action to ensure that the U.S. can compete and succeed on the international stage. This Commission is already offering thorough and actionable policy recommendations that will unlock new potential in the biotechnology industry in and beyond defense and national security that hold true to the values and opportunities that make this country an exceptional place to live and innovate.

To fulfill our goal, we want to include perspectives from all Americans and from friends and allies abroad, including academia and educators, private companies, research facilities, government agencies, military and service organizations, and more. We invite your engagement and feedback on this report and look forward to sharing more with you in the year ahead.

Dr. Jason Kelly
Chair

Dr. Michelle Rozo
Vice-Chair

Commissioners

Dr. Jason Kelly, Chair

Dr. Michelle Rozo, Vice Chair

Senator Alex Padilla

Senator Todd Young

Representative Stephanie Bice

Representative Ro Khanna

Paul Arcangeli

Dr. Angela Belcher

Dawn Meyerriecks

Dr. Eric Schmidt

Dr. Alexander Titus

Dr. Dov Zakheim

We, the Commissioners, want to give a special thanks to the Commission staff. This work would not be possible without your tireless effort to understand and improve the way the U.S. approaches biotechnology, and we are proud to work with you.

Executive summary

The National Security Commission on Emerging Biotechnology ("the Commission") is exploring the opportunities and challenges facing the United States at the intersection of national security and emerging biotechnology. This interim report discusses our findings thus far and the research plan that will inform our comprehensive policy recommendations to be issued in 2024. It also highlights the concrete actions we have already taken to advance emerging biotechnology in the United States.

Most Americans already are aware of biotechnology through the drugs in our medicine cabinets or the crops in our fields. Yet recent advances in biotechnology are unlocking the ability to program biology just as we program computers. Emerging biotechnologies could enable the world to improve human and planetary health, secure food and energy production, ensure supply chain resiliency, and grow the economy at a massive scale. Biotechnology has the potential to bolster economic development in every community. If we capitalize on this unique opportunity, we can make this century the age of biology.

Congress has rightly recognized the growing potential of emerging biotechnology, including its applications for defense and national security. We can imagine a future in which our warfighters are fed, fueled, equipped, protected, and healed on the battlefield, all thanks in part to biotechnology. This is not science fiction; the research is happening today.

Continued U.S. leadership in biotechnology development is not guaranteed. Researchers, inventors, and investors agree that there are significant policy and investment roadblocks that could hinder biotechnology growth and innovation in the United States. One such roadblock is U.S. Government oversight for biotechnology, which needs to be clarified and streamlined. Another roadblock is a lack of both physical infrastructure and the workforce required to operate it. An investment in both human capital and physical infrastructure is critical to continued U.S. leadership in biotechnology. This investment need not come just from government but should draw on both public and private sources of funding, as did the CHIPS and Science Act.

The stakes are high as biotechnology, like all emerging technologies, can be misused. This makes it even more imperative that the United States, along with its allies and partners, continues to lead in the development of biotechnology and associated guardrails.

If we do not lead, others will, and we risk a future in which biotechnology undermines, rather than supports, our security. Notably, the People's Republic of China (PRC) intends to win the age of biology and is making serious investments and shrewd policy decisions that could put it on track to outpace us. Our failure to seize this moment and act decisively could empower China and others to deploy biotechnologies for the surveillance of vulnerable populations, to

develop strangleholds on key supply chains, or to create weapons that could harm Americans.

The United States needs to work closely with our international friends and allies on a government-to-government level now. To have these informed conversations, the U.S. Government needs access to the technical expertise required to understand biotechnology advancements. These conversations will lead to development of international standards and norms that support our common goals.

From the creation of our Commission to the issuance of a major Executive Order on advancing biotechnology and biomanufacturing innovation, U.S. policymakers have initiated fresh momentum in this area. Although many U.S. Government entities have already taken steps to advance biotechnology, we must continue to set a blistering pace toward the future. We are nowhere near the finish line. The U.S. Government must continue to advance and embrace biotechnology to maintain our technological advantage.

Congress and the Executive Branch can take meaningful actions to advance U.S. biotechnology policy. The Commission intends to explore bold policy considerations that can position us to lead as well as common-sense changes to existing legislation that can smooth the path for future innovation.

A thriving biotechnology industry will enhance U.S. national security, strengthen and diversify the U.S. economy, and bolster a growing workforce. The Commission's recommendations, when implemented, will ensure that the United States continues to lead the world in biotechnology development and deployment.

Seizing the age of biology

The United States, alongside the rest of the world, stands at the brink of a transformative biotechnological revolution, one that could yield countless innovations and bring advanced manufacturing to every part of America. Biotechnology products already solve problems today, such as developing more targeted medications for cancer and other diseases, improving agricultural sustainability, and creating novel types of materials.

Biotechnology can help people live longer and healthier lives. Biotechnology-based products in development today could drastically reduce the global burden of disease *(for examples of tools commonly used in biotechnology, see Figure 1)*. For example, precision medicine, like cell and gene therapies, can treat diseases that were previously considered incurable. Synthetic biology and genome editing make it possible for our bodies to learn to fight diseases with greater precision and efficacy than previously available treatments. Researchers are also using biotechnologies to create improved vaccines, including the advancement of mRNA vaccine platforms, that significantly reduce the time from the emergence of a new pathogen or disease to treatment.

> "Biotechnology presents tremendous opportunities for manufacturing, agriculture, defense, biomedicine, and many other fields. Preserving America's leading role in biotechnology is essential for our long-term economic and national security and will open up new opportunities across our nation."
>
> *— Senator Todd Young*
> *(Indiana)*

In the food and agriculture sector, biotechnology can produce healthier and more accessible foods, such as fruits and vegetables with added nutrients or longer shelf life. Biotechnology-enabled plants and animals have the potential to increase crop yields, withstand pests, and endure weather events, improving the resilience of American agriculture. Advancements in biotechnology have led to engineered microbes that provide local nutrients to plants, potentially increasing yields while reducing the need for fertilizers that contribute to nutrient pollution. Engineered microbes are also being used to safely produce food ingredients from flavors and colors to needed vitamins and high-quality protein.

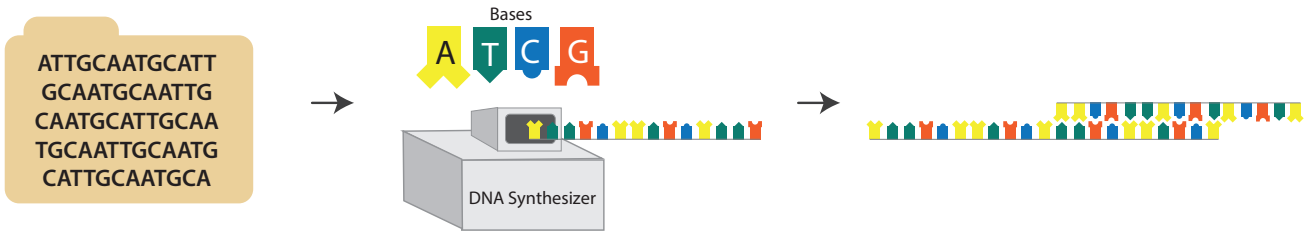
Biotechnology can also bring critical supply chains back to the United States. Biomanufacturing offers new ways to sustainably make the products we rely on for everyday life, including plastics, packaging, clothing, detergents, tires, and much more. Engineered microbes can produce carbon building blocks that are molecularly identical to petrochemicals. Biotechnology can also enable more efficient recycling and capture of critical minerals like rare earth elements, together addressing fragile supply chains.

Environmental applications of biotechnology can help reduce and mitigate pollution. For example, microbes can be engineered to use waste as the starting material for desired chemicals and materials. We can also use biotechnologies for environmental remediations: engineered microbes and plants can break down waste and remove contaminants from soil and water. Biotechnologies can also aid with carbon capture from industrial plants and remove waste products created by manufacturing.

The Commission notes that biotechnologies could be misused to intentionally harm the United States and its partners and allies through creation of novel weaponry. However, emerging biotechnologies may also be the best

Figure 1. Common Tools used in Biotechnology

DNA writing, or synthesis, builds custom genetic sequences for biological research and development. These genetic sequences can impart new properties into living organisms to create new materials such as biopharmaceuticals and more resilient crops.

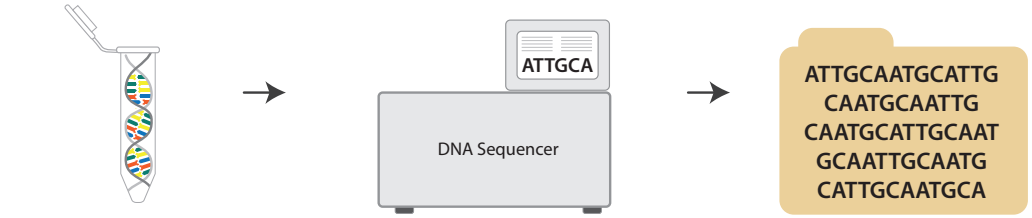


Researcher creates genetic sequence of interest

Sequence is uploaded to a DNA synthesizer that assembles nucleotide bases into sequence of interest

DNA strand is produced with genetic sequence of interest

DNA reading, or sequencing, is the process of determining the order of individual bases in a sample of DNA. Determining the DNA sequence can help identify an organism or understand some of its properties.

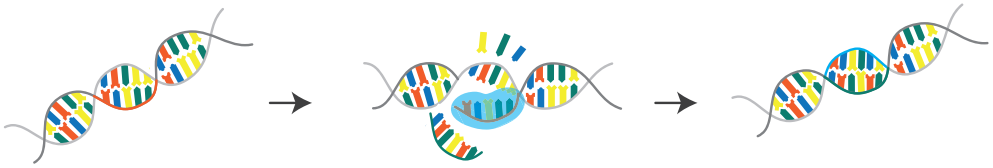


Researcher acquires DNA sample with unknown genetic sequence

DNA is deposited into a DNA sequencer, where it is amplified and analyzed

Sequence of the DNA sample is generated

DNA editing involves changing, adding, or removing bases of DNA. DNA editing can be used to change cellular properties that might enhance gene expression or eliminate disease.



Researcher acquires DNA sample that needs to be modified

Section of the DNA is edited using a gene editing tool such as CRISPR-Cas9 or TALENs

DNA is repaired with new genetic sequence

defense against that misuse, as these technologies could be used to develop on-demand diagnostics, therapeutics, and vaccines to defend against any attack.

More needs to be done to arrive at the age of biology. It still takes too long and costs far more than it should to move a potential biotechnology product from the lab to the marketplace. More recently, financing has become more difficult to access. companies may not be able to develop biotechnology products, particularly for defense applications, by means of market forces alone.

Beyond wide civilian applications, biotechnology offers the potential to develop novel products that will better support our defense and intelligence professionals and can mitigate persistent Department of Defense (DoD) challenges. For defense capabilities, emerging biotechnology offers two promises. First, synthetic biology and biomanufacturing can provide alternative means of producing chemicals and materials that our warfighters employ every day, increasing supply chain resilience. Second, emerging biotechnologies offer the means to improve products, from materials with novel properties to therapeutics with greater precision and efficacy.

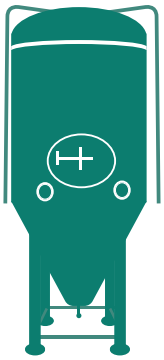
Our military's ability to deter adversaries and protect servicemembers anywhere in the world depends on reliable logistics, particularly in a contested or austere environment. Small-scale, light-footprint production of commodity materials through biotechnology could be valuable to DoD. For example, small, table-top bioreactors could bring biomanufacturing anywhere, including contested environments.[1] This could make it possible to produce medicines closer to areas of operations to support wounded warfighters and medical personnel. While DoD has funded research into table-top bioreactors for the past decade, the technology is yet to be widely used.

There are several other biotechnology use cases for defense. Biomaterials can satisfy existing needs, such as rocket fuel, and biomaterials for next-generation explosives show promise in research.[2] Biological systems can also produce novel products, such as materials that prevent diffusion of toxic chemicals into cells by enveloping the chemicals in a tight membrane.[3] Microbes engineered to digest waste, including plastics, could change the way that DoD manages waste disposal in forward operating environments, allowing DoD to reduce dependence on expensive, cumbersome disposal technologies and lessen environmental and human health impacts.[4]

As DoD seeks new ways to improve warfighter resilience, cutting-edge biotechnologies offer many enhanced tools. Novel material resembling spider silk, made with synthetic biology, could make lighter, stronger, and more flexible body armor, allowing warfighters to operate under reduced physical strain.[5] Biological sensors could recognize a chemical or biological agent in real time, potentially saving lives in the event of an attack. An engineered human enzyme could deactivate nerve agents (e.g., sarin) in blood. Medical synthetic biology research may enable the development of organisms that can produce treatments inside the body.

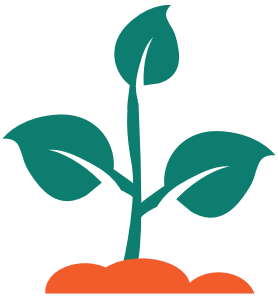
> "California is the birthplace of the U.S. biotechnology industry and has long led the way in biotechnology research, patents, and innovation that save lives, stimulate our economy, and provide good-paying jobs. At this crucial moment in shaping the future of biotechnology, our Commission will continue to examine opportunities to ensure this sector promotes vital American priorities, such as managing global diseases, improving agricultural sustainability and food security, and protecting our national security."
>
> *— Senator Alex Padilla (California)*

Figure 2. Examples of Biotechnology



Biomanufacturing

Using microorganisms like yeast and bacteria for faster and more efficient manufacturing

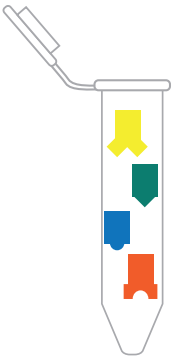


Plants & animals

Engineering plants and animals for desired traits, such as disease resistance or improved performance

Next-generation therapeutics

Therapeutics that involve new technologies like mRNA vaccines, monoclonal antibodies, and cell therapies



Cell-free synthesis

Using components of cells, like proteins or nucleic acids, to synthesize chemicals and materials such as pharmaceuticals or fragrances

Like the introduction of computers, the emergence of biotechnology offers a tool with the potential to revolutionize a variety of different economic sectors. Even with the rapid pace of discovery, the United States can do more to integrate biotechnology across the domestic economy to ensure we are reaping the economic and security benefits that biotechnology can offer.

Our nation is at an inflection point, with potential for a new age of opportunity to revitalize and transform our industries and our way of life using biology. The Commission is developing recommendations that, if enacted, will enable the U.S. Government, especially Congress, to seize this opportunity and ensure that the United States leads the coming age of biology.

China's sprint to close the gap

Failing to meet this moment will have far-reaching consequences. Countries like the People's Republic of China (PRC) recognize that advancements in biotechnology, such as DNA synthesis, gene editing, and precision fermentation, are essential to meeting the basic needs of their populations. In addition, these same countries could employ biotechnology for nefarious purposes.

The PRC specifically is positioning itself as a leader in biotechnology and plans to take advantage of the economic benefits and military advances biotechnology presents.[6,7] The PRC aims to close the gap in biotechnology through its top-down government strategy and coordination, talent recruitment programs, and relatively high research and development (R&D) spending. The PRC has prioritized biotechnology in its last three Five-Year Plans and invested billions of dollars in the sector.[8] It seeks to control global supply chains and dominate key elements of the biotechnology industry.

The PRC has expressly invested in biotechnologies that create military advantages. Under the national policy of "military-civil fusion," PRC officials have blurred the lines between military and civilian applications. If the United States were to fall behind in biotechnology research, any advances that occur in other countries that do not share our values and interests could one day be used against the American people.[9]

Ultimately, there is a risk that adversaries may develop and weaponize biotechnology against the United States. Military applications are no longer confined to the realm of science fiction and could pose threats to American forces in the not-too-distant future. There is an ongoing contest to determine who will shape global norms and values around research, development, and deployment of biotechnology. The United States must win to maintain Americans' prosperity, health, and well-being and to ensure that development of biotechnologies aligns with democratic values.

As with other technologies that have the potential for weaponization, preventing misinterpretation of each other's actions and intent is essential for the safe development of biotechnologies. For example, with the increased reliance on digital systems, nations have created normative and legal structures for optimizing the opportunities of the digital era while deterring cyberattacks.[10] Though biotechnology is significantly different from cybertechnology, there are commonalities with cybersecurity in that both technologies can be used for civilian and defense purposes, and agreement upon and understanding of state actors' use of biotechnologies for civilian purposes can help prevent misinterpretation that could lead to escalation.

The past year: establishing the Commission and taking action

Our mission and approach

Congress imbued the National Security Commission on Emerging Biotechnology ("the Commission") with the responsibility of examining the critical intersection of emerging biotechnology and national security. When Congress created the Commission, it defined our formal mandate: to conduct a thorough review of how advancements in emerging biotechnology and related technologies will shape current and future national defense activities, including activities of the DoD.[11]

This interim report describes the Commission's efforts as of December 2023 and our research plans for the duration of the Commission's authority. The Commission will submit its comprehensive report to Congress in December 2024, including policy recommendations that align with our charge. The Commission will continue through June 2026 as we work to educate and expand upon our recommendations.

Within the context of biotechnology and national security, Congress specifically directed the Commission[12] to consider the following topics:

- global competitiveness;
- ways to maintain and protect the United States' technological advantage;
- trends in international cooperation and competitiveness;
- ways to foster research, development, and testing;
- incentives for workforce and education;
- risks and threats of military use of biotechnologies;
- ethical, legal, social, and environmental considerations;
- international standards for the tools of biotechnology;
- data sharing, both within and outside the U.S. Government; and
- biotechnology developments and biomanufacturing innovation.

The Commission recognizes that other advisory groups have done extensive work on biotechnology opportunities, challenges, and risks, including on biological weapons defense. To the extent that our work deals with biodefense policy, we will focus on the ways that technological advancements, particularly convergence of emerging technologies, may raise or lower barriers on either the development of biological weapons or the use of biotechnologies to cause harm. We will remain mindful of the risk that activities led by the United States to serve defense or

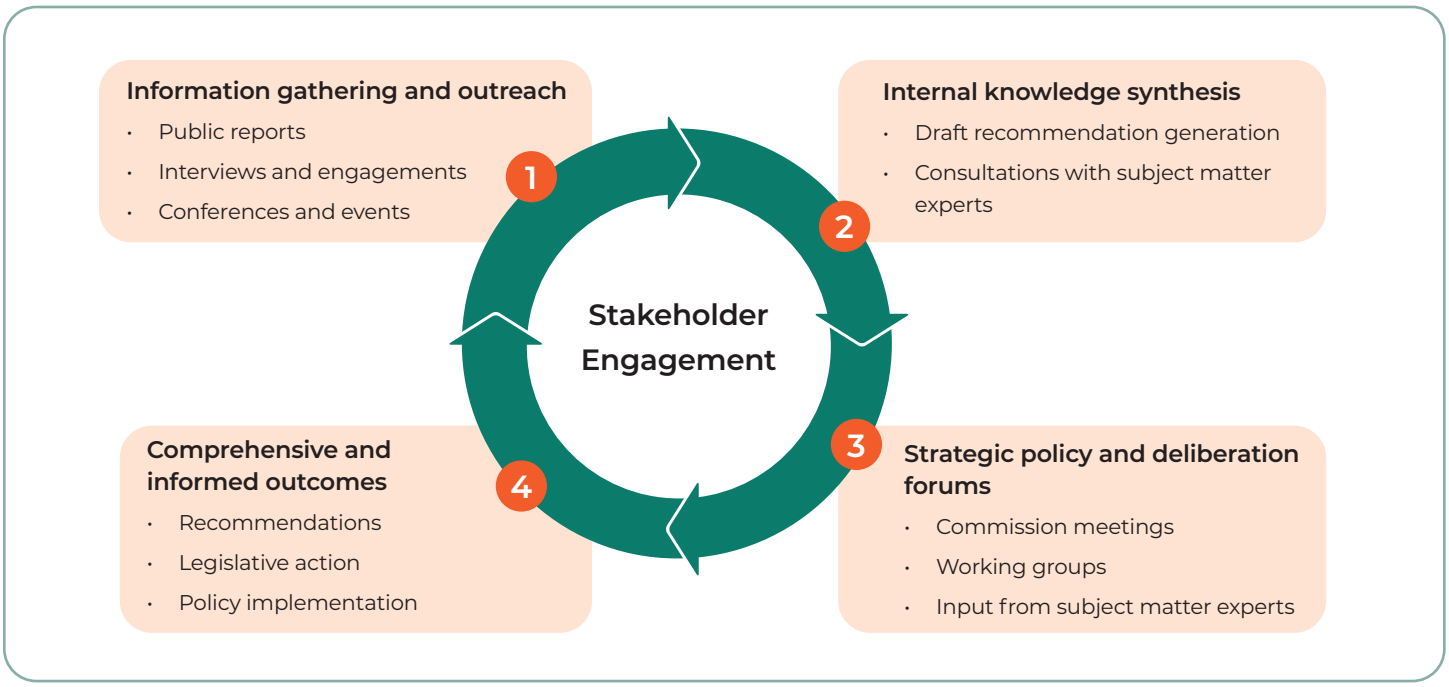
Common definitions

Biotechnology: *the application of science and engineering in the direct or indirect use of living organisms, or parts or products of living organisms, including in modified forms.*

Emerging biotechnology: *the use of new knowledge or the creative application of existing knowledge to create novel biotechnologies.*

National security: *the security and defense of the United States, encompassing national defense, economic competitiveness (including energy security, food security, and resilience of critical supply chains), and strategic geopolitical influence.*

Figure 3. Stakeholder Process



civilian purposes could be misinterpreted by other nations, and we may consider ways to mitigate that risk.

The Commission aims to drive policy change and enhance our national security by supporting biotechnology discovery, development, and deployment in the United States. We have and will continue to offer recommendations for Congressional and Executive action that align with these goals and our broad mandate.

Our process

Since the Commission's first official meeting in April 2023, the full Commission convened every four to six weeks to learn from subject matter experts and to shape its research plans. In addition to full Commission meetings, smaller groups of Commissioners met regularly on more focused research topics, such as identifying and mitigating chokepoints, evaluating risks for misuse, anticipating the future of biotechnology advances, and establishing partnerships to build a more bio-ready U.S. Government and a more bioliterate American public. These research topics respond to the policy considerations in our authorizing

Chokepoints in the biotechnology industry

A ***chokepoint*** is a technical focus area that is both necessary and limited. For example, demand for high-fidelity DNA synthesis has exploded as the technology has become more accessible. Enzymatic DNA synthesis — a new way of writing DNA — holds the potential to revolutionize the market that can create sequences that are longer, cheaper, and more accurate. The country or company that successfully develops this technology at scale may have a strategic position in the next era of DNA synthesis. The Commission is evaluating technologies like this to determine whether they are currently chokepoints or could become so in the future.

statute and provide practical context for the Commission's policy recommendations.

To develop these recommendations, we are:

- engaging with the biotechnology industry so that the U.S. Government can partner with and learn from industry to meet national security needs;
- reviewing Federal biotechnology funding to ensure it is appropriately matched to U.S. needs and goals;
- reviewing the landscape of biotechnology policy, to ensure our work will both add value and promote good policy that has yet to be implemented; and
- requesting and analyzing information from Federal agencies and meeting with Federal agency officials to hear their perspectives.

We draw extensively on stakeholder expertise and input to shape our lines of inquiry (*see Figure 3)*. The Commission solicits input by reaching out to experts across the U.S. Government (Appendix I), industry, national security, academia, international entities, and related expert groups. As of November 2023, the Commission has already engaged with approximately:

- 60 Government departments, agencies, and offices;
- 22 think tanks and federally funded research and development centers/national laboratories;
- 174 companies and industry associations;
- 33 colleges and universities; and
- 51 international entities.

Our actions so far

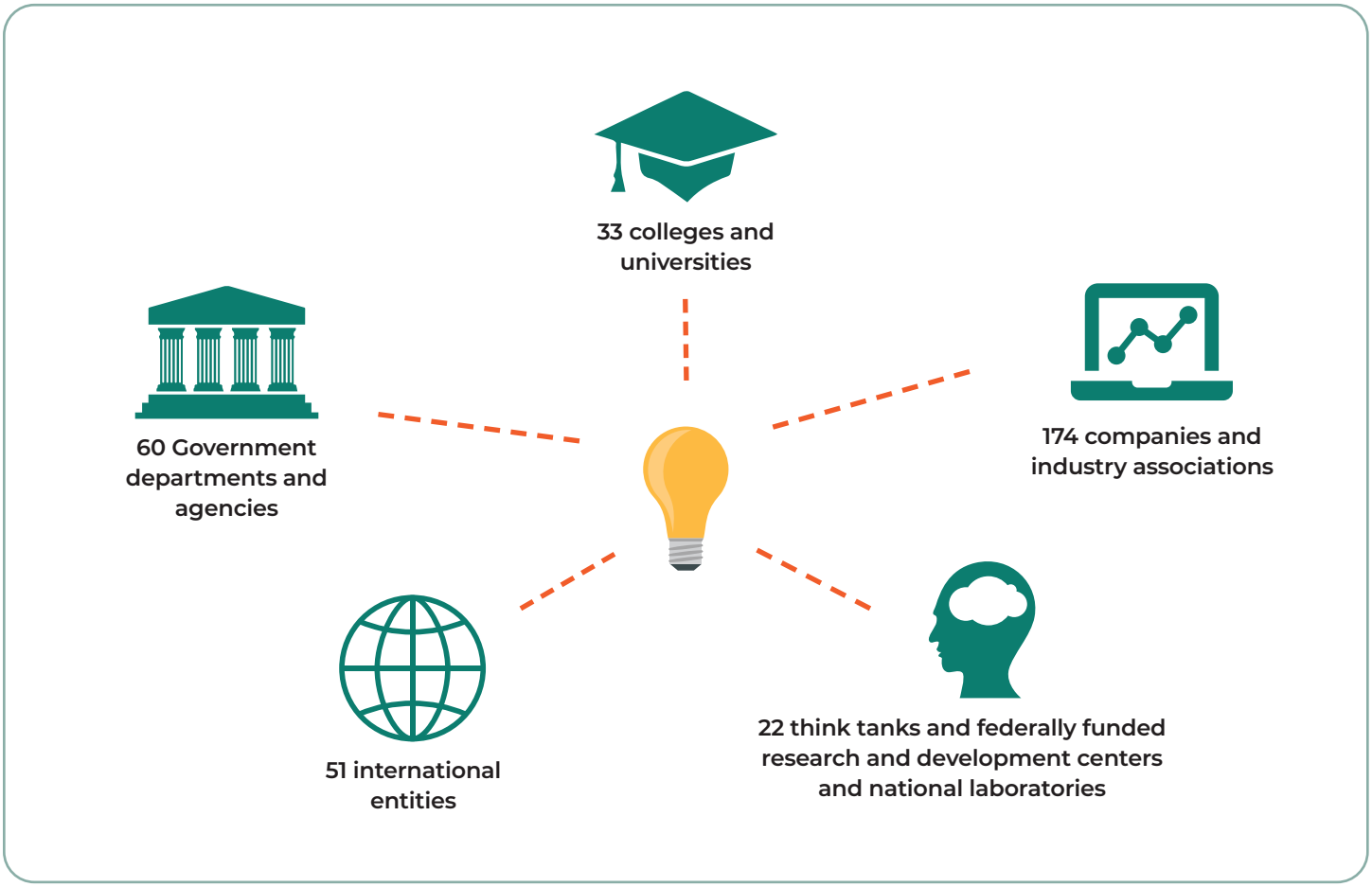
In addition to our broader research strategy, the Commission will be proactive in offering expertise, analysis, and recommendations to policymakers as opportunities arise to advance emerging biotechnology and national security. To date, we have proposed new legislation, endorsed existing legislation, and submitted formal requests to U.S. officials for specific action.

Earlier this year, Congress initiated the Farm Bill reauthorization, which sets U.S. agriculture policy. Recognizing that food security and agricultural supply chains are key elements of national security, the Commission developed three legislative proposals intended for inclusion in the Farm Bill reauthorization or other legislation. These nonpartisan, common-sense ideas were developed to lay the groundwork for further recommendations, particularly with regard to biotechnology regulation and coordination. Full bill text and additional explanation is provided in Appendix II.

> "Based on my experience working in many countries, food security is a primary concern within the United States and across the globe. Our continued excellence and global leadership in providing safe and abundant food mandate a serious commitment, reflected in judicious resource allocations and proactive governance. One of the primary duties of the Commission is to ensure we fulfill our societal and moral obligations to assure healthy and sustainable food supplies into the foreseeable future."
>
> *— Commissioner Dawn Meyerriecks*

- **The Agriculture and National Security Act** would improve connections between the U.S. Department of Agriculture (USDA) and national security agencies by establishing a senior advisor for national security and requiring USDA to identify any gaps or limitations related to food and agriculture in existing national security efforts.
- **The Biotechnology Oversight Coordination Act** would take important steps towards efficient,

Figure 4. Stakeholder Input



risk-proportionate biotechnology regulation in the United States through a formal coordination committee.

- **The Agriculture Biotechnology Coordination Act** would establish an Office of Biotechnology Policy within the USDA to coordinate agricultural biotechnology activities across USDA agencies and between USDA and other Federal agencies..

In addition to the new bills described above, the Commission endorses the following existing pieces of legislation for inclusion in the Farm Bill reauthorization:

- **The Plant Biostimulant Act**[13] (sponsored by Commissioner Senator Padilla) would establish a Federal definition for plant biostimulant and exempt these products from regulation under pesticide regulatory authorities. Biostimulants can help increase crop yields and improve a plant's ability to survive under stressors such as drought or floods.
- **The Food Supply Chain Capacity and Resiliency Act**[14] (sponsored by Commissioner Representative Khanna) would reauthorize a USDA loan guarantee program for infrastructure in the middle of food supply chains, including for companies using biotechnology or biomanufacturing to manufacture or process food products.
- **The Biomanufacturing and Jobs Act**[15] would reauthorize the BioPreferred Program, which helps to create and expand markets for biobased products through mandatory Federal purchasing

requirements and voluntary labeling for biobased products.

- **The Synthetic Biology Advancement Act** (sponsored by Commissioner Senator Young) would create a Synthetic Biology Center under USDA, with a focus on the application of synthetic biology to food security and agriculture.

We have also advocated for Congress and the Administration to prioritize biotechnology and biomanufacturing by using existing resources:

- In September 2023, Commissioners urged the Secretary of Commerce to prioritize investment in biotechnology capacity during the Regional Technology and Innovation Hubs (Tech Hubs) award process. In October 2023, the Department of Commerce (DOC) announced 31 Tech Hubs, of which 11 are biotechnology-related.[16]
- In October 2023, Commissioners urged the House and Senate Appropriations Committees to provide the highest funding possible for the Defense Production Act (DPA) account for Fiscal Year (FY) 2024. Robust DPA funding would represent a significant investment in the biomanufacturing economy that will benefit both our national defense and our economic competitiveness. However, both the House and Senate Appropriations Committees have proposed funding cuts to the overall DPA account. If the funding cuts to the DPA topline are signed into law, the DoD will likely reduce its investment in biomanufacturing.
- In November 2023, Commissioners urged the Secretary of Defense to prioritize biotechnology investments within the DPA account for FY24. Depending on the final enacted level of FY24 DPA funds, DoD may have to reprioritize its funds. If biotechnology is deprioritized, the Commission believes that the DoD will miss an invaluable opportunity to harness emerging biotechnology for long-term national security goals.

The complete text of each letter is included in Appendix III.

The Commission's path forward

Prepare the U.S. Government for the age of biology

The U.S. Government has not yet positioned itself to shape the age of biology in ways that will support, rather than undermine, American security in a competitive landscape. While there is substantial enthusiasm for biotechnology across Federal departments and agencies, current interagency coordination does not provide the ability to holistically assess the U.S. position or to recommend paths forward, from R&D to regulation. Biotechnology lacks the institutional structures and growing workforce that other emerging technologies (like AI/ML or quantum) already enjoy. To prepare the U.S. Government, the Commission is considering the Government's role both in oversight of biotechnologies and as a user of biotechnologies. We are also considering how the Government coordinates biotechnology activities internally, and how it works with industry, academia, and international partners and allies. For a timeline of some milestone Federal actions around biotechnology, see Figure 6.

There is a wealth of information that Congress and the Executive Branch can use to assess the United States' position, strengths, and weaknesses and to develop strategies that incentivize innovation and mitigate misuse. To gather and analyze this information, Federal agencies will need to make a concerted effort and collaborate with industry, academia, and with international allies and partners. For instance, the intelligence community could prioritize the production of foreign competitive intelligence, the State Department could work with international groups for market intelligence and technology forecasts, and the Department of Commerce could convene CEOs from industry to inform analysis. Insufficient information on the state-of-play for the U.S. biotechnology industry hinders the United States' ability to advance innovation, bolster the U.S. economy, and safeguard national security.

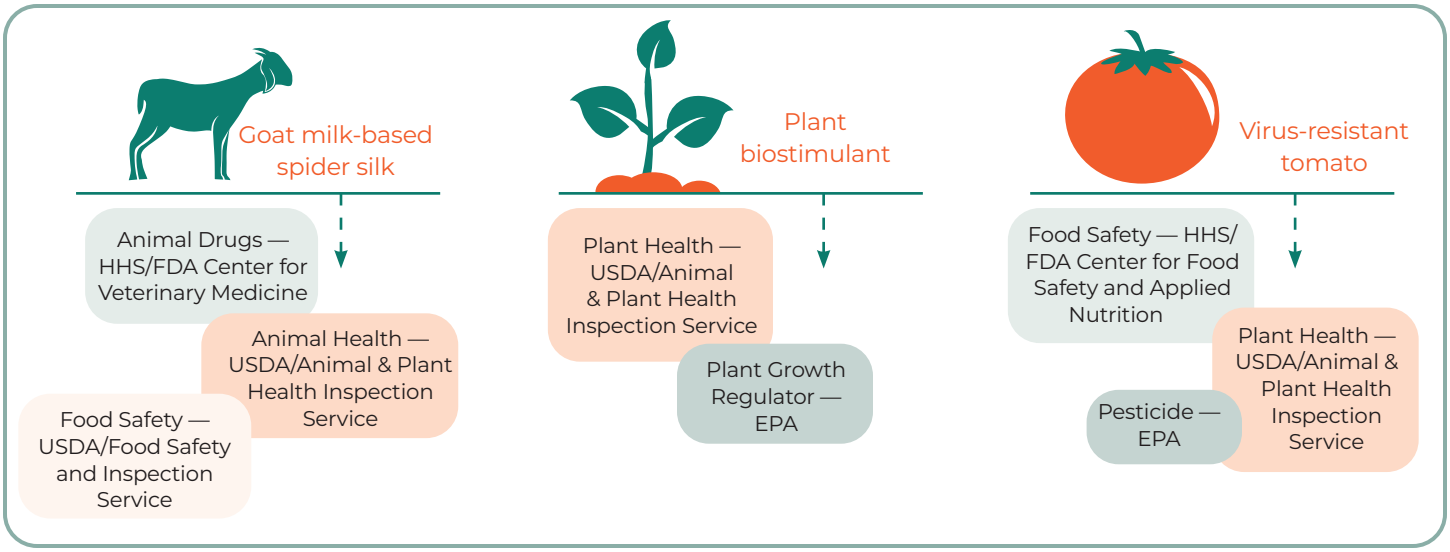
Harmonize the U.S. system for biotechnology product oversight

The United States uses existing laws (many of which predate modern biotechnology advances) to give Federal agencies the authority to regulate biotechnology products. This approach, called the Coordinated Framework for Regulation of Biotechnology ("the Coordinated Framework"), is unlike that of many countries that have passed specific laws for regulation of biotechnology products (such as Argentina,[17] Australia,[18] or South Africa[19]). Over time, the Coordinated Framework has resulted in duplicative regulatory processes, particularly across the Animal and Plant Health Inspection Service (APHIS) within USDA, the U.S. Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS), and the U.S. Environmental Protection Agency (EPA) (*see Figure 5).*

Since the establishment of the Coordinated Framework in 1986, the Office of Science and Technology Policy (OSTP) was instructed (but not statutorily required) to provide regulatory coordination.[20] Coordination has been inconsistent across administrations, and criticisms of the Coordinated Framework have remained virtually unchanged since the framework's early days.[21] While there have been efforts to better coordinate biotechnology oversight, reduce barriers to innovation, and improve Federal biotechnology outreach, we find that the regulatory framework is still too fragmented. Even plain-language descriptions of the system remain complex.[22]

In 2022, Executive Order (EO) 14081 ordered renewed efforts to improve the clarity and efficiency of regulatory processes for biotechnology products and to increase

Figure 5. Examples of Overlapping Regulatory Authorities



coordination and communication between Federal regulatory agencies.[23] A request for information associated with EO 14081 regarding ambiguities, gaps, or uncertainties in the Coordinated Framework drew many comments calling for improvement of U.S. Government biotechnology oversight.[24, 25]

Reducing ambiguity in regulation and clarifying exemptions may reduce regulatory burden both for developers and regulators. In addition, stakeholders have noted that insufficient agency staffing continues to be a concern, and we are considering options to facilitate higher staffing levels. We identified that regulatory improvements are particularly necessary as genome editing and other emerging technologies lower barriers of entry and potentially allow more companies to develop products intended for commercialization. We are considering policy options that would improve U.S. regulatory oversight of biotechnology products and have identified three potential paths thus far:

- discrete changes to individual statutes to reduce redundancies and gaps in biotechnology oversight;
- a single, unified regulatory process to assess any novel risks associated with biotechnology products relative to their conventional counterparts; and
- a hybrid approach that legislatively mandates coordination while facilitating individual agency review and risk assessment.

We seek additional feedback from regulators, industry, and other stakeholders about the best approach to accelerate innovation while protecting human health and the environment.

Improve the bioliteracy of the U.S. Government workforce

Within the U.S. Government, the community of bioliterate personnel or teams is relatively small, even as demand for expertise is growing. We routinely hear from agencies about work they could do if they had the appropriate personnel with the right skills, including technical experts, program managers, intelligence professionals, acquisition officers, foreign service officers, and others. Bolstering biotechnology expertise within the U.S. Government would create a Federal workforce whose skills match agency needs. Such a workforce could enable the U.S. Government to keep up with advances in biotechnology and better leverage biotechnologies to safeguard national

Common definitions

Bioliteracy: *the concept of imbuing people, personnel, or teams with an understanding of and comfort with biology and biotechnology. We believe that in the near future, Americans should understand biology and biotechnology in the same way that they understand how computing interacts with their daily life.*

security and address global challenges.

We plan to analyze different hiring and employment mechanisms across the U.S. Government. Some proposed strategies to recruit biotechnology talent to the U.S. Government include:

- devising new public-private partnerships for the exchange of talent across sectors;
- establishing new fellowship programs to cultivate biotechnology talent;
- better leveraging under-utilized Federal hiring authorities;
- expanding pathways for short- and long-term Federal employment, as well as facilitating movement in and out of government where appropriate; and
- creating new mechanisms that fast-track necessary security clearances for qualified experts.

Leverage international partners and allies

The vibrant U.S. innovation ecosystem has attracted researchers, entrepreneurs, and top science, technology, engineering, and mathematics (STEM) talent from across the globe for decades. We believe international engagement and collaboration with friends, allies, and like-minded countries are integral to U.S. national security and its continued leadership in biotechnology. We are identifying existing bilateral and multilateral mechanisms that could be modernized to keep pace with advancements in biotechnology and developing recommendations for new partnership mechanisms (*see Table 1*).

Figure 6. Milestone Federal Actions Taken So Far

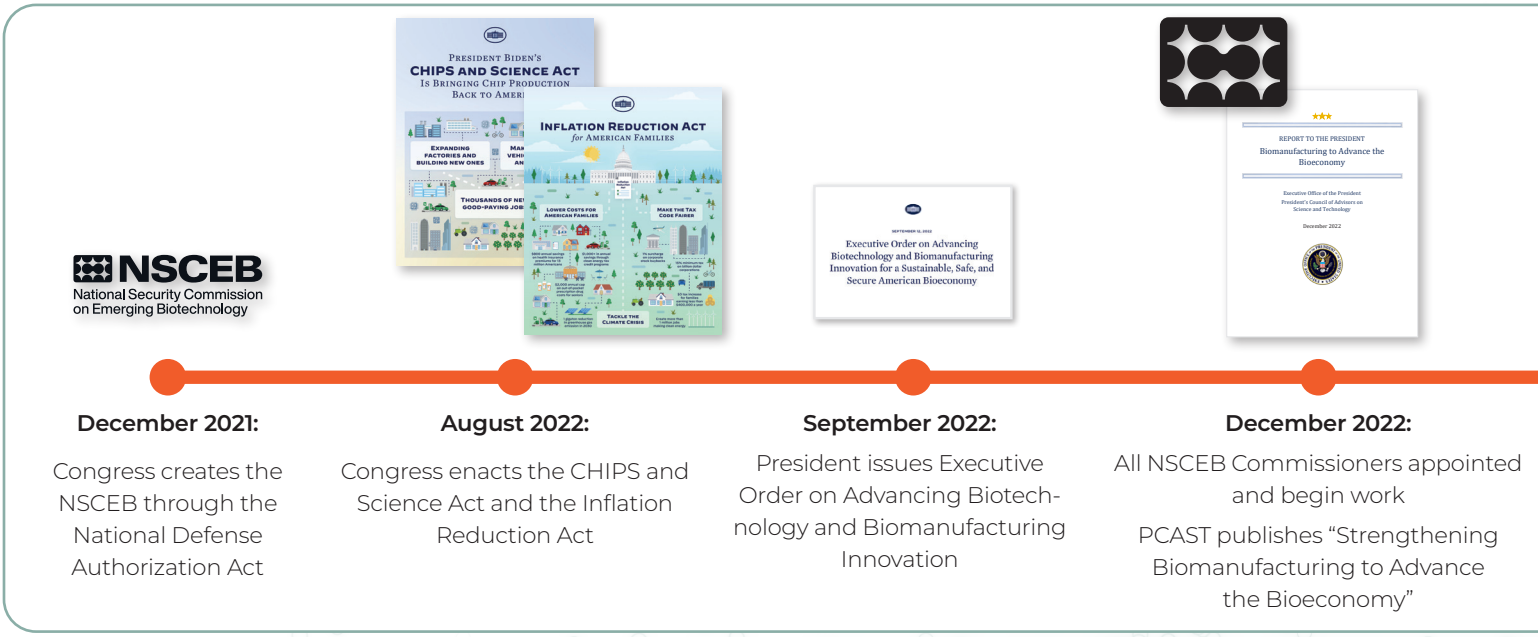
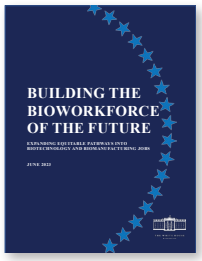
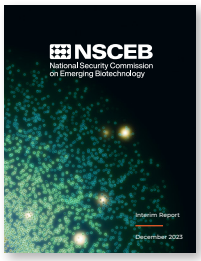


Table 1: Examples of bilateral and multilateral agreements and partnerships relevant to biotechnology

Agreement	Description and pertinence to biotechnology	Membership / Partners
Biological Weapons Convention (BWC)[26]	Disarmament treaty effective since 1975 that bans biological and toxin weapons by prohibiting their development, production, acquisition, transfer, stockpiling, and use.	185 States Parties, 4 Signatory States (U.S. ratified)
United Nations Convention on Biological Diversity[27]	Multilateral treaty for the conservation of biological diversity. Its supplements, the Cartagena Protocol (2003) and the Nagoya Protocol (2014), seek to protect biological diversity from potential risks posed by living modified organisms and to enable fair and equitable sharing of the benefits arising out of the utilization of genetic resources.	196 nations (U.S. did not ratify)
Atlantic Declaration for a Twenty-First Century U.S.-U.K. Economic Partnership[28]	Modernized version of the Atlantic Charter originally issued in 1941. The updated 2023 action plan describes 1) deepening U.S.-U.K. cooperation on synthetic biology, including a joint workplan and improving supply chain pathways for biomanufacturing and biotechnologies, and 2) strengthening bilateral cooperation on biological and health security.	United States & United Kingdom
U.S.-Malaysia Trade and Investment Framework[29,30]	Bilateral agreement that supports technology improvements for trade and investments, and establishes a Joint Council on Trade and Investment, which is directed to consult on technologies, including biotechnology. There are a number of bilateral agreements like this one with a range of other countries.	United States & Malaysia
World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)[31]	Multilateral agreement among WTO members to protect intellectual property rights within international trade and promote technological innovation via transfer and development, with specific provisions for biotechnology.	All WTO members (164 nations, including the U.S.)

This table is not exhaustive and is not meant to include every agreement relevant to biotechnology.





March 2023:

White House publishes Bold Goals for U.S. Biotechnology and Biomanufacturing

DoD publishes Biomanufacturing Strategy

June 2023:

White House publishes Building the Bioworkforce of the Future

December 2023:

NSCEB publishes Interim Report

This timeline is not exhaustive and is not meant to include every Federal action. See Appendix IV for more details.

> "The United States must lead global biotechnology development, use, and governance. Yet we cannot do this without the closest partnership with our international allies, partners and friends. It is a national security imperative that we partner with like-minded nations to ensure safe, responsible use of biotechnology around the world."
>
> *— Commissioner Dov Zakheim*

We have identified these priority areas for international partnerships:

- aligning strategies for the use of biotechnology in defense and national security with allies and major organizations such as the North Atlantic Treaty Organization (NATO);
- establishing shared international standards and norms for biotechnology that align with U.S. values and ethics, and that help prevent the misuse of biotechnologies;
- strengthening global biomanufacturing and biotechnology supply chains for economic security and emergency preparedness;
- harmonizing biotechnology oversight across borders to promote market access and trade in biotechnology products;
- developing international classifications of biomanufactured products to stimulate growth of the global biotechnology sector;
- collaborating on regional and global scale R&D projects (e.g., biobanking, genome analysis, and data governance and security); and
- sharing data to better leverage computation tools to advance biotechnology research, while protecting privacy.

We are mapping U.S. advantages and gaps compared with those of other countries. When other countries with less developed biotechnology sectors look for leadership, the United States and our partners should be first in line, or we risk our competitors jumping at the opportunity to gain market access and setting the norms for use. For example, the PRC has a well-documented history of offering technological solutions, access to capital, and infrastructure more cheaply and with fewer legal or ethical requirements than the United States.[32,33] Strengthening existing bilateral and multilateral partnerships and strategically cultivating new partnerships to anticipate advances in biotechnology and shifts in geopolitics will enable greater security and a more robust global biotechnology industry for both the United States and our friends and allies.

Use biotechnology to solve government problems

The U.S. Government is a large purchaser of goods and services, especially innovative technologies that support national security missions. Biotechnology and biomanufacturing offer a variety of solutions to governmental problems and needs. The DoD requires chemicals, fuels, high-performance materials, and food to support the warfighter, all of which can be produced using biotechnology. Engineered plants and microorganisms can also help remediate of pollution, such as per- and polyfluoroalkyl substance (PFAS) contamination around DoD installations.

We are considering how the U.S. Government, industry, and academia can more effectively work together to ensure that innovative biotechnology solutions are available to meet government needs, including, but not limited to, defense-related technologies. We plan to consider options to enhance communication and collaboration so that:

- the U.S. Government clearly articulates R&D to industry and academia as appropriate;
- the U.S. Government uses its buying power to create demand for biobased products;
- industry has the capability and resiliency to meet U.S. Government demand; and
- the U.S. Government, industry, and academia work

together to identify key technologies that should be protected.

Increase DoD's adoption and advancement of biotechnology

The DoD recognizes that adopting emerging technologies is key to maintaining the United States' military advantage. Biotechnology is one of those critical technologies. However, not all elements of the DoD are positioning themselves to realize the full potential of biotechnology for the future of defense. While some DoD offices, such as the Office of the Under Secretary of Defense for Research and Engineering, are working to advance biotechnology, many DoD entities have yet to recognize or embrace its full potential. In much of DoD, any discussion of biotechnology focuses overwhelmingly on bioweapons. We contend that biotechnology, from biologically produced energetics to novel materials, has much more to offer DoD.

Over the next year, we will evaluate how DoD views, develops, and employs biotechnologies. We want to better understand both DoD's objectives for advancing biotechnology and how biotechnology can help DoD reach its strategic objectives, including, but not limited to:

- using biotechnology to address vulnerable supply chains;
- employing biotechnology to address DoD capability gaps; and
- maintaining U.S. leadership in emerging technologies.

We will assess DoD's metrics, where they exist, to measure progress towards its biotechnology goals. Additionally, we will examine how DoD manages biotechnology research and whether the current DoD structure empowers programs to advance DoD's biotechnology goals. We plan to better understand the military's biotechnology research portfolio and evaluate if DoD weighs the risks of failure commensurately against the potential benefits of nascent technologies. Finally, we want to ensure the DoD is set up for success and has appropriate agile governance structures in place to adapt to emerging technologies that can impact every aspect of the DoD's mission, from warfighting to personalized medicine.

> ***Common definitions***
>
> ***Biological weapons (bioweapons):*** *living organisms, or substances made from living organisms, which are deliberately produced and used to cause harm.*[37]

Improve interagency coordination

Many Federal departments and agencies are involved both in formulating biotechnology policy and in supporting biotechnology development. There is no single agency with primary or clear responsibility for developing and implementing a strategy for promoting and protecting U.S. biotechnology advancements.[35] Federal coordination is increasingly imperative as biotechnology advances and converges with other technologies, its applications broaden to a wider range of sectors, and its potential for misuse grows.[36]

Improved coordination across Federal agencies would allow for cross-functional biotechnology projects that capitalize on strengths and reduce redundancy. For example, research agencies could assist regulatory agencies in horizon scanning for novel products that may not fit within existing authorities. Coordination between research and regulatory agencies could also reduce bureaucratic burden for developers. Regulatory agencies could alert trade and diplomatic agencies of biotechnology products that are nearing approval to prepare markets to receive the products. And, cooperation on outreach activities could improve consistency in how Federal agencies talk about biotechnology with the public.

We intend to identify necessary actions to ensure effective coordination across the U.S. Government on areas such as R&D, regulatory oversight, biosafety and biosecurity, norms and standards, education and workforce, outreach,

and strategic planning. Toward that goal, we are identifying frameworks that may serve as examples for Federal coordination, such as the National Quantum Initiative, the National Nanotechnology Initiative[37,38] and the National Artificial Intelligence Initiative.[39]

Accelerate innovation and embrace biotechnology

The world has arrived at this critical moment for biotechnology following years of growth and innovation. Fifteen years of low interest rates[40] allowed access to capital and supercharged private investment in biotechnology innovation. Breakthrough discoveries and high degrees of public-private cooperation during the COVID-19 pandemic also contributed to the rapid pace of innovation. In 2020, global private investments in the biotechnology sector totaled more than $23 billion, a 60% increase from 2019.[41] These investments occurred alongside rapid developments in complementary fields, like artificial intelligence and machine learning (AI/ML), automation, robotics, and quantum computing. Viewed together, these developments can dramatically change the landscape of discovery and accelerate the rate of innovation in biotechnology.

However, more recently, the financial environment has cooled, and there is less access to capital. Biotechnology discovery, development, and deployment are capital-intensive and time-consuming. Researchers and financiers agree that it still takes too long and costs more than it could to get new products from the lab to the commercial market. We are considering ways the U.S. Government can reduce barriers at each stage.

The U.S. Government can foster innovation, for example, by supporting areas where biotechnology converges with other emerging technologies, such as AI and quantum. The U.S. Government already invests in both basic and applied R&D, and we are looking for unexplored areas where research may accelerate biotechnology discovery for specific defense and intelligence applications, particularly where no other funder is likely to invest.

The Government could support the development of flexible biomanufacturing infrastructure and other incentives to help lower production costs, ensuring what is invented here can be made here. The Commission is examining whether existing or new governmental tools and incentives (e.g., loan guarantees, tax incentives, and public-private ventures) are needed to stimulate industry investment in infrastructure and biomanufacturing capacity. We are also looking at ideas to increase American understanding of biotechnology, as well as ensure that Americans who want to join the biotechnology workforce have access to needed skills training.

Leverage convergence with other advancing technologies

Other emerging technologies such as automation, advanced computing, and additive manufacturing have the potential to enable and accelerate biotechnology development. For example, nanoscale quantum dots (extremely tiny crystals that can emit different colors of light), a discovery that led to the 2023 Nobel Prize in Chemistry,[42] are being used as biosensors to detect selected pathogens.[43]

Similarly, biotechnology will play a critical role in supporting the maturation of other emerging technologies. For example, researchers are exploring DNA as a new form of high-density data storage as demand for storage is estimated to increase by orders of magnitude by 2025.[44]

The combination of different technologies and research areas with biotechnology is sometimes referred to as "bioconvergence."[45] We find that U.S. Government agencies are not currently equipped with the policies and tools needed to adequately encourage, facilitate, and assess developments in bioconvergence to advance national security goals. While the U.S. Government supports several initiatives on emerging technologies including biotechnology, AI/ML, quantum, and nanotechnology, we believe more can be done to assess and encourage convergent and interdisciplinary R&D.

To successfully foster a future biotechnology landscape that

enables, and is enabled by, other emerging technologies, we will consider what policies or authorities are needed for agencies to more actively assess bioconvergence, foster innovation, and encourage collaboration. To guide our efforts, we have generated a list of emerging technologies and research areas of interest to explore how these may codevelop with biotechnology R&D (*see Figure 7*).

We will explore which technologies hold the greatest promise for codeveloping with biotechnology, and we will identify what policies are needed to unlock their full potential. These policies include promoting multidisciplinary research approaches and breaking down silos between technology areas. Ultimately, we aim to ensure that the U.S. Government remains the leader in biotechnology innovation by fully leveraging the opportunities presented by bioconvergence.

Support computation and data analytics for biology

Data analytics (e.g., AI/ML and its subdisciplines such as deep learning, large language models, and natural language processing) are rapidly changing what is possible for research and discovery. By accurately predicting and modeling protein structures using AI/ML, developers can design molecules better, saving time and resources while creating more effective treatments. For example, AI/ML systems are accurately predicting protein structures from their corresponding genetic sequences,[46,47] allowing drug developers to create more effective medications.[48]

Many of these new systems for advanced data analytics are still in early phases of development and will continue to mature in sophistication and capability. We are exploring whether and how these innovations raise national

Figure 7. Convergence Areas

Computation

Enables biotech
- Quantum computers
- Human-machine training
- Advanced computing
- Quantum simulations

Enabled by biotech
- Biological computing
- Neural networks
- DNA data storage
- Neuromorphic computing
- Bioelectronics

Measurement

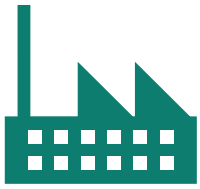
Enables biotech
- Virtual biological models
- Quantum sensors
- Physiological sensors
- DNA, RNA, and protein sequencing
- New sensing and analytical technologies
- Animal-free experimental models

Enabled by biotech
- Biological sensors

Robotics

Enables biotech
- Automation and self-driving labs
- Precision control mechanisms

Enabled by biotech
- Nature-inspired robotics
- Biohybrid robots



Advanced Manufacturing

Enables biotech
- Fit-for-purpose materials
- Virtual biological models
- Nanofabrication

Enabled by biotech
- Synthetic organs
- Synthetic organisms
- DNA, RNA, and protein synthesis
- Engineered microbes for chemical production
- Biological additive manufacturing
- Engineered organisms for production
- Bioengineered materials

> "The rapid progress in AI/ML and quantum technologies are propelling a significant surge in biotechnology advancement. This emerging wave of innovation will profoundly impact medicine, industry, agriculture, and defense. These developments will swiftly permeate every facet overseen by Congress. It is imperative for Congressional leaders to proactively address this impending wave, offering guidance and allocating necessary funding to navigate these changes effectively. By doing so, the United States can harness the full potential of these advancements for the benefit of its citizens and national interests."
>
> *— Commissioner Paul Arcangeli*

security concerns and are assessing policies to mitigate those concerns.[49,50]

Other U.S. Government entities have explored the promises and risks of AI/ML in depth.[51] In contrast, we are specifically interested in policy mechanisms to help experts adopt advanced data analytics to responsibly accelerate the development of biotechnologies. We are considering several important components, including:

- **Encouraging development and implementation:** AI/ML and other types of advanced computing can help many different components of biotechnology workflows but require collaboration and platform building for easier access to different tools.
- **Ensuring the quality and quantity of biological data:** the data used to train algorithms will need to be of sufficient quality and diversity so that the software can produce helpful results.
- **Exploring safeguards**: advanced computing systems could be misused, and we need to understand what protections could or should be adopted.

Collect and leverage biological data for future innovation

Biological data, including but not limited to genomic and other "-omics" data, phenotypic data, biological imaging, and whole organism physiology, are the foundation of biotechnology discovery across medicine, agriculture, and other sectors. Such data are vital not only for initial discovery, but also for refining manufacturing processes, and gaining efficiencies along the research-to-product continuum. Further, data assets of adequate size, type, and biological diversity are necessary to realize AI/ML's potential.

Biological data come with challenging policy considerations that must balance openness and security. Open access to data is necessary for researchers to maximize the potential of their discoveries and accelerate innovation. Data security and protection remain important for a variety of scenarios, including to protect personal information, national security, and data that provide a strategic economic advantage, such as company data related to the development of a new product. We are considering realistic steps to encourage innovation through findable, accessible, interoperable, and reusable biological data while also appropriately protecting information. To remain competitive globally, we are considering the following lines of investigation and policy actions:

- **Data asset identification and sustainability**: We are identifying and cataloging open-source, privately owned, and non-public U.S. Government data assets that are relevant to biotechnology and that contain information of value to national security. Our goals are to identify gaps in data assets

in which the U.S. Government could invest and to provide recommendations to improve access to datasets as appropriate. We also aim to offer recommendations that would promote sustained access to useful databases.

- **Interoperability:** To facilitate interoperability, we want to understand the necessary tools to connect different databases. As government programs continue to generate and acquire data, it will be critical to ensure that data are compatible with and available for a variety of end uses.
- **Partnerships**: Data sharing collaboration is critical for continued and accelerated biotechnology innovation. We plan to explore options to encourage robust relationships related to data, including public-private, international, and government agencies partnerships.
- **Security and protections:** Through an analysis of the existing data landscape in the United States, we intend to consider what cybersecurity and policy tools are needed to ensure sufficient data protection. The U.S. Government maintains significant public databases of biotechnology-related data, but the use and integrity of these databases need attention.[52] We will consider research into cyber attacks on private systems with valuable biological data to identify patterns and threats.[53] Specific data types (e.g., human genomic data, data from wearable digital health devices, and biomedical research data) pose security and privacy concerns and lack standards to promote safe storage and sharing.[54] We plan to analyze if current privacy laws, such as the Health Insurance Portability and Accountability Act (HIPAA), are sufficient to ensure we are protecting critical information about every American. To inform our policy recommendations, we plan to review global policies on data sharing and research regarding data that do not fall under existing security frameworks.

China's data fusion

The People's Republic of China (PRC) has a holistic, government-led approach to data generation, storage, and analysis. This coordination includes leveraging data from companies within the PRC, U.S. open-source resources, and data generation activities globally, including in low- and middle-income countries where there are significant data gaps.[55, 56] For example, the BGI Group, which has a demonstrated history of collaboration with the PRC military,[57] collected massive amounts of genetic information from around the world during the COVID-19 pandemic.[58, 59] Stakeholders and U.S. Government officials note that it is difficult, if not impossible, to know how these data are being used and combined with other data by the PRC. As a result, it is challenging to understand the threats this data fusion may present.

Scan the horizon for new and emerging technologies

To maintain a competitive advantage on the global stage, the U.S. Government must identify emerging biotechnologies and be prepared to act on opportunities those technologies create. Horizon scanning, a practice used to identify opportunities and risks associated with emerging technologies, can offer those insights. However, we have seen that horizon scanning practices and capacity are not always consistent and adequate across agencies, and existing biotechnology horizon scanning practices may not always be conducted in a way that is oriented toward specific goals or that helps an agency accomplish its missions. There are several groups that have elucidated methodologies for horizon scanning,[60,61,62] and the U.S. Government has also undertaken several efforts in science and technology horizon scanning.[63]

> "In the age of advanced computing, having access to biological data provides a critical strategic advantage. The U.S. must make use of and maintain the data it has, incorporate new data into existing systems, and design systems with adaptability for future uses in mind."
>
> *— Commissioner Alexander Titus*

We and others have identified three deficiencies that may be addressed through future policy recommendations:[64,65]

- **Ineffectiveness of horizon scanning activities:** Federal agencies do not consistently or effectively conduct horizon scanning to identify relevant opportunities presented by emerging biotechnologies. This limits the U.S. Government's ability to prepare for technology advances and best position itself to take advantage of new capabilities. In addition, agencies do not always have visibility into, or awareness of, emerging biotechnologies that might address their national security concerns, especially when those technologies are developed without U.S. Government involvement.
- **Lack of deliberation and planning when applying horizon scanning:** Many Federal agencies have not identified specific situations where biotechnology horizon scanning will be effective and valuable, nor have they established end goals to justify horizon scanning. We want to ensure that U.S. Government agencies employ horizon scanning with intention.
- **Lack of expert participation:** We have heard the need for Federal agencies to engage with experts to develop national security recommendations. Appropriately incorporating non-governmental subject matter expertise will ensure that the U.S. Government has a complete set of information regarding research questions and opportunities.

Fund opportunities for innovative research

The Commission believes there is a thriving biotechnology innovation ecosystem in the United States that should not only be maintained but strengthened. We have heard from several sources that diverse U.S. Government funding opportunities to pursue groundbreaking biotechnology research are critical components of maintaining our current pace of innovation. Several Federal agencies including DoD, USDA, DOC, National Institutes of Health (NIH) within HHS, Department of Energy (DOE), and National Science Foundation (NSF) have specific research funding for biotechnology that include both basic research and technology-driven funding calls (*see Table 2*).

Table 2: Illustrative Examples of Biotechnology Funding in the U.S. Government

Federal Agency	Funding Opportunity	Description
DoD	Defense Advanced Research Projects Agency (DARPA)-Biological Technologies Office (BTO)[66]	An end-goal driven funding mechanism where program staff pursue breakthrough research for DoD. Other Federal agencies have adopted the DARPA model, including HHS (Advanced Research Projects Agency for Health [ARPA-H]), DOE (Advanced Reseach Projects Agency-Energy [ARPA-E]), USDA (Agriculture Advanced Research and Development Authority [AgARDA]) and the Office of the Director of National Intelligence (Intelligence Advanced Research Projects Activity [IARPA]). BTO harnesses biology to develop innovative technologies.
	Multidisciplinary University Research Initiative (MURI) Program[67]	Meant to accelerate innovation through multidisciplinary research. The goal is to encourage convergent research that will have specific national security applications.
NSF	Regional Innovation Engines[68]	A program within the Directorate for Technology, Innovation and Partnerships (TIP), each Engine is built to foster regional innovation in technology development and partnerships across sectors. As of December 2023, 14 development awards were given to biotechnology-related consortia, and two proposed biology-related Engines were selected as finalists.
DOC	Regional Innovation and Technology Hubs (Tech Hubs)[69]	A program within the Economic Development Administration that is meant to fund regional capacity toward emerging industries such as biotechnology. Through capacity building, the programs spur regional innovation, manufacturing, and deployment of new technologies.
	Manufacturing USA[70]	Within Manufacturing USA, three Manufacturing Innovation Institutes (MIIs) are specifically focused on biotechnology: BioFabUSA, working on methods related to cell and tissue culture;[71] the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL);[72] and the Bioindustrial Manufacturing and Design Ecosystem (BioMADE).[73] The MIIs work with and fund interested public and private entities to advance innovative manufacturing. The DoD provides funding for BioFabUSA and BioMADE; the DOC provides funding for NIIMBL.

This table is not meant to be exhaustive and does not include all funding calls or mechanisms that exist.

Preserving data for posterity

Some valuable government data assets are not accessible due to lack of continued funding. One example is the multi-omic, multi-species data from the Defense Advanced Research Projects Agency (DARPA) Technologies for Host Resilience (THoR) and Prometheus programs.[69, 70] DARPA ended the programs without transferring data to an organization with persistent resources to support their preservation. The DoD has stated that once a DARPA program ends, any acquired data should not be submitted into open or government-sponsored data repositories, therefore limiting the ability to maintain important datasets.[71]

We continue to learn about new mechanisms that can be adopted to encourage a strong biotechnology innovation ecosystem or address research gaps. We are particularly interested in exploring innovation models that have been successful in more discrete areas, such as engaging with foreign partners, investing at the state and regional level, partnering with philanthropies, and providing opportunities within biotechnology incubators.

Protect sensitive technological information important to U.S. national security

Innovation and technology maturation rely on protection of intellectual property to assure ownership, control, and returns on intellectual capital. The evolution of knowledge, scientific findings, and intellectual property from discovery to application requires a careful balance between security and collaboration.[77]

Intellectual property protection takes on additional importance when critical technologies, like biotechnologies, are lost to foreign competitors and threaten U.S. economic competitiveness and national security.[78] The illicit transfer of intellectual property disincentivizes innovation as individuals and companies no longer benefit from their original work. Intellectual property theft of emerging technologies and national security assets could also lead to foreign military advantages.

For example, the PRC has targeted American critical technology and established a variety of methods to gain access to technologies critical to national security. The licit and illicit means of technology transfer include foreign direct investment, venture capital investments, joint ventures, licensing agreements, cyber espionage, and talent acquisitions.[79]

We plan to further examine how discoveries are captured by competitors and whether new policies may be necessary to protect biotechnology innovations. We will evaluate means of intellectual property protection and their limitations, including export controls, foreign investment restrictions, visa controls, research security, and others.

Build an ecosystem conducive to innovation

Scaling a discovery into a final product is difficult, and many novel ideas do not transition into commercial products. The process to create a new product or technology involves several steps, including discovery, development of prototypes, scaling, and sustained production (*see Figure 8*).

We plan to examine the necessary attributes of ecosystems in which more innovators can discover, scale, and commercialize novel ideas. Stakeholders confirmed to us that scientists, management professionals, and investors must collaborate for a product to find success.

Even with the right combination of sound science, good management, and sufficient funding, other hurdles may stand in the way of commercial success. We intend to examine these bottlenecks, whether they result from the pace of regulatory decisions, market failures, or other causes. We also plan to examine current mechanisms that support the transition from discovery through commercialization and whether these mechanisms are adequately resourced. For example, the CHIPS and Science

Act supports technology transfer offices, the creation of Collaborative Innovation Resource Centers, and workforce development for entrepreneurial students and faculty.

Expand domestic infrastructure

As more biotechnologies mature and come to market, we will need increased manufacturing infrastructure. We have learned that companies need different types of infrastructure at each scale and that each process must be tested and proven at different scales. This infrastructure varies by sector, as vaccine production infrastructure is different from food or chemical production infrastructure.

We learned that access to appropriate infrastructure is a recurring challenge for many companies. For example, companies looking to secure financing must demonstrate success on a pilot scale, but American companies often go overseas to test their products before scaling up production due to scarcity of domestic pilot-scale facilities.[80,81] We are exploring recommendations that would enable both more pilot- and commercial-scale production in the United States.

Create a resilient supply chain through biomanufacturing

Domestic biomanufacturing can improve resilience by creating redundancies within the supply chain and securing U.S. access to essential chemicals.[82] Major U.S. chemical manufacturing companies are already embracing biotechnology to provide alternative pathways to making critical materials with novel properties and lower carbon footprints. Building biomanufacturing facilities near sources of biomass reduce the need to move supplies throughout the supply chain,[83] making supply chains more efficient for domestic biomanufacturing.

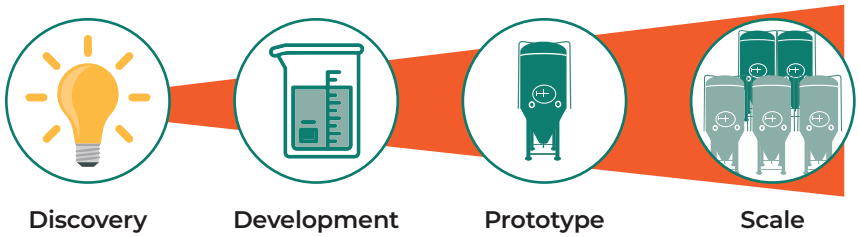
U.S. Government action in support of domestic biomanufacturing could help ensure American innovations create American economic opportunity and increase resilience to geopolitical shocks.

We have found that biomanufacturing faces barriers to innovation because of regulatory questions, inefficient biological yields, lack of standardization, and difficult scaling processes (*see Figure 9 on page 31*).[84,85] Recent failures and stagnation in certain sectors highlight the need for manufacturing that will optimize processes, lower cost, and enable the workforce.[86,87] We are evaluating how to improve manufacturing in the U.S. biotechnology industry, including:

- development of standards and metrics in biomanufacturing;[88]
- smart manufacturing and computer modeling;[89]
- research into bioprocess optimization and scaling;[90]
- standardization and automation of equipment;[91]
- data sharing between processes and facilities;[92]
- increasing biomanufacturing infrastructure and capacity;
- non-model organism R&D;[93] and
- shifting infrastructure models from large, single production facilities to smaller, regional, or more flexible facilities.

> "Advancing biomanufacturing in the United States is key to strengthening our national security. Biomanufacturing can scale up the innovations happening in laboratories across America, diversify our supply chains, and provide good paying jobs to workers with diverse skill sets throughout the country."
>
> *— Representative Ro Khanna*
> *(California, District 17)*

Figure 8. Production Process: From Idea to Products



Promote biotechnology education to increase bioliteracy and bolster the biotechnology workforce

As biotechnology usage expands, building widespread bioliteracy will stimulate interest in biotechnology careers. Expanded bioliteracy will also help consumers to make educated assessments about biotechnologies for a wide range of applications. We plan to identify best practices to engage and educate the public about the benefits of biotechnology and to examine U.S. Government partnerships with public libraries, museums, national parks, and other spaces to expand opportunities for community engagement and education.

Our goals of enabling growth in the biotechnology sector and increasing public bioliteracy require intentional development of a talent pipeline, from K-12 education to professional training (including whether an individual seeks vocational training or pursues graduate studies). The U.S. education system, at all levels, should recognize biology instruction as our earliest opportunity to train future biotechnology sector workers and to raise the overall level of national bioliteracy.

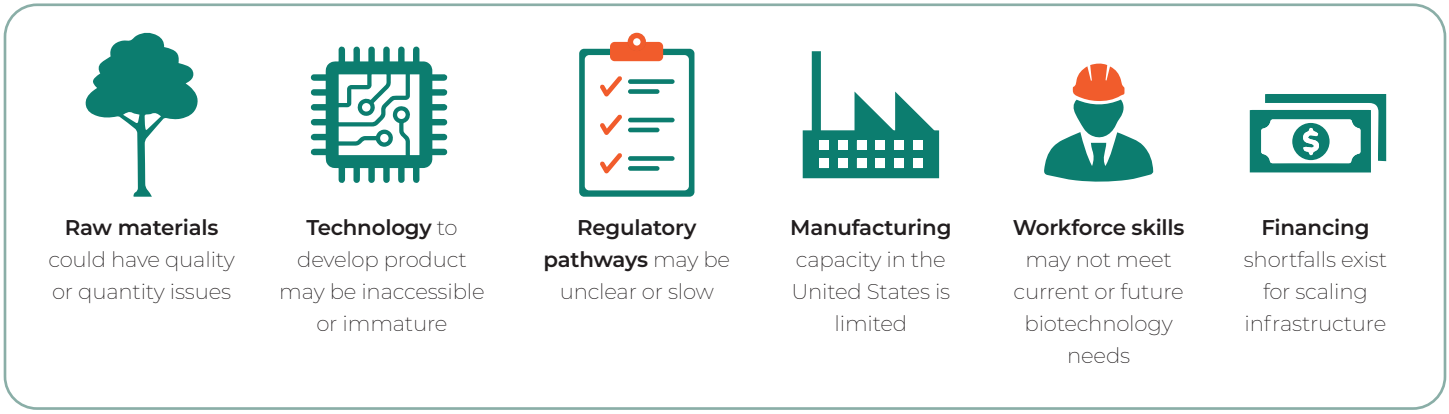
Various reports have highlighted the importance of building capacity for training a larger U.S. biotechnology workforce.[94,95,96] However, quantitative data on the number of current jobs in the biotechnology industry, and the availability of qualified applicants to fill them, are limited and insufficient to make informed estimates on future workforce needs. We are looking at ways to catalog and quantify the types of jobs and workers needed across different biotechnology sectors (including health, medicine, agriculture, environment, and energy) to better understand the current workforce for each sector, make projections for future needs, and develop specific and strategic policy recommendations.

After engaging with education experts and practitioners, we are identifying talent development strategies and learned that promoting student awareness and interest in biotechnology careers starts with early engagement at

Defining the biotechnology workforce

The National Center for Science and Engineering Statistics recently expanded its definition of the STEM workforce and estimated that of the 146.4 million people in the U.S. workforce, 34.9 million (24%) were employed in STEM occupations in 2021.[89] The Bureau of Labor Statistics employs North American Industry Classification System (NAICS) codes to collect data on workforce, but codes for biotechnology and biomanufacturing are not comprehensive. Developing NAICS codes specific to the biotechnology industry will more accurately capture the current number of jobs across different sectors of biotechnology and inform projections for the future workforce needs.

Figure 9. Potential Barriers for a Company Seeking to Scale a Biotech Product



the K-12 level. Experts and professionals have shared how internships and apprenticeships provide students with opportunities for meaningful hands-on training and learning experiences and provides a pathway to biotechnology careers. We are considering how to support biotechnology training programs to build critical talent pipelines for the biotechnology industry. Moreover, we plan to hear from academic institutions, including community colleges, vocational and technical schools, minority-serving institutions, and land-grant universities about how to best engage students and amplify opportunities to develop talent for future biotechnology careers.

Workforce development experts have reported challenges training the next generation of skilled technical workers to support the biotechnology industry. We are examining strategies to cultivate domestic biotechnology talent across different geographic regions of the United States as well as strategies to attract and retain foreign STEM talent. We understand that an overall lack of training programs for bioprocessing and biomanufacturing severely limits the number of skilled technical workers available to fill jobs in those spheres. For instance, while there are associate degree programs for entry-level technician jobs in small molecule manufacturing, there are few such degree or certification programs for cell and gene therapy manufacturing. There is also a limited number of qualified bioprocessing and biomanufacturing instructors in U.S. academia, contributing to a skills mismatch in industry when students ultimately enter the workforce.

We plan to explore how the U.S. can expand existing public-private partnerships such as BioMADE, BioFabUSA, and NIIMBL. We will also explore opportunities to bolster industry-academia collaboration that can improve training and education, build capacity where needed, and develop a skilled biotechnology workforce. As techniques and methodologies evolve, providing workers with training opportunities to up-skill or re-skill will create a nimble workforce that can advance with the industry. We are also considering options for increased Federal support for biotechnology apprenticeships and training programs at community colleges, technical, and vocational schools.

> "Biomanufacturing is the next great American industry. A vibrant private sector and thriving bioeconomy will create jobs, power innovation, and ensure sustainability. By capitalizing on new biotechnology opportunities, we'll be able to tackle challenges facing our nation and our security."
>
> *— Commissioner Eric Schmidt*

Protect against misuse and promote norms for responsible use

As new biotechnologies emerge and paint an exciting picture for the future, it is important to recognize that this technology can cause harm, both through its misuse and through unintended consequences. With a responsibility to protect the American people, the United States should be at the forefront of global efforts to anticipate, prevent, and mitigate harm stemming from advancements in biotechnologies. Existing forms of oversight are insufficient to address ethical and legal considerations; for example, human genome editing or the redrawing of the line around what constitutes a bioweapon. The Commission believes that continued, proactive conversations on the responsible development and use of biotechnologies are warranted to prevent harm and to ensure that our nation realizes the technology's many opportunities.

The Commission has collected a variety of perspectives about how governance and regulatory frameworks must evolve to responsibly advance and secure the development of biotechnologies, biomanufacturing, and associated technologies. As we consider any changes in the U.S. governance landscape for emerging biotechnology, we will focus on how to prevent the misuse of biotechnologies while also identifying and promoting norms around responsible innovation.

Prevent, detect, and respond to misuse

The Commission is examining the potential ways that misuse of emerging biotechnologies may strain existing governance capabilities, such as by lowering barriers to access to technology that could be used to cause harm, or that increase the likelihood of the creation of bioweapons. Changes may be needed to strengthen governance systems to deter, detect, and defend against the deliberate or accidental misuse of these technologies. We are engaging with a broad set of stakeholders to determine what specific organizational changes or policy options would help the United States prepare for a variety of threat vectors.

Emerging technologies may themselves provide the technical capabilities to preempt, detect, and mitigate misuse concerns, and we are actively exploring ways that the Commission may further encourage the development and implementation of these technologies. For example, wastewater surveillance could help with early detection of biological threats.

We plan to explore best practices for responsible innovation that prevents misuse. For example, there are currently no codified best practices for DNA synthesis screening or development of hardware and software safeguards within synthesizers. We plan to assess options for codifying those best practices, including identifying private and government stakeholders responsible for implementing the best practices.

Promote reasonable and responsible governance

While rapid growth in biological data, knowledge, and technologies comes with a host of opportunities, wider accessibility presents unique risks. These risks are exacerbated by factors ranging from cybersecurity concerns[98] to decreasing input costs for technologies such as DNA synthesis.

Earlier in this report, we articulated the Commission's interest in convergence of nascent technologies. During initial conversations with a broad cross-section of stakeholders, we learned about the risks associated with the convergence of biology and other emerging technologies and the significance of the United States' strategic competition with other countries in this space such as the PRC.[99]

The proliferation of biotechnologies featuring smaller footprints could make centralized oversight more difficult, underscoring the importance of surveillance methods that may be more effective despite wider distribution. In this context, the Commission recognizes the importance of the United States' leading the international community in a cooperative effort designed to promote peaceful, safe, and secure uses of biotechnology.

We are considering paths forward including:

- collaborating with industry and federal leaders to build more resilience and self-sufficiency into domestic supply chains and data storage systems; and
- connecting with allies and partner countries on legislative approaches to biotechnology misuse cases, highlighting common challenges, and encouraging international dialogue.

Engage with those guiding innovation

Threats to the United States arising from advances in biotechnology come not only from foreign state and non-state actors but also from accidents that will inevitably occur as the technology is developed and deployed. Moreover, apart from the risk of accidental or malicious misuse of biotechnologies, our current governance systems may fail to prevent harming, marginalizing, or leaving behind vulnerable people.[100,101,102] Tensions with countries like the PRC around emerging biotechnology are not only about who leads innovation in this field but also reflect a competition over different beliefs regarding what good innovation looks like and how and what types of societies it serves.[103]

As the landscape of emerging biotechnology continues to shift and grow, the Commission believes in the need for governance systems to evolve appropriately alongside it. To do so, we first plan to better understand the relationship between public trust and the means and methods of biotechnology innovation, and use that understanding to build policy and legislative options to strengthen trust between biotechnology developers, the public, and others. Our potential paths forward include:

- understanding the unintended past and potential harms of biotechnology, particularly to populations who may have experienced disproportionate levels of harm;
- identifying specific examples where ethical guardrails may be needed in biotechnology research or application; and
- evaluating specific incentives for biotechnology users, researchers, and developers to participate in governance development and implementation.

> "Much of the fundamental biotechnology used in the world today was catalyzed by innovations in the United States. In order to remain leaders as the field of biotechnology continues to advance in ways that affect so many aspects of our lives, from health to energy and the environment, it is imperative that we continue to engage the public sector and encourage the future workforce in this emerging field and economy."
>
> *— Commissioner Angela Belcher*

Ensure governing frameworks are adaptable

We intend to highlight the real-world experience of practitioners who carry out the day-to-day tasks of governing misuse. As we explore potential recommendations to mitigate misuse and encourage responsible innovation, we will seek to incorporate the expertise of all relevant practitioners, from lab bench workers and operations managers to academic researchers and intelligence community professionals.

We have learned that companies and research groups in areas of emerging biotechnology are actively testing ways to create adaptive governing capacity on biosafety, biosecurity, and ethical concerns, even without Federal incentives to do so. One example is the development of systems for screening gene sequences being synthesized to check

> "The United States has high ethical and moral standards, and it is crucial that these are applied to the fields of biotechnology and the emerging bioeconomy. The United States must be a leader in this area as we work to secure threats to our national security."
>
> — *Representative Stephanie Bice*
>
> *(Oklahoma, District 5)*

not only for known pathogens but also other "sequences of concern."

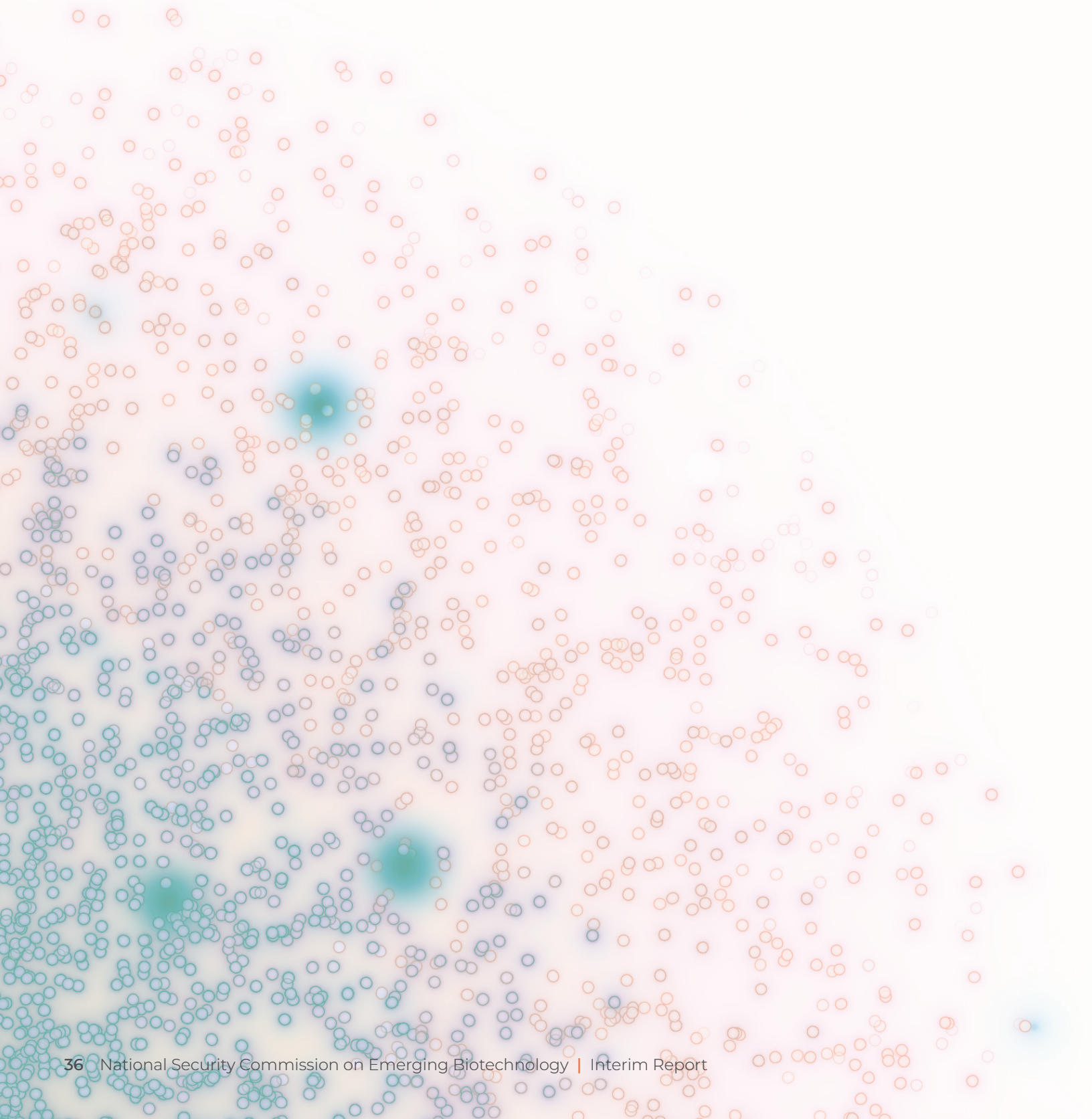
Over the next year, we will examine how biotechnologies or other emerging technologies impact the ease of misuse scenarios. We will also consider scenarios to test how existing proposals and recommendations could fail, including cases of insufficient resources, oversight, and coordination between and within government agencies.

Looking ahead

The Commission recognizes its unique platform as a legislative entity with the authority to not only gather and analyze information but also to produce substantive policy reports and recommendations. For the remainder of our authorization, we intend to drive the U.S. Government towards policies and practices that best leverage American biotechnology and biomanufacturing to bolster our national security.

As we continue our work, we invite you to engage with us and share feedback to inform our recommendations. To contact the Commission, please visit https://www.biotech.senate.gov or email us at ideas@biotech.senate.gov.

Appendices



Appendix I: NSCEB Federal agency engagement

The Commission initiated a concerted stakeholder engagement effort in May 2023. As of mid-November 2023, that effort included contact with the following Federal government entities. We assert that this contact is just the beginning of an extensive effort to meet and work with a wide range of Federal, state, and international government entities, as well as entities in industry, academia, and elsewhere, to further our understanding of biotechnology opportunities and challenges in order to form our recommendations. This outreach will continue throughout the duration of the Commission.

Department of Defense

- United States Army
- Department of the Navy
- Office of the Secretary of Defense (DoD Manufacturing Technology Program)
- Office of the Undersecretary of Defense (Acquisition and Sustainment)
- Office of the Undersecretary of Defense (Intelligence and Security)
- Office of the Undersecretary of Defense (Research and Engineering)
- Office of Net Assessment
- Defense Intelligence Agency
- Defense Innovation Unit
- Defense Sciences Board
- Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense

Department of State

- Bureau of Intelligence and Research
- Bureau of International Security and Nonproliferation
- Office of Science and Technology Cooperation
- Office of the Special Envoy for Critical and Emerging Technology

Department of Justice

- Federal Bureau of Investigation

Department of Agriculture

- Agricultural Research Service
- Foreign Agricultural Service
- National Institute for Food and Agriculture
- Office of the Secretary
- Office of the Chief Economist
- Office of the Chief Scientist
- Rural Business-Cooperative Service

Department of Commerce

- Economic Development Administration
- National Institute for Standards and Technology
- Bureau of Industry and Security

Department of Health and Human Services

- Administration for Strategic Preparedness & Response
- Food and Drug Administration
- National Institutes of Health
- Advanced Research Programs Agency for Health

Department of Energy

- Lawrence Berkeley National Laboratory

- Lawrence Livermore National Laboratory
- Los Alamos National Laboratory
- National Renewable Energy Laboratory
- Office of Energy Efficiency and Renewable Energy
- Pacific Northwest National Laboratory
- Sandia National Laboratories

Department of Homeland Security

- Cybersecurity and Infrastructure Security Agency

Environmental Protection Agency

- Office of Pesticide Programs

Executive Office of the President

- Office of Management and Budget
- Office of the United States Trade Representative
- Office of Science and Technology Policy
- National Security Council

Office of the Director of National Intelligence

Central Intelligence Agency

National Science Foundation

Appendix II: Proposed legislative text

Recognizing that food security and agricultural supply chains are key elements of national security, the Commission developed the following three legislative proposals: the Agriculture and National Security Act, the Biotechnology Oversight Coordination Act, and the Agricultural Biotechnology Coordination Act. These proposals are intended to lay the groundwork for further recommendations.

Securing agricultural production and supply chains

Designated as critical infrastructure[104], U.S. agricultural systems are complex, integrated networks that have many potential failure points and that are often a target of efforts by the People's Republic of China to strengthen its own agricultural systems.[105] This bill recognizes the importance of identifying and mitigating threats to food and agriculture, particularly with regard to emerging technologies, by instructing the U.S. Department of Agriculture (USDA) to identify and resolve any gaps or limitations related to food and agriculture in existing Federal national security efforts. Specifically, the bill has USDA consider such issues as the influence of state-owned enterprises; foreign acquisition of intellectual property, agricultural assets, and land[106,107]; and supply chain and trade disruptions.

The bill would also establish a Senior Advisor for National Security in the USDA Office of the Secretary to work in partnership with the USDA Office of Homeland Security to elevate these issues, interact with national security agencies, and advise the Secretary of Agriculture. While some previous USDA Senior Advisors have had national security in their portfolio, this would be the first time such a position would be required in statute.

The Agriculture and National Security Act

To improve connections between the Department of Agriculture and national and homeland security agencies, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Agriculture and National Security Act".

SEC. 2. SENSE OF CONGRESS RELATING TO AGRICULTURE AND NATIONAL SECURITY.

It is the sense of Congress that there are increasingly robust federal activities to address homeland security vulnerabilities across the food and agriculture sector, including with regard to agriculture and food defense, critical infrastructure, emergency management, and high consequence and catastrophic events; however, additional efforts are needed to identify national security vulnerabilities related to food and agriculture, particularly with regard to emerging technologies.

SEC. 3. NATIONAL SECURITY.

(a) In General.—In recognition that food and agriculture are critical to the national security of the United States, the

Secretary of Agriculture (referred to in this Act as the "Secretary") shall prioritize national security in addition to homeland security in the Department of Agriculture (referred to in this Act as the "Department"), including by increasing the number of staff at the Department with security clearances and access to classified systems and networks.

(b) Senior Advisor for National Security.—

(1) Appointment.—Not later than 180 days after the date of enactment of this Act, the Secretary shall—

(A) establish within the Office of the Secretary the position of Senior Advisor for National Security (referred to in this Act as the "Senior Advisor"); and

(B) appoint an individual to the position of Senior Advisor.

(2) Duties.—The Senior Advisor shall, in coordination with and complementary to the duties of the Office of Homeland Security of the Department—

(A) serve as the principal advisor to the Secretary on national security;

(B) act as the primary liaison on behalf of the Department with the National Security Council and other Federal departments and agencies in activities relating to national security;

(C) coordinate national security activities across the Department, including to ensure that national security concerns are integrated into the Department's homeland security activities, wherever appropriate; and

(D) communicate with stakeholders to identify national security vulnerabilities and risk mitigation strategies relevant to food and agriculture.

(c) Interagency Coordination.—Section 221(e) of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6922(e)) is amended by adding at the end the following:

"(3) Detailees authorized.—The Secretary may provide detailees to and accept and employ personnel detailed from defense, national and homeland security, law enforcement, and intelligence agencies, with or without reimbursement, to improve information sharing, vulnerability identification, and risk mitigation related to food and agriculture.".

(d) Biennial Reports.—Section 221 of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6922) is amended by adding at the end the following:

"(f) Biennial Reports.—Not later than 180 days after the date of enactment of this subsection, and not less frequently than once every 2 years thereafter, the Secretary shall submit to Congress and the National Security Council a report that includes—

(1) from the Department's perspective, an assessment of any gaps or limitations in national security efforts related to food and agriculture in the United States, including—

(A) influence of foreign state-owned enterprise;

(B) control of and access to agricultural data;

(C) foreign acquisition of intellectual property, agricultural assets, and land;

(D) agricultural input shortages and dependance on foreign-sourced inputs;

(E) supply chain and trade disruptions;

(F) science and technology cooperation;

(G) unequal investments in research, development, and scale-up;

(H) incongruent regulatory policies; and

(I) other vulnerabilities throughout food and agriculture, particularly with regard to emerging technologies;

(2) the actions taken by the Secretary to address any gaps or limitations identified under paragraph (1), including through interagency coordination, threat information sharing, and stakeholder outreach;

(3) policy recommendations, including recommendations for executive actions and legislative proposals—

(A) to reduce any gaps or limitations identified under paragraph (1), and

(B) to address any identified vulnerabilities with respect to the gaps or limitations identified under paragraph (1); and

(4) resources the Department requires to address current and future national security vulnerabilities related to food and agriculture."

Coordinating regulation of biotechnology products

Biotechnology developers have cited a longstanding need for regulatory efficiency and clarity. This bill would, for the first time in the nearly 40-year history of U.S. biotechnology regulation, require in statute that the Office of Science and Technology Policy coordinate biotechnology oversight. The bill would establish a coordination committee across Federal agencies responsible for biotechnology oversight, building toward a truly coordinated U.S. regulatory system for biotechnology. Through this coordination committee, agencies would provide Congress with information needed for further regulatory improvement. The bill would instruct the committee to develop a unified process for regulation of biotechnology products that could have occurred naturally or with conventional breeding, and to consider how to incorporate this unified process into agency oversight. The bill would also instruct the committee to identify characteristics that may reduce risk of producing substances intended for extraction (i.e., molecular farming and precision fermentation) in plants, animals, and microorganisms. As described above, the Commission is considering further recommendations to improve the U.S. biotechnology regulatory system and how regulation by trading partners affects U.S. biotechnology companies.

The Biotechnology Oversight Coordination Act

To establish an interagency committee to coordinate activities of the Federal Government related to biotechnology oversight, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Biotechnology Oversight Coordination Act".

SEC. 2. FINDINGS, PURPOSE.

(a) Findings.—Congress finds that—

(1) biotechnology harnesses the power of biology to create new products and provides opportunities to grow the United States economy, provide jobs for a skilled workforce, improve resilience of supply chains, and improve the quality of human lives and the environment; and

(2) a science-based, risk-proportionate, predictable, efficient, and transparent system to support the safe use of products of biotechnology will enable the United States to continue to be a world leader in biotechnology research and development.

(b) Purpose.—The purpose of this Act is to coordinate and enhance the efforts of the Federal Government under the Coordinated Framework for Regulation of Biotechnology to protect health and the environment while enabling development, commercialization, and safe use of products derived from plants, animals, and microorganisms developed with biotechnology.

SEC. 3. BIOTECHNOLOGY OVERSIGHT COORDINATION COMMITTEE.

(a) Establishment of Committee.—

(1) In General.—The President, acting through the Office of Science and Technology Policy and the Office of Management and Budget, shall establish an interagency committee to coordinate activities of the Federal Government related to biotechnology-specific regulation and oversight (in this section referred to as the "Committee").

(2) Charter.—Not later than 90 days after the date of the enactment of this Act, the Committee shall make publicly available on the Unified Website for Biotechnology Regulation developed pursuant to Executive Order 13874 (relating to modernizing the regulatory framework for agricultural biotechnology products) (in this section referred to as the "Unified Website") a ratified charter for the operation of the Committee; this initial charter may be expanded upon or modified by the Committee as needed.

(b) Membership.—The Committee shall be composed of the heads, or their designees, of agencies responsible for biotechnology oversight, including—

(1) the Animal and Plant Health Inspection Service, the Agricultural Marketing Service, and the Food Safety and Inspection Service of the Department of Agriculture;

(2) the Food and Drug Administration and the National Institutes of Health of the Department of Health and Human Services;

(3) the Environmental Protection Agency;

(4) the Office of Management and Budget;

(5) the Office of Science and Technology Policy; and

(6) other Federal agencies or entities as determined appropriate by the Chair of the Committee.

(c) Chair.—The Director of the Office of Science and Technology Policy shall serve as the Chair of the Committee.

(d) Regulatory Streamlining.—The Committee shall expand build upon efforts to coordinate biotechnology oversight, including through measurable steps to:

(1) align or clarify regulatory timelines, approaches, and data requirements;

(2) facilitate information sharing between regulatory agencies, notwithstanding other provisions of law;

(3) identify an initial point of contact for each type of biotechnology product, including emerging products, and clear hand-offs from one process or agency to another;

(4) identify and minimize any areas of delay relative to established timeframes, including by reducing duplicative review and building upon prior reviews to the maximum extent possible; and

(5) conduct periodic horizon scanning for emerging biotechnology processes and products to ensure appropriate oversight.

(e) Report to Congress.—Not later than one year after the date of the enactment of this Act, and annually thereafter, the Committee shall submit to Congress and make publicly available on the Unified Website the following:

(1) Measurable actions taken and next steps to address paragraph (c), with description of successes, specific staffing and resource needs, and recommendations for removing any identified barriers, including changes to statutes, regulations, or guidance.

(2) A summary of oversight duration from initial contact with the developer to a decision for biotechnology products during a minimum of five fiscal years preceding the date of the report, indicating the type of product, type(s) of review, and the agency or agencies that reviewed that product, with explanation of timelines where needed.

(f) Unified Process.—Not later than 180 days after the date of the enactment of this Act, and annually thereafter, the Committee shall submit to Congress and make publicly available on the Unified Website the following:

(1) A singular, unified process to identify whether a plant, animal or microorganism produced with biotechnology could reasonably have occurred naturally or been developed by conventional means (i.e., resulting in genetic sequences that are present in the organism's gene pool or that could have arisen through natural mutation mechanisms), taking into account existing agency assessments where appropriate.

(2) Measurable actions the Committee and any member of the Committee will take to implement or consider the unified process in subparagraph (1) in their oversight of biotechnology products, taking into account that organisms identified via the process in subparagraph (1) would continue to be regulated with product-specific oversight.

(3) Actions taken and progress made with respect to subparagraph (2).

(g) Molecular Farming and Precision Fermentation.—Not later than 180 days after the date of the enactment of this Act, and annually thereafter, the Committee shall submit to Congress and make publicly available on the Unified Website the following:

(1) Characteristics of organisms that may increase risk pathways or otherwise hinder production of substances intended for extraction.

(2) Characteristics of organisms that may reduce risk pathways associated with production of substances intended for extraction.

(3) Conditions that are useful for containing or segregating organisms produced with biotechnology that may reduce risk pathways associated with production of substances intended for extraction.

(4) Examples of organisms that fit some or all of the characteristics under subparagraph (2) and that are amenable to some or all of the conditions under subparagraph (3).

(5) Measurable actions the Committee and any member of the Committee will take to implement or consider the characteristics under subparagraph (2) and the conditions under subparagraph (3) into their oversight of biotechnology products.

(6) Actions taken and progress made with respect to subparagraph (5).

(h) Coordination and Consultation.—

(1) Coordination.—The Committee shall coordinate, as appropriate, with other working groups and committees of the Federal Government and with other relevant agencies.

(2) Consultation.—The Committee shall regularly consult in a coordinated fashion regarding biotechnology oversight, including with respect to the reports in paragraph (d), with States, Indian Tribes, territories, local governments, biotechnology developers and relevant industries, academic institutions, nongovernmental organizations, and other stakeholders.

(i) Executive Secretariat.—The U.S Department of Agriculture shall appoint an Executive Secretary to serve the Committee, who shall be a permanent employee of and remain in the employ of that Department; the Department of Health and Human Services, and the Environmental Protection Agency may similarly appoint one employee each to the Executive Secretariat.

(j) Comptroller General Review.—The Comptroller General of the United States shall—

(1) not later than one year after the date of the enactment of this Act, begin a review to assess the efficacy of interagency coordination and other activities conducted by the Committee;

(2) not later than 18 months after the date of the enactment of this Act, brief to Congress the initial findings of the Comptroller General with respect to the activities of the Committee; and

(3) not later than 24 months after the date of the enactment of this Act, provide a report to Congress describing the current statutory authorities and oversight processes applicable to biotechnology-specific regulation of products derived from plants, animals, and microorganisms developed with biotechnology, including a description of opportunities to reduce gaps, duplication, overlap, and fragmentation.

(k) Exclusions.—This Act shall not apply to human medical research and products that are regulated solely by the Food and Drug Administration.

Coordinating agricultural biotechnology within the Department of Agriculture

Within the USDA, biotechnology policies and activities span multiple agencies, including research and development (R&D), extension and education, regulatory oversight, labeling, and trade. This bill would establish a USDA Office of Biotechnology Policy, similar to the Office of Pest Management Policy that was established in the 1998 Farm Bill.[108] This Office of Biotechnology Policy would be responsible for coordinating agricultural biotechnology activities within USDA and across the U.S. Government and would serve as a point of contact for biotechnology developers, academics, agricultural producers, and other entities that may be affected by biotechnology policies at the state, Federal, or international level.

The Agricultural Biotechnology Coordination Act

To establish an Office of Biotechnology Policy in the Department of Agriculture, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Agricultural Biotechnology Coordination Act”.

SEC. 2. OFFICE OF BIOTECHNOLOGY POLICY.

(a) In General.—The Secretary of Agriculture (referred to in this section as the “Secretary”) shall prioritize biotechnology in the Department of Agriculture (referred to in this section as the “Department”) by providing for the effective

coordination of policies and activities with respect to biotechnology, biomanufacturing, synthetic biology, and related emerging technologies.

(b) Establishment.—The Secretary shall establish within the Department an Office of Biotechnology Policy (referred to in this section as the "Office").

(1) Director.—The Office shall be headed by a Director, who shall report directly to the Secretary or a designee of the Secretary.

(c) Duties of the Office.—The Office shall be responsible for—

(1) the development and coordination of policies, activities, and services of the Department with respect to biotechnology and related topics, including research and development; communication, extension, and education; regulation and labeling; and commercialization, use, and trade;

(2) assisting other offices and agencies of the Department in fulfilling their responsibilities related to biotechnology under applicable law; and

(3) carrying out such other duties as may be required under law or as determined by the Secretary.

(d) Interagency Coordination.—In support of the duties required under subsection (c), the Office shall provide leadership to ensure coordination of interagency activities with the Environmental Protection Agency, the Food and Drug Administration, and other Federal and State agencies.

(e) Outreach.—In carrying out the duties of the Office under this section, the Office shall consult as necessary with biotechnology developers, academics, agricultural producers, and other entities that may be affected by biotechnology-related activities or actions of the Department or other Federal or State agencies.

Appendix III: Commission letters

National Security Commission on Emerging Biotechnology

September 15, 2023

The Honorable Gina Raimondo
Secretary of Commerce
U.S. Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

Dear Secretary Raimondo,

As members of the bipartisan National Security Commission on Emerging Biotechnology (NSCEB), we write to urge that the Department of Commerce prioritize investment in biotechnology capacity during the Regional Technology and Innovation Hub (Tech Hub) award process. Greater adoption of biotechnology has the potential to reduce supply chain risk, create R&D and manufacturing jobs across our country, and yield benefits for human health and the environment. Biotechnology has myriad applications important for our national security, including for health, food, and energy security as well as advanced capabilities for our warfighters and intelligence professionals. The United States must continue to invest in biotechnology discovery and deployment to maintain our technological advantage as other countries rapidly invest to close the gap.

We believe the Tech Hub award process presents an important opportunity to maintain the U.S. advantage in this rapidly growing sector and provide significant economic impact. One or more biotechnology-focused Tech Hubs across the country will expand the regional reach of bioeconomy-related prosperity. A biotech Tech Hub designation will also attract additional investment of federal and private funds for regional economies outside that have not previously been centers of biotechnology and biomanufacturing work.

The global economic impact of the biotechnology sector, including advances in biotechnologies, bio-based products, services, and related life sciences processes, is projected to scale in value to $4 trillion per year over the next 10 years according to a McKinsey report published in 2020. With its key technology focus area in biotechnology, the Department of Commerce can support domestic economic and national security interests by awarding Tech Hub designations to eligible biotechnology-focused consortia.

We appreciate your consideration of our request and welcome the opportunity to discuss future initiatives by the Department of Commerce that are aimed at enhancing biotechnology commercialization, job creation and federal investment in maintaining national competitiveness in biotechnology innovation.

Sincerely,

Dr. Jason Kelly, Chair

Dr. Michelle Rozo, Vice-Chair

Sen. Alex Padilla, Commissioner

Sen. Todd Young, Commissioner

Rep. Stephanie Bice, Commissioner

Rep. Ro Khanna, Commissioner

Paul Arcangeli, Commissioner

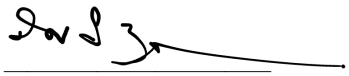
Dr. Angela Belcher, Commissioner

Dawn Meyerriecks

Dawn Meyerriecks, Commissioner

Dr. Eric Schmidt, Commissioner

Dr. Alexander Titus, Commissioner



Dr. Dov Zakheim, Commissioner

National Security Commission on Emerging Biotechnology

October 19, 2023

The Honorable Patty Murray
Chair
Committee on Appropriations
United States Senate

The Honorable Susan Collins
Vice Chair
Committee on Appropriations
United States Senate

The Honorable Kay Granger
Chair
Committee on Appropriations
United States House of Representatives

The Honorable Rosa DeLauro
Ranking Member
Committee on Appropriations
United States House of Representatives

The Honorable Jon Tester
Chair
Subcommittee on Defense Committee
on Appropriations
United States Senate

The Honorable Susan Collins
Ranking Member
Subcommittee on Defense
Committee on Appropriations
United States Senate

The Honorable Ken Calvert
Chair
Subcommittee on Defense Committee
on Appropriations
United States House of Representatives

The Honorable Betty McCollum
Ranking Member
Subcommittee on Defense
Committee on Appropriations
United States House of Representatives

Dear Chair Murray, Vice Chair Collins, Chair Granger, Ranking Member DeLauro, Senator Tester, Representative Calvert, Representative McCollum:

Scaling up biotechnology manufacturing affords the U.S. the opportunity to create high paying jobs across the country, shore up supply chains of key goods like chemicals, materials, and fuel, and create better performing products with fewer associated environmental impacts. As members of the National Security Commission on Emerging Biotechnology, we urge you to consider providing the highest amount possible for the Defense Production Act (DPA) account for Fiscal Year (FY) 2024.

The Department of Defense (DOD) proposed a robust budget for DPA for FY24, including a significant investment to support a jump-start to the biomanufacturing economy that will be beneficial to both our national defense and our economic competitiveness in this rapidly growing sector. China is rapidly closing the technology gap by investing in biotechnology research, development, and production across sectors. We cannot afford to lose a step to China in scaling our biomanufacturing capacity by failing to prioritize these investments in a moment when they are urgently needed.

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In 2022, DOD announced plans to invest $1 billion in domestic manufacturing infrastructure for the biotechnology industry over the next five years. This approach is consistent with work across administrations to harness the potential of advanced biotechnology capabilities that meet warfighter needs. Accordingly, the FY24 President's Budget for DPA purchases included $200M for biomanufacturing capacity development.

As we have canvassed the biotechnology industry and engaged with DOD, we have learned two things: First, biomanufacturing has the potential to address a range of DOD capability gaps and supply chain vulnerabilities in a cost-effective and environmentally responsible manner. Innovators are routinely developing and scaling biotech alternatives to existing products as well as developing products with novel properties.

Second, biomanufacturing infrastructure is capital intensive to develop, just like any manufacturing infrastructure. We have met with several biotechnology companies that are ready to scale that cannot find appropriate infrastructure in the U.S. do so. For example, we recently heard from a U.S. company that is using biotechnology to lessen our dependence on China for the Active Pharmaceutical Ingredients that go into all of our small molecule medicines. This company is currently manufacturing in Europe because there was not adequate infrastructure in the U.S. for their needs.

The U.S. stands to lose scale-up and commercial production capacity to other countries, including in Europe and Asia, that are investing more rapidly and intentionally in biomanufacturing infrastructure than we are. The DPA funding intended for biomanufacturing represents a timely opportunity to inject much-needed government capital into a sector that holds enormous potential for meeting national defense needs and creating jobs across our country, especially near feedstock sources in the U.S. heartland.

Given these considerations, we ask you to consider providing historic, robust DPA funding in any final FY24 appropriations package and to support critical investments in biomanufacturing infrastructure. This demonstration of commitment to this critical industry will support the important work of scaling up biomanufacturing infrastructure as planned, maintaining our technological edge over China, providing certainty to this important industry, and realizing the enormous job-creating potential of this technology. We would be glad to provide the Committee with any additional information that you require and thank you for your consideration of our views.

Sincerely,

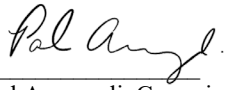
Dr. Jason Kelly, Chair

Dr. Michelle Rozo, Vice-Chair

Sen. Alex Padilla, Commissioner

Sen. Todd Young, Commissioner

Rep. Ro Khanna, Commissioner

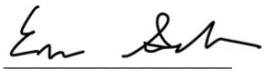


Paul Arcangeli, Commissioner

Dr. Angela Belcher, Commissioner

Dawn Meyerriecks

Dawn Meyerriecks, Commissioner



Dr. Eric Schmidt, Commissioner

Dr. Alexander Titus, Commissioner

Dr. Dov Zakheim, Commissioner

National Security Commission on Emerging Biotechnology

November 30, 2023

The Honorable Lloyd J. Austin III
Secretary of Defense
1000 Defense Pentagon
Washington, D.C. 20301-1000

Dear Secretary Austin:

As a critical emerging technology, biotechnology can help ensure US economic and national security by strengthening our domestic manufacturing abilities. Biomanufacturing provides new opportunities to create jobs, onshore supply chains, and create novel products for our military. The Department of Defense (DoD) is uniquely positioned to support the growth of US biomanufacturing capabilities and secure our competitive leadership in biotechnology. As members of the National Security Commission on Emerging Biotechnology, we urge you to prioritize funding for biotechnology within the Defense Production Act (DPA) account for Fiscal Year (FY) 2024.

The Commission is supportive of DoD's proposed budget for biomanufacturing investments through DPA for FY24. If appropriated, these funds would support emerging biotechnology investments that will address vulnerabilities in critical supply chains. This significant investment in US biomanufacturing comes at an opportune time for securing our economic and technological competitiveness, and for taking advantage of the convergence of other emerging technology fields. International competitors, such as the People's Republic of China, are increasingly encroaching on our leadership in the industry through considerable investments in their own biotechnology research, development, and production.

We understand the FY24 funding levels being considered by the Congressional Appropriations Committees for the DPA Purchases account, while notably higher than the FY23 enacted level, are not to the full level of the FY24 President's Budget request for this account. In any scenario, DoD will have both unobligated funds from prior fiscal years and some FY24 funding to invest in biomanufacturing. It would be a mistake for the Department to deprioritize biotechnology relative to other uses of DPA funds, regardless of the final enacted level for FY24. We urge you to maintain plans to prioritize DPA funding for biomanufacturing in FY24.

In 2022, DoD announced plans to invest $1 billion over five years into the domestic biomanufacturing infrastructure. These goals are consistent with our nation's policies across administrations in harnessing the potential of biotechnology. Innovations in biomanufacturing can address various DoD capability gaps and supply chain vulnerabilities while creating jobs domestically. We ask that DoD adhere to its long-term investments into domestic biomanufacturing capabilities to meet national defense needs by prioritizing funding for biotechnology in FY24.

Moreover, this investment in biomanufacturing comes at a critical time; this funding combined with advancements in other emerging technologies like artificial intelligence (AI), automation, and robotics, create an environment conducive to supporting an accelerated pace of innovation and biomanufacturing. We also face threats to our supply chain, and the funding line for biomanufacturing is for the explicit purpose of scaling "emerging biotechnology for critical materials and precursors." It is critical for our economic and national security that we harness this unique time and grasp the potential of emerging biotechnology.

Given these concerns, we urge the Department to prioritize biotechnology investments. These investments in biotechnology are critical to scaling US biomanufacturing infrastructure, securing critical supply chains, meeting DoD capability gaps, and maintaining our competitive leadership in the industry. Thank you for your consideration of our views, and we look forward to working with you on this important issue.

Dr. Jason Kelly, Chair

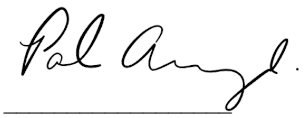
Dr. Michelle Rozo, Vice-Chair

Sen. Alex Padilla, Commissioner

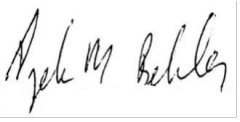
Sen. Todd Young, Commissioner

Rep. Stephanie Bice, Commissioner

Rep. Ro Khanna, Commissioner



Paul Arcangeli, Commissioner



Dr. Angela Belcher, Commissioner

Dawn Meyerriecks, Commissioner

Dr. Eric Schmidt, Commissioner

Dr. Alexander Titus, Commissioner

Dr. Dov Zakheim, Commissioner

Identical Letter Sent to:

Honorable Michael J. McCord
Honorable Dr. William A. LaPlante
Honorable Heidi Shyu

Appendix IV: Federal actions taken so far

There is a long history of executive actions and programs around biotechnology and biomanufacturing. Several key actions include:

- **National Bioeconomy Blueprint**: Released in 2012, this report from the Obama White House outlined an initial roadmap for developing the U.S. bioeconomy, defined in the report as "economic activity that is fueled by research and innovation in the biological sciences."[109]
- **BioPreferred Program**: Established in the 2002 Farm Bill, expanded by the 2014 Farm Bill,[110] and operated by the U.S. Department of Agriculture (USDA), this program helps to create and expand markets for biobased products through mandatory Federal purchasing requirements and voluntary labeling for biobased products.
- **Billion-Ton Reports**: The Bioenergy Technologies Office (BETO) within the Department of Energy (DOE) has led the development of reports to understand the amount of biomass in the U.S. The first study was completed in 2005,[111] with updates in 2011,[112] 2016,[113] and a new update expected in 2023.[114]
- **Precision Medicine Initiative**: In 2015, the Obama White House launched the Precision Medicine Initiative aimed at increasing funding to diagnose and treat complicated human diseases through innovative new technologies.[115]
- **Modernizing the Regulatory System for Biotechnology Products**: This 2015 memorandum[116] from the Obama White House instructed the USDA, the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA) to "improve predictability, increase efficiency, and reduce uncertainty in their regulatory processes and requirements" for biotechnology. In response, the agencies worked with the Office of Science and Technology Policy (OSTP) to develop a national strategy for biotechnology regulation in 2016,[117] and an update to the Coordinated Framework for Regulation of Biotechnology in 2017.[118]
- **Agile Biofoundry**: Established in 2016 under BETO, the Agile Biofoundry is a distributed consortium of national laboratories that could create and analyze biobased products.[119]
- **Manufacturing USA's Manufacturing Innovation Institutes**: The U.S. Government established three different Manufacturing Innovation Institutes that are specifically focused on biotechnology. In 2016, the Department of Commerce (DOC) National Institutes of Standards and Technology (NIST) established NIIMBL[120] to advance innovative biopharmaceutical manufacturing and the Department of Defense (DoD) established BioFabUSA[121] to advance regenerative medicine. In 2020, DoD established the BioIndustrial Manufacturing and Design Ecosystem (BioMADE) to specifically focus on biomanufacturing.[122]
- **Modernizing the Regulatory Framework for Agricultural Biotechnology Products**: In 2019, the Trump White House issued Executive Order (EO) 13874, which instructed the USDA, EPA, and FDA to continue work described in the 2015 memorandum on modernizing biotechnology regulations, with a focus on agricultural biotechnology.[123]
- **National Virtual Biotechnology Laboratory (NVBL)**: DOE established NVBL in 2020 to mobilize computational research toward understanding and treating SARS-CoV-2.[124]

- **Operation Warp Speed**: In 2020, the Trump White House initiated this public-private partnership between multiple Federal agencies and vaccine manufacturers to expedite the discovery and production of medical countermeasures against SARS-CoV-2.[125]

Recently, the U.S. Government has increased its efforts to advance biotechnology and biomanufacturing in the United States, in response to the Biden White House issuance of EO 14081, Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, in 2022.[126] This EO established the need for a U.S. biotechnology and biomanufacturing strategy and highlighted key prerequisites to advance biotechnology and biomanufacturing, including government coordination, research and development (R&D), data, procurement, workforce, regulation, measurement of the biotechnology industry, threat assessment, and international engagement. The resulting executive agency publications include:

- **Biomanufacturing to Advance the Bioeconomy**: In December 2022, the President's Council of Advisors on Science and Technology (PCAST) released a report on "how to maintain United States competitiveness in the global bioeconomy."[127].
- **Bioeconomy Lexicon**: In December 2022, DOC published a lexicon of terms related to biotechnology and biomanufacturing that was developed by an interagency working group and that considered relevant domestic and international definitions.[128]
- **Bold Goals for U.S. Biotechnology and Biomanufacturing**: In March 2023, OSTP released a strategy document that outlined specific areas of innovation for biotechnology and biomanufacturing, with sections by DOE, USDA, DOC, the Department of Health and Human Services (HHS), and the National Science Foundation (NSF) that describe specific innovations necessary to use biotechnology and biomanufacturing to address societal goals.[129]
- **Developing a National Measure of the Economic Contributions of the Bioeconomy**: In March 2023, DOC released a report that analyzes the "feasibility, scope, and costs" of measuring contributions of biotechnology and biomanufacturing to the U.S. economy.[130]
- **Building the Bioworkforce of the Future**: In June 2023, OSTP released a report which outlined a roadmap for strategic development of a skilled workforce for biotechnology that includes individuals of all education and skill levels.[131]
- **DoD Biomanufacturing Strategy**: In March 2023, DoD released a strategy that "supports a self-sustaining domestic biomanufacturing ecosystem" and outlines investments in U.S. biomanufacturing.[132]
- **Biotechnology Regulation:** In November 2023, the USDA, EPA, and FDA published[133] a report summarizing stakeholder outreach about ambiguities, gaps, and uncertainties in biotechnology regulation, [134] and a report containing plain-language information about the U.S. biotechnology regulatory system. [135]

In addition to the above executive actions, recent legislation included mandates related to biotechnology:

- **The Inflation Reduction Act**: This law supports biotechnologies that can reduce greenhouse gas emissions and expand production of renewable energy through a variety of mechanisms such as grants, tax credits, and loans. Eligible biotechnologies include biofuels, biomass, and bioprocessing equipment, among others.[136]
- **The CHIPS and Science Act**: This law supports biotechnology by funding domestic semiconductor manufacturing, investing in science, technology, engineering, and mathematics (STEM) talent, and supporting R&D in the biotechnology industry. For example, the National Engineering Biology Research and Development Initiative tasks the OSTP with advancing biotechnology R&D throughout government.[137]

Appendix V: Commission staff

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Jenn Beddor

Anastasia Bodnar

Bronwen Boyd

Joe Buccina

Nathan Dinh

Elle Ekman

Sam Weiss Evans

Caitlin Frazer, Executive Director

Katy Hamilton

Jamie Hammon

Michelle Holko

Elizabeth Hinton

Nils Justen (Fellow)

Kimberly Ma

Dennis Mayo

Alina Meltaus

Joe Mertens

Laurel Prucha Moran (Contractor)

Peter Morgan

Steven Moss

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Balaji Narain

Zeena Nisar

Anna Puglisi

Jessica Souder

Anmei Zeng

References

1 Weintraub, K. (2013, October 7). MIT Researchers Aim to Make Drugs on the Battlefield. *The Boston Globe*. https://www.bostonglobe.com/business/2013/10/06/mit-researchers-aim-make-drugs-battlefield/K2oxOgujBln5BhyGTvutcO/story.html

2 Marler, T., & Gerstein, D. M. (2022, October 25). *Biotechnology and Today's Warfighter*. RAND Corporation. https://www.rand.org/blog/2022/10/biotechnology-and-todays-warfighter.html

3 Department of Defense Office of Technical Intelligence. (2015). *Technical Assessment: Synthetic Biology*. https://defenseinnovationmarketplace.dtic.mil/wp-content/uploads/2018/02/OTI-SyntheticBiologyTechnicalAssessment.pdf

4 Gore-Langton, L. (2021, December 14). *Militant Recycling: US Department of Defense Partners with Conagen on Fermentation Tech*. Packaging Insights. https://www.packaginginsights.com/news/militant-recycling-us-department-of-defense-partners-with-conagen-on-fermentation-tech.html

5 Rose, P. (2021, February 23). *Spider Silk Research: From Bone Regeneration to Bulletproof Vests*. Military Times. https://www.militarytimes.com/opinion/commentary/2021/02/23/spider-silk-research-from-bone-regeneration-to-bulletproof-vests/

6 Zhang, X., Zhao, C., Shao, M., Chen, Y., Liu, P., & Chen, G. (2022). The roadmap of bioeconomy in China. *Engineering Biology*, *6*(4), 71–81. https://doi.org/10.1049/enb2.12026

7 Australian Strategic Policy Institute. (2023, September 22). *Critical Technology Tracker - Sensors & Biotech updates*. https://www.aspi.org.au/report/critical-technology-tracker

8 Lo, K. (2023, August 14). *China Investment: Beijing Hones in on Biotech in Fresh Pitch to Woo Foreign Business*. South Morning China Post. https://www.scmp.com/economy/china-economy/article/3231056/china-investment-beijing-hones-biotech-fresh-pitch-woo-foreign-business

9 Kania, E. B., & Vorndick W. (2019, August 14) *Weaponizing Biotech: How China's Military Is Preparing for a "New Domain of Warfare."* Defense One. https://www.defenseone.com/ideas/2019/08/chinas-military-pursuing-biotech/159167/

10 National Academies of Sciences Engineering and Medicine. (2010). Informing Strategies and Developing Options for U.S. Policy. *Proceedings of a Workshop on Deterring Cyberattacks*. https://doi.org/10.17226/12997

11 Defense Authorization Act for Fiscal Year 2022, Pub. L. No. 117-81, Sec. 1091(e)-(f) (2022). https://www.govinfo.gov/app/details/PLAW-117publ81

12 Defense Authorization Act for Fiscal Year 2022, Pub. L. No. 117-81, Sec. 1091(f) (2022). https://www.govinfo.gov/app/details/PLAW-117publ81

13 Plant Biostimulant Act of 2023, S.802, 118th Cong. (2023). https://www.congress.gov/bill/118th-congress/senate-bill/802/text

14 Food Supply Chain Capacity and Resiliency Act, H.R.4873, 118th Cong. (2023). https://www.congress.gov/bill/118th-congress/house-bill/4873/text

15 Biomanufacturing and Jobs Act of 2023, S.2452, 118th Cong. (2023). https://www.congress.gov/bill/118th-congress/senate-bill/2452/text

16 U.S. Department of Commerce. (2023, October 23). *Biden-Harris Administration Designates 31 Tech Hubs Across America*. https://www.commerce.gov/news/press-releases/2023/10/biden-harris-administration-designates-31-tech-hubs-across-america

17 Vesprini, F., Whelan, A. I., Goberna, M. F., Murrone, M. L., Barros, G. E., Frankow, A., Godoy, P., & Lewi, D. M. (2022). Update of Argentina's Regulatory Policies on the Environmental Risk Assessment. *Frontiers in Bioengineering and Biotechnology*, *9*. https://doi.org/10.3389/fbioe.2021.834589

18 Australian Department of Agriculture, Fisheries, and Forestry. (n.d.). *Regulatory framework in Australia*. Retrieved November 15, 2023, from https://www.agriculture.gov.au/agriculture-land/farm-food-drought/biotechnology/framework

19 Biosafety South Africa. (n.d.). *Overview of the South African Regulatory Framework for GMOs*. Retrieved October 30, 2023, from https://biosafety.org.za/cms/modules/media/scripts/documents/document.handler.php?media_files_id=853

20 Office of Science and Technology Policy. (1986, June 26). Coordinated Framework for Regulation of Biotechnology. 51 Fed. Reg. 23213, page 23301. https://tile.loc.gov/storage-services/service/ll/fedreg/fr051/fr051123/fr051123.pdf

21 Administrative Conference of the United States. (1989). *Federal Regulation of Biotechnology*. https://www.acus.gov/recommendation/federal-regulation-biotechnology

22 The U.S. Department of Agriculture, U.S. Environmental Protection Agency, and U.S. Food and Drug Administration. (2023, November). The Coordinated Framework for the Regulation of Biotechnology: Plain language information on the biotechnology regulatory system. https://usbiotechnologyregulation.mrp.usda.gov/eo14081-8b-plain-language.pdf

23 President's Council of Advisors on Science and Technology. (2022, December). *Biomanufacturing to Advance the Bioeconomy*. https://www.whitehouse.gov/wp-content/uploads/2022/12/PCAST_Biomanufacturing-Report_Dec2022.pdf

24 Office of Science and Technology. (2022). Request for Information: Identifying Ambiguities, Gaps, Inefficiencies, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology. *Federal Register*, *87*(243). https://www.federalregister.gov/documents/2022/12/20/2022-27599/request-for-information-identifying-ambiguities-gaps-inefficiencies-and-uncertainties-in-the

25 The U.S. Department of Agriculture, U.S. Environmental Protection Agency, and U.S. Food and Drug Administration. (2023, March 11). Report on Stakeholder Outreach Related to Ambiguities, Gaps, Uncertainties in Regulation of Biotechnology Under the Coordinated Framework. https://usbiotechnologyregulation.mrp.usda.gov/eo14081-8a-stakeholder-engagement.pdf

26 UN Office for Disarmament Affairs. (n.d.). *Biological Weapons Convention*. Retrieved October 30, 2023, from https://disarmament.unoda.org/biological-weapons/

27 UN Secretariat of the Convention on Biological Diversity. (n.d.). *Convention on Biological Diversity*. Retrieved October 30, 2023, from https://www.cbd.int/

28 The White House. (2023, June 8). *The Atlantic Declaration: A Framework for a Twenty-First Century U.S.-UK Economic Partnership*. https://www.whitehouse.gov/briefing-room/statements-releases/2023/06/08/the-atlantic-declaration-a-framework-for-a-twenty-first-century-u-s-uk-economic-partnership/?utm_source=twitter&s=03

29 Office of the United States Trade Representative. (n.d.). *Trade and Investment Framework Agreement Between the Government of the United States of America and the Government of Malaysia*. Retrieved November 29, 2023, from https://ustr.gov/sites/default/files/US-Malaysia%20TIFA.pdf

30 Office of the United States Trade Representative. (n.d.). *Malaysia*. Retrieved November 28, 2023, from https://ustr.gov/countries-regions/southeast-asia-pacific/malaysia

31 World Trade Organization. (n.d.). *Overview: the TRIPS Agreement*. Retrieved November 28, 2023, from https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#:~:text=The%20TRIPS%20Agreement%20requires%20Member,novelty%2C%20inventiveness%20and%20industrial%20applicability

32 Council on Foreign Relations. (2023) China's Massive Belt and Road Initiative. Retrieved November 1, 2023, from https://www.cfr.org/backgrounder/chinas-massive-belt-and-road-initiative

33 ChinaPower Project. (2023). *How Is the Belt and Road Initiative Advancing China's Interests?* https://chinapower.csis.org/china-belt-and-road-initiative/

34 World Health Organization. (n.d.). *Biological Weapons*. Retrieved October 30, 2023, from https://www.who.int/health-topics/biological-weapons#tab=tab_1

35 National Academies of Sciences Engineering and Medicine. (2020). Overall Conclusions and Recommendations. pp 347-348.In *Safeguarding the Bioeconomy*. National Academies Press. https://doi.org/https://doi.org/10.17226/25525

36 Carter, Sarah. Federation of American Scientists (2023). Coordinating The U.S. Government Approach To The Bioeconomy. https://fas.org/publication/coordinating-government-bioeconomy/

37 21st Century Nanotechnology Research and Development Act, Pub. L. No. 108-153 (2003). https://www.congress.gov/108/plaws/publ153/PLAW-108publ153.pdf

38 National Nanotechnology Initiative. Retrieved November 11, 2023, from https://www.nano.gov/

39 William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Pub. L. No. 116-283 (2021), § 5101 *et seq*. https://www.congress.gov/116/plaws/publ283/PLAW-116publ283.pdf

40 Federal Reserve Bank of St. Louis. (2023, October 2). *Federal Funds Effective Rate (FEDFUNDS)*. Federal Reserve Economic Data (FRED). https://fred.stlouisfed.org/series/FEDFUNDS#0

41 Senior, M. (2021). Biotech Bubbles During the Global Recession. *Nature Biotechnology 2021 39:4*, *39*(4), 408–413. https://doi.org/10.1038/s41587-021-00876-w

42 The Nobel Foundation. (2023, October 4). *The Nobel Prize in Chemistry 2023*. https://www.nobelprize.org/prizes/chemistry/2023/press-release/

43 Zor, E., Mollarasouli, F., Karadurmus, L., Ozcelikay, G., & Ozkan, S. A. (2022). Carbon Dots in the Detection of Pathogenic Bacteria and Viruses. *Critical Reviews in Analytical Chemistry*. https://doi.org/10.1080/10408347.2022.2072168

44 Doricchi, A., Platnich, C. M., Gimpel, A., Horn, F., Earle, M., Lanzavecchia, G., Cortajarena, A. L., Liz-Marzán, L. M., Liu, N., Heckel, R., Grass, R. N., Krahne, R., Keyser, U. F., & Garoli, D. (2022). Emerging Approaches to DNA Data Storage: Challenges and Prospects. *ACS Nano*, *16*(11), 17552–17571. https://pubs.acs.org/doi/epdf/10.1021/acsnano.2c06748

45 Garijo, B. (2023, January 4). *What is "Bioconvergence" and Is It the Future of Science?* World Economic Forum. https://www.weforum.org/agenda/2023/01/future-of-science-bioconvergence-davos2023/

46 Baek, M., DiMaio, F., Anishchenko, I., Dauparas, J., Ovchinnikov, S., Lee, G. R., Wang, J., Cong, Q., Kinch, L. N., Dustin Schaeffer, R., Millán, C., Park, H., Adams, C., Glassman, C. R., DeGiovanni, A., Pereira, J. H., Rodrigues, A. v., van Dijk, A. A., Ebrecht, A. C., … Baker, D. (2021). Accurate Prediction of Protein Structures and Interactions Using a Three-Track Neural Network. *Science*, 373(6557), 871–876. https://www.science.org/doi/10.1126/science.abj8754

47 Jumper, J., Evans, R., Pritzel, A., Green, T., Figurnov, M., Ronneberger, O., Tunyasuvunakool, K., Bates, R., Žídek, A., Potapenko, A., Bridgland, A., Meyer, C., Kohl, S. A. A., Ballard, A. J., Cowie, A., Romera-Paredes, B., Nikolov, S., Jain, R., Adler, J., … Hassabis, D. (2021). Highly Accurate Protein Structure Prediction with AlphaFold. *Nature 2021 596:7873*, *596*(7873), 583–589. https://doi.org/10.1038/s41586-021-03819-2

48 Kolluri, S., Lin, J., Liu, R., Zhang, Y., & Zhang, W. (2022). Machine Learning and Artificial Intelligence in Pharmaceutical Research and Development: A Review. *The AAPS Journal*, *24*(1). https://doi.org/10.1208/S12248-021-00644-3

49 Carter, S. R., Wheeler, N., Chwalek, S., Isaac, C., & Yassif, J. M. (2023). The Convergence of Artificial Intelligence and the Life Sciences. In *Nuclear Threat Initiative*. https://www.nti.org/analysis/articles/the-convergence-of-artificial-intelligence-and-the-life-sciences/

50 The White House. (2023). *Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence*. https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/

51 National Security Commission on Artificial Intelligence. (2021). *Final Report*. https://www.nscai.gov/wp-content/uploads/2021/03/Full-Report-Digital-1.pdf

52 Caswell, J., Gans, J. D., Generous, N., Hudson, C. M., Merkley, E., Johnson, C., Oehmen, C., Omberg, K., Purvine, E., Taylor, K., Ting, C. L., Wolinsky, M., & Xie, G. (2019). Defending Our Public Biological Databases as a Global Critical Infrastructure. *Frontiers in Bioengineering and Biotechnology*, 7(APR), 446755. https://www.frontiersin.org/articles/10.3389/fbioe.2019.00058/full

53 Newman, L. H. (2023, October 6). 23andMe User Data Stolen in Targeted Attack on Ashkenazi Jews. *Wired*. https://www.wired.com/story/23andme-credential-stuffing-data-stolen/

54 Frist, B. (2023, April 20). Your Health Data Is Not Secure: What Can We Do About It? *Forbes*. https://www.forbes.com/sites/billfrist/2023/04/20/your-health-data-is-not-secure-what-can-we-do-about-it/

55 National Counterintelligence and Security Center. (2021, February). *China's Collection of Genomic and Other Healthcare Data from America: Risks to Privacy and U.S. Economic and National Security.* https://www.dni.gov/files/NCSC/documents/SafeguardingOurFuture/NCSC_China_Genomics_Fact_Sheet_2021revision20210203.pdf

56 Dolan, C. B., Malik, A. A., Zhang, S., Mao, W., McDade, K. K., Svoboda, E., & Odhiambo, J. N. (2023). Chinese Health Funding in Africa: The Untold Story. *PLOS Global Public Health, 3*(6), e0001637. https://doi.org/10.1371/JOURNAL.PGPH.0001637

57 Needham, K., & Baldwin, C. (2021, July 7). China's Gene Giant Harvests Data From Millions of Pregnant Women. *Reuters*. https://www.reuters.com/investigates/special-report/health-china-bgi-dna/

58 Warrick, J., & Brown, C. (2023, October 19). China's Quest for Human Genetic Data Spurs Fears of a DNA Arms Race. *The Washington Post*. https://www.washingtonpost.com/world/interactive/2023/china-dna-sequencing-bgi-covid/

59 Barnes, J. E. (2021, October 22). U.S. Warns of Efforts by China to Collect Genetic Data. *The New York Times*. https://www.nytimes.com/2021/10/22/us/politics/china-genetic-data-collection.html

60 Farris, A. L., Pineda, J. M., Bishop, K., Cubeta, R., Shah, J., & Zhang, J. (2023). *Horizon Scanning of Biotechnologies with Chemical and Biological Defense Applications: A 12-Month Pilot Study*. https://www.ida.org/-/media/feature/publications/h/ho/horizon-scanning-of-emerging-biotechnologies-a-12-month-pilot-study/d-33388.ashx

61 Department of Defense, Office of the Assistant Secretary of Defense for Research and Engineering. (2015). *Technical Assessment: Data-Enabled Technology Watch & Horizon Scanning*. https://defenseinnovationmarketplace.dtic.mil/wp-content/uploads/2018/02/OTI_Data_Enabled_Tech_Watch_Horizon_Scanning_Tech_Assessment_vPublic.pdf

62 Intelligence Advanced Research Projects Activity (IARPA). (n.d.). *ForeST: Forecasting Science and Technology*. Retrieved October 30, 2023, from https://www.iarpa.gov/research-programs/forest

63 U.S. Department of Homeland Security. (2022, February 24). *Science and Technology Horizon Scanning*. https://www.dhs.gov/science-and-technology/horizon-scanning

64 National Academies of Sciences, Engineering, and Medicine. 2017. *Preparing for Future Products of Biotechnology*. The National Academies Press. https://doi.org/10.17226/24605.

65 Schmidt Futures. (2022, April) *The US Bioeconomy: Charting a Course for a Resilient and Competitive Future*, https://www.schmidtfutures.com/wp-content/uploads/2022/04/Bioeconomy-Task-Force-Strategy-4.14.22.pdf

66 Defense Advanced Research Projects Agency. (n.d.). *Biological Technologies Office (BTO)*. Retrieved October 30, 2023, from https://www.darpa.mil/about-us/offices/bto

67 Office of Naval Research. (2023). *Multidisciplinary University Research Initiatives (MURI) Program*. https://www.nre.navy.mil/education-outreach/sponsored-research/university-research-initiatives/muri

68 National Science Foundation. (n.d.). *Regional Innovation Engines*. Retrieved October 30, 2023, from https://new.nsf.gov/funding/initiatives/regional-innovation-engines

69 U.S. Economic Development Administration. (2023). *Regional Technology and Innovation Hubs (Tech Hubs)*. https://www.eda.gov/funding/programs/regional-technology-and-innovation-hubs

70 Manufacturing USA. (2023). List of Institutes. https://www.manufacturingusa.com/institutes

71 Advanced Regenerative Manufacturing Institute. (n.d.). *BioFabUSA: Where Manufacturing Meets Science*. Retrieved October 30, 2023, from https://www.armiusa.org/biofabusa/

72 The National Institute for Innovation in Manufacturing Biopharmaceuticals. (n.d.). *About NIIMBL*. Retrieved October 30, 2023, from https://niimbl.my.site.com/s/about-niimbl

73 BioMADE. (n.d.). *About BioMADE*. Retrieved October 30, 2023, from https://www.biomade.org/about-biomade

74 Chrisey, L. (n.d.). *Technologies for Host Resilience*. Defense Advanced Research Projects Agency. Retrieved October 30, 2023, from https://www.darpa.mil/program/technologies-for-host-resilience

75 Defense Advanced Research Projects Agency. (n.d.). *Prometheus*. Retrieved October 30, 2023, from https://www.darpa.mil/program/prometheus

76 U.S. Government Accountability Office. (2015). *Defense Advanced Research Projects Agency: Key Factors Drive Transition of Technologies, but Better Training and Data Dissemination Can Increase Success*. https://www.gao.gov/assets/gao-16-5.pdf

77 The World Intellectual Property Organization. (n.d.). *Intellectual Property and Technology Transfer*. Retrieved October 30, 2023, from https://www.wipo.int/technology-transfer/en/

78 Hannes, W., & Chang, H.-M. (2021). Unwanted Foreign Transfers of U.S. Technology: Proposed Prevention Strategies. In *Center for Security and Emerging Technology*. https://cset.georgetown.edu/article/unwanted-foreign-transfers-of-u-s-technology-proposed-prevention-strategies/

79 O'Connor, S. (2019). How Chinese Companies Facilitate Technology Transfer from the United States. In *U.S.-China Economic and Security Review Commission*. https://www.uscc.gov/sites/default/files/Research/How%20Chinese%20Companies%20Facilitate%20Tech%20Transfer%20from%20the%20US.pdf

80 Stowers, C. (2023, June 1). *Strengthening the U.S. Biomanufacturing Sector Through Standardization*. Federation of American Scientists. https://fas.org/publication/strengthening-the-u-s-biomanufacturing-sector-through-standardization/

81 Synonym, Inc. (2023, November). *State of Global Fermentation*. https://www.capacitor.bio/trends

82 Sanchez, Justin. Federation of American Scientists. (2023) BioNETWORK: The Internet Of Distributed Biomanufacturing. https://fas.org/publication/bionetwork-biomanufacturing/

83 RedCorn, R., Croft, G., McGill, R., Reich, J. 2023. Feedstocks of the Future for a Circular U.S. Bioeconomy: A Summary from a Stakeholder Convening. Washington, DC: Foundation for Food and Agriculture Research / Schmidt Futures. https://foundationfar.org/wp-content/uploads/2023/06/Feedstocks-of-the-Future-Convening-Report_FINAL.pdf

84 Chung, E., & Fracchia, C. (2023, January 23). *Project BOoST: A Biomanufacturing Test Facility Network for Bioprocess Optimization, Scaling, and Training*. Federation of American Scientists.

85 National Academies of Sciences Engineering and Medicine. (2023). *Successes and Challenges in Biomanufacturing: Proceedings of a Workshop - in Brief*. https://nap.nationalacademies.org/read/26846/chapter/1

86 Elvidge, S. (2010, July 1). *It All Starts With The API*. Life Science Leader. https://www.lifescienceleader.com/doc/it-all-starts-with-the-api-0001

87 Shah-Neville, W. (2023, July 27). *Cell and Gene Therapy Manufacturing: Challenges and Progress*. Labiotech. https://www.labiotech.eu/in-depth/cell-and-gene-therapy-manufacturing/

88 National Academies of Sciences Engineering and Medicine. (2023). *Successes and Challenges in Biomanufacturing: Proceedings of a Workshop - in Brief*. https://nap.nationalacademies.org/read/26846/chapter/1

89 Hodgson, A., & Maxon, E. (2022). *The U.S. Bioeconomy: Charting a Course for a Resilient and Competitive Future*. https://doi.org/https://doi.org/10.55879/d2hrs7zwc

90 Chung, E., & Fracchia, C. (2023, January 23). *Project BOoST: A Biomanufacturing Test Facility Network for Bioprocess Optimization, Scaling, and Training. Federation of American Scientists*. https://fas.org/publication/project-boost-a-biomanufacturing-test-facility-network-for-bioprocess-optimization-scaling-and-training/

91 BioFabUSA. (2020). *Technical Roadmap 2020*. https://www.armiusa.org/wp-content/uploads/2022/05/ARMIBioFabUSARoadmap-2020DIGITAL.pdf

92 Hodgson, A., & Maxon, E. (2022). *The U.S. Bioeconomy: Charting a Course for a Resilient and Competitive Future*. https://doi.org/https://doi.org/10.55879/d2hrs7zwc

93 Russell, J. J., Theriot, J. A., Sood, P., Marshall, W. F., Landweber, L. F., Fritz-Laylin, L., Polka, J. K., Oliferenko, S., Gerbich, T., Gladfelter, A., Umen, J., Bezanilla, M., Lancaster, M. A., He, S., Gibson, M. C., Goldstein, B., Tanaka, E. M., Hu, C. K., & Brunet, A. (2017). Non-Model Model Organisms. *BMC Biology 2017 15:1, 15*(1), 1–31. https://doi.org/10.1186/S12915-017-0391-5

94 President's Council of Advisors on Science and Technology. (2022). *Report to the President: Biomanufacturing to Advance the Bioeconomy*. https://www.whitehouse.gov/wp-content/uploads/2022/12/PCAST_Biomanufacturing-Report_Dec2022.pdf

95 The White House. (2023). *Building the Bioworkforce of the Future: Expanding Equitable Pathways into Biotechnology and Biomanufacturing Jobs*. https://www.whitehouse.gov/wp-content/uploads/2023/06/Building-the-Bioworkforce-of-the-Future.pdf

96 National Academies of Sciences Engineering and Medicine. (2020). *Safeguarding the bioeconomy*. https://nap.nationalacademies.org/catalog/25525/safeguarding-the-bioeconomy

97 National Center for Science and Engineering Statistics. (2023). Diversity and STEM: Women, Minorities, and Persons with Disabilities. https://ncses.nsf.gov/pubs/nsf23315/report/the-stem-workforce

98 Johns Hopkins Applied Physics Laboratory and BIO-ISAC. (2023) Going Viral: Bioeconomy Defense: Summary Report. https://www.isac.bio/post/going-viral-bioeconomy-defense-summary-report

99 Kazmierczak, M., Ritterson, R., Gardner, D., Casagrande, R., Hanemann, T., & Rosen, D. (2019). *China's Biotechnology Development: The Role of US and Other Foreign Engagement*. https://www.uscc.gov/sites/default/files/Research/US-China%20Biotech%20Report.pdf

100 *Centers for Disease Control and Prevention. (2022, December 5). The Untreated Syphilis Study at Tuskegee Timeline*. https://www.cdc.gov/tuskegee/timeline.htm

101 Skene, L., & Brumfield, S. (2023, August 1). Henrietta Lacks' Family Settles Lawsuit with a Biotech Company that Used her Cells Without Consent. *AP News*. https://apnews.com/article/henrietta-lacks-hela-cells-thermo-fisher-scientific-bfba4a6c10396efa34c9b79a544f0729

102 Molenti, M. (2023, March 7). With CRISPR cures on horizon, sickle cell patients ask hard questions about who can access them. *STAT*. https://www.statnews.com/2023/03/07/crispr-sickle-cell-access/

103 The National Counterintelligence and Security Center. (2021). *China's Collection of Genomic and Other Healthcare Data from America: Risks to Privacy and U.S. Economic and National Security*. https://www.dni.gov/files/NCSC/documents/SafeguardingOurFuture/NCSC_China_Genomics_Fact_Sheet_2021revision20210203.pdf

104 U.S. Department of Homeland Security. Critical Infrastructure Sectors. https://www.cisa.gov/topics/critical-infrastructure-security-and-resilience/critical-infrastructure-sectors

105 Greenwood, Lauren. U.S.-China Economic and Security Review Commission. China's Interests in U.S. Agriculture: Augmenting Food Security through Investment Abroad. (2022, May 26). https://www.uscc.gov/research/chinas-interests-us-agriculture-augmenting-food-security-through-investment-abroad

106 Congressional Research Service. Foreign Ownership and Holdings of U.S. Agricultural Land. (2023, January 24). https://crsreports.congress.gov/product/pdf/IF/IF11977

107 American Farm Bureau Federation. Foreign Investment in U.S. Ag Land – The Latest Numbers. (2023, November 2). https://www.fb.org/market-intel/foreign-investment-in-u-s-ag-land-the-latest-numbers

108 *See* Public Law 105-185, the Agricultural Research, Extension, and Education Reform Act of 1998, Sec. 614.

109 White House. National Bioeconomy Blueprint. (2012, April) https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/national_bioeconomy_blueprint_april_2012.pdf

110 U.S. Department of Agriculture. Fact Sheet: Overview of USDA's BioPreferred Program. Retrieved November 16, 2023, from https://www.usda.gov/media/press-releases/2016/02/18/fact-sheet-overview-usdas-biopreferred-program

111 Department of Energy. Biomass as Feedstock for a Bioenergy and Bioproducts Industry: The Technical Feasibility of a Billion-Ton Annual Supply. (2005, April) https://www1.eere.energy.gov/bioenergy/pdfs/final_billionton_vision_report2.pdf

112 Department of Energy. U.S. Billion-Ton Update: Biomass Supply for a Bioenergy and Bioproducts Industry. (2011, August) https://www.energy.gov/sites/prod/files/2015/01/f19/billion_ton_update_0.pdf

113 Department of Energy. Billion-Ton Report: Advancing Domestic Resources for a Thriving Bioeconomy. (2016, July) https://www.energy.gov/eere/bioenergy/articles/2016-billion-ton-report-advancing-domestic-resources-thriving-bioeconomy

114 Department of Energy. 2023 Billion-ton Report, in Preparation. (2023, June) https://www.energy.gov/sites/default/files/2023-06/beto-01-energy-crops-saf-panel-june-2023-langholtz.pdf

115 National Institutes of Health. Precision Medicine Initiative (PMI) Working Group. (2018, March 16) https://acd.od.nih.gov/working-groups/pmi.html

116 Office of Science and Technology Policy. Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture: Modernizing the Regulatory System for Biotechnology Products. (2015, July 2) https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

117 Office of Science and Technology Policy. (2016, September). *National Strategy for Modernizing the Regulatory System for Biotechnology Products: Product of the Emerging Technologies Interagency Policy Coordination Committee's Biotechnology Working Group*. https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf

118 Office of Science and Technology Policy. (2017, January). *Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology*. https://www.epa.gov/sites/default/files/2017-01/documents/2017_coordinated_framework_update.pdf

119 Agile BioFoundry. (n.d.). *How we got here*. Retrieved November 16, 2023, from https://agilebiofoundry.org/history-foundation/

120 The National Institute for Innovation in Manufacturing Biopharmaceuticals. (n.d.). *About NIIMBL*. Retrieved October 30, 2023, from https://niimbl.my.site.com/s/about-niimbl

121 Advanced Regenerative Manufacturing Institute. (n.d.). *BioFabUSA: Where Manufacturing Meets Science*. Retrieved October 30, 2023, from https://www.armiusa.org/biofabusa/

122 BioMADE. (n.d.). *About BioMADE*. Retrieved October 30, 2023, from https://www.biomade.org/about-biomade

123 Executive Office of the President. (2019, June 14). Modernizing the Regulatory Framework for Agricultural Biotechnology Products. 84 Fed. Reg. 27899. https://www.federalregister.gov/documents/2019/06/14/2019-12802/modernizing-the-regulatory-framework-for-agricultural-biotechnology-products

124 Department of Energy. (2020, July 8). *National Virtual Biotechnology Laboratory Unites DOE Labs Against COVID-19*. https://www.energy.gov/science/articles/national-virtual-biotechnology-laboratory-unites-doe-labs-against-covid-19

125 Congressional Research Service. (2021, March 1). *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials*. https://crsreports.congress.gov/product/pdf/IN/IN11560

126 Executive Office of the President. (2022, April 27). *Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*. 88 Fed. Reg. 25711. https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/

127 President's Council of Advisors on Science and Technology. (2022, December). *Biomanufacturing to Advance the Bioeconomy*. https://www.whitehouse.gov/wp-content/uploads/2022/12/PCAST_Biomanufacturing-Report_Dec2022.pdf

128 Department of Commerce, National Institute of Standards and Technology. (2022, December). *Bioeconomy Lexicon*. https://www.nist.gov/bioscience/nist-bioeconomy-lexicon

129 Office of Science and Technology Policy. (2023, March). *Bold Goals for U.S. Biotechnology and Biomanufacturing: Harnessing Research and Development to Further Societal Goals*. https://www.whitehouse.gov/wp-content/uploads/2023/03/Bold-Goals-for-U.S.-Biotechnology-and-Biomanufacturing-Harnessing-Research-and-Development-To-Further-Societal-Goals-FINAL.pdf

130 Department of Commerce, Bureau of Economic Analysis. (2023, March). *Developing a National Measure of the Economic Contributions of the Bioeconomy*. https://www.bea.gov/system/files/papers/bea-bioeconomy-report.pdf

131 Office of Science and Technology Policy. (2023, June). *Building the Bioworkforce of the Future: Expanding Equitable Pathways Into Biotechnology and Biomanufacturing Jobs*. https://www.whitehouse.gov/wp-content/uploads/2023/06/Building-the-Bioworkforce-of-the-Future.pdf

132 Department of Defense. (2023, March 21). *U.S. Department of Defense Biomanufacturing Strategy*. https://media.defense.gov/2023/Mar/22/2003184301/-1/-1/1/BIOMANUFACTURING-STRATEGY.PDF

133 U.S. Department of Agriculture. (2023, November 13). Reports Available: Executive Order 14081. *Program Updates*. https://www.aphis.usda.gov/aphis/newsroom/stakeholder-info/stakeholder-messages/biotechnology-news/brs-eo14081

134 The U.S. Department of Agriculture, U.S. Environmental Protection Agency, and U.S. Food and Drug Administration. (2023, March 11). *Report on Stakeholder Outreach Related to Ambiguities, Gaps, Uncertainties in Regulation of Biotechnology Under the Coordinated Framework*. https://usbiotechnologyregulation.mrp.usda.gov/eo14081-8a-stakeholder-engagement.pdf

135 The U.S. Department of Agriculture, U.S. Environmental Protection Agency, and U.S. Food and Drug Administration. (2023, November). *The Coordinated Framework for the Regulation of Biotechnology: Plain language information on the biotechnology regulatory system*. https://usbiotechnologyregulation.mrp.usda.gov/eo14081-8b-plain-language.pdf

136 Inflation Reduction Act of 2022, Pub. L. No. 117-169 (2022). https://www.govinfo.gov/content/pkg/PLAW-117publ169/pdf/PLAW-117publ169.pdf

137 CHIPS and Science Act of 2022, Pub. L. No. 1402 (2022). https://www.congress.gov/117/plaws/publ167/PLAW-117publ167.pdf