



EXECUTIVE SUMMARY OF REPORT TO THE PRESIDENT

Biomanufacturing to Advance the Bioeconomy

Executive Office of the President
President's Council of Advisors on
Science and Technology

December 2022



EXECUTIVE OFFICE OF THE PRESIDENT
PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY
WASHINGTON, D.C. 20502

President Joseph R. Biden, Jr.
The White House
Washington, D.C.

Dear Mr. President,

We are on the cusp of a new industrial revolution—a revolution emerging from astounding advancements in biotechnology, such as the RNA-based vaccines that are now saving countless lives around the world. Biotechnology will soon provide us with the ability to program our own cells to cure disease, harvest meat without the worries of climate impact, engineer microbes to break down plastic in landfills, and use biomass—in place of petrochemicals—to make the materials and chemicals we use in our daily lives. Many of these scientific developments and innovations were seeded by Federal R&D funding provided over the past two decades, accelerated by the policies of the Obama-Biden Administration. In a recent report, the National Academies of Sciences, Engineering, and Medicine estimated the value of the direct economic inputs from the U.S. bioeconomy to be approximately \$402 billion in 2016; when including indirect and induced effects, they estimated the total economic impact to be \$959 billion. As companies continue to shift to biologically based processes or develop novel bioproducts, the bioeconomy is poised for enormous growth over the coming decades.

With this revolution comes great opportunity: desirable new jobs for skilled workers, a reduced carbon footprint, and new products that will expand U.S. manufacturing and accelerate our economy, all with the potential to enhance access to these benefits in underserved regions of the country. Indeed, critical discoveries in biological science and biotechnology, such as gene editing and cell engineering, were developed in the United States. If we act now, we have the chance to leverage these and other scientific and engineering advances to achieve your goal that biotechnologies invented in America lead to products that are made in America. Inaction could carry significant costs that include impeding the ability of the United States to reach its climate goals, continuing the loss of manufacturing jobs, curbing usage of innovative biotechnology, and increasing reliance on imported products.

The Biden Administration's recent Executive Order (EO) 14081, *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*, sets in motion numerous new policies and actions in support of American competitiveness in this fast-developing sector. With our report, we are pleased to fulfill the charge in EO 14081 for PCAST to deliver a report on "how to maintain United States competitiveness in the global bioeconomy." Our recommendations synergize with, but are distinct from, the actions described in EO 14081. We hope that our recommendations will establish a systematic approach to investment and engagement in the bioeconomy while enabling equity and access across the country, transitioning to climate-friendly manufacturing platforms, and fostering strong economic growth. Specifically, PCAST has identified **three key gaps that are slowing the country's progress and must be addressed** if we are to realize this enormous potential and remain in the forefront of global markets: **insufficient manufacturing capacity, regulatory uncertainty, and an outdated national strategy.**

The first and biggest gap—insufficient biomanufacturing capacity—has been emphasized by key stakeholders in every sector of the bioeconomy. Too often companies encounter a bottleneck when searching for available biomanufacturing facilities and trained workforce needed to expand production to market scale. This bottleneck leads some companies to move to Europe or Asia where manufacturing facilities and trained workforce are more readily available. Much like the American semiconductor industry turned to countries in Asia to bring their products to commercial scale, China is rapidly becoming a leader in biobased production and a source of manufacturing expertise and assistance. Federal investment is critical now to create large, shared, and scalable facilities that can be utilized by American product developers at transitional stages of growth. **Biomanufacturing infrastructure hubs could provide these critical facilities in locations across America, advancing manufacturing methods for complex new bioproducts¹ and providing training opportunities for skilled workers.** These hubs should be public-private partnerships, established in geographically diverse regions of the United States, and catalyzed by a Federal investment on the order of \$50 million per hub. The hubs would expand equitable access to job opportunities and enable better utilization of the unique natural resources and industrial capabilities located in different parts of the country. Investing in this infrastructure would spur the growth of companies and lead to good-paying jobs making needed medicines, consumer goods, and materials across all regions of the country.

The second key gap is regulatory uncertainty. The regulatory approval process can be a significant hurdle for companies with novel, complex, and often transformative ideas and products. Primary regulatory responsibilities are assigned to three agencies, and all three may be involved in approving a new product before it goes to market. In this report, **we recommend the creation of more clear and transparent pathways for evaluating new bioproducts.** Streamlined regulatory paths and cross-trained, rapid response regulatory experts would provide more consistent, efficient, agile, and timely product evaluations while still ensuring consumer safety.

The third key gap is that we need an updated national strategy for the bioeconomy. The *National Bioeconomy Blueprint*, published in 2012 by the Obama-Biden Administration, helped to launch us on a path of vigorous innovation that created many new products and companies. However, in the past 10 years much has changed. **Therefore, we recommend that the National Science and Technology Council develop a new, long-term, data-driven plan to secure our Nation's future leadership in the expanding bioeconomy.** The plan should provide a clear vision for improvements in safety, access and affordability, and ethical issues; improving national security; and strengthening the bioeconomy supply chain. To keep up with the rapid changes in this field, we need a quantitative, fact-based means of measuring the key drivers in this field and a coordinated means of adapting our approach to secure America's competitive advantage as the biotechnology industrial revolution sweeps the globe.

Sincerely,

The President's Council of Advisors on Science and Technology

¹ Products produced using biological systems and/or often derived from biobased precursors.

Executive Summary

Advances in biotechnology over the past decade have led to an explosion of innovative new products that touch many aspects of American life, from novel RNA vaccines and cell-based medicines, to engineered meats and plants, to fuels and chemicals made from renewable resources, and much more. Science and engineering continue to unveil new ways of leveraging biological resources and biological processes to create innovative products in America for the benefit of the American people. The potential for enormous growth in this sector over the coming decades is widely recognized, as companies shift to biologically based processes or develop novel bioproducts.² The United States has been the source of key advances that launched biotechnology and the bioeconomy—but we need to take action now to ensure the benefits of these advances are reaped at home.

Biomanufacturing is the engine by which the innovative products of the bioeconomy are brought to commercial scale. It is integral to the solutions for many of our national and global challenges, including resource utilization, climate change, economic stability, and environmental justice. The newly released Executive Order (EO) 14081, *Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy*,³ and the CHIPS and Science Act⁴ could bolster the bioeconomy, support a diverse domestic workforce, and catalyze the country's scientific and technological pursuits. Combined with accelerating private sector activity across all areas of the bioeconomy, these historic efforts by the Federal Government will help ensure that the research performed in America is translated into products made in America. Over the last decade, government and private sector efforts have spawned hundreds of new businesses and product innovations. Without these strategic investments, the United States will not be able to make the necessary growth to fully capitalize on our current global leadership in the biological sciences and bioengineering.

As a part of a whole-of-government effort to advance biomanufacturing and in turn advance the bioeconomy, PCAST has identified three key challenges that must be addressed to ensure the United States maintains its competitive edge and maximizes the benefits of the bioeconomy: 1) *U.S. biomanufacturing capacity and workforce* are not keeping pace with the bioproducts in development nor with the emerging biomanufacturing approaches that can expeditiously move new ideas and discoveries to commercial scale products; 2) the *regulatory review and approval process* for many new cross-cutting bioproducts, particularly those emerging from new companies with innovative technologies, is complex and uncertain, which can delay or even stop the commercialization process; and 3) *an integrated and overarching bioeconomy strategy* is needed to help guide Federal agencies in managing the development and transfer of these powerful biotechnologies toward social and economic advancements. This strategy should establish achievable objectives, provide options for adapting the strategy to a continually evolving bioeconomy landscape, and identify data and metrics that will be used to monitor progress and reorient programs and funding.

² Products produced using biological systems and/or often derived from biobased precursors

³ Executive Order 14081: Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy (2022). <https://www.federalregister.gov/documents/2022/09/15/2022-20167/advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american>

⁴ Division A (“CHIPS Act of 2022”) of Public Law 117-167 (commonly known, and referred to herein, as the “CHIPS and Science Act”).

PCAST's recommendations to address these three critical issues are synergistic with, but distinct from actions and policies set forth in EO 14081, and leverage the provisions of the CHIPS and Science Act as well as coordination among our science and regulatory agencies to implement a long-term vision for advancing biomanufacturing in support of our growing bioeconomy.

Recommendations

Recommendation 1: Biomanufacturing Infrastructure Hubs

1.1 The Secretary of Commerce should establish biomanufacturing infrastructure hubs⁵ with the authorities and resources necessary to successfully scale up from prototype components in a production relevant environment (Manufacturing Readiness Level [MRL] 6) to low-rate production capability (MRL 8) by expanding the capability and capacity of the Manufacturing USA Institutes and leveraging the Regional Technology Hubs authorized in the CHIPS and Science Act.

1.2 The Office of Science and Technology Policy (OSTP) Director and the Secretary of Commerce, in consultation with the Secretary of Defense, the Director of the National Science Foundation (NSF), and the Secretary of Energy, should develop a plan that A) includes a competitive process for determining biomanufacturing infrastructure hubs' specific foci, funding allocations, and geographic locations and B) directs the creation of a network that connects the hubs established via any of the available innovation hub programs, including the Manufacturing USA Institutes, the Department of Commerce Regional Technology Hubs, the Department of Defense (DOD) biomanufacturing initiatives, Department of Energy (DOE) Agile BioFoundry Consortium, and the NSF Regional Innovation Engines. The plan should be completed within 180 days of the publication of this report.

1.3 NSF, DOD, DOE, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the United States Department of Agriculture (USDA), and other relevant agencies should form partnerships and establish funding opportunities with local university and research institutions that coordinate with the biomanufacturing infrastructure hubs. These partnerships should focus on bioprocessing and biomanufacturing, establish advanced biomanufacturing research opportunities that leverage or expand the biomanufacturing infrastructure hub network and facilities, and support programs across the spectrum of postsecondary training opportunities in this area.

Recommendation 2: Regulatory Approval Process

2.1 The Environmental Protection Agency (EPA) Administrator, Secretary of Agriculture, and FDA Commissioner should establish a standing Rapid Response Team of key agency representatives that meets regularly to vet new, cross-cutting products and provide recommended regulatory routes for bioproducts to developers. This team should be involved with the continued development of the Unified Website for Biotechnology Regulation that is required by EO 14081. The Rapid Response Team should provide opportunities to cross-train

⁵ Consistent with the criteria for hubs established in the CHIPS and Science Act, biomanufacturing infrastructure hubs at MRLs 6 to 8 will help to fill a number of important roles in supporting the growth of the bioeconomy, including physical facilities, continuing education and hands-on training, research and development related to bioproducts/bioprocessing, and touchpoints between regulators and industry.

regulatory staff members as guides that would reside within each agency to support the review of bioproducts.

2.2 EPA, FDA, and USDA should develop streamlined and model pathways for regulatory review and approval of emergent bioproducts of similar type by either: a) drawing from the evolution of pathways as a result of past product review processes, and/or b) creating an open access, searchable library of previously determined routes or pathways for new bioproducts as they are established.

2.3 EPA, FDA, and USDA should create a training and information network that links across the biomanufacturing infrastructure hubs and existing or future federally funded advanced biomanufacturing centers (e.g., BioMade, BioFAB, NIIMBL, and other relevant centers), and to assign regulatory scientists as affiliates to the biomanufacturing infrastructure hubs.

Recommendation 3: A New, Data-Based Strategy for the Bioeconomy

3.1 The National Science and Technology Council (NSTC) should prepare a long-term (10-year) strategy for the bioeconomy. This strategy should be informed by the reports required by the CHIPS and Science Act and EO 14081. The strategy should be completed and delivered within 18 months to the OSTP Director. The strategy must consider the long-term economic, environmental, and societal benefits and liabilities of the proposed actions and policies as well as national security implications.

3.2 The OSTP Director should include research needs of the bioeconomy as a key component of the National Biotechnology and Biomanufacturing Initiative outlined in EO 14081, and the National Engineering Biology Research and Development Initiative and the 5-year coordinated research report designated by the CHIPS and Science Act to be delivered in 2023. These plans should emphasize the fundamental and translational research needed to accelerate the growth of the bioeconomy and other key objectives for international competitiveness.

3.3 The Secretary of Commerce should direct the Bureau of Economic Analysis to establish a satellite account for the bioeconomy as soon as possible and no later than FY 2024. Federal statistical agencies should plan to provide data for the strategy's established metrics and request the resources necessary to do so in their budget requests for FY 2025. The plan should provide the data necessary for the metrics defined by the NSTC strategy and with the cadence necessary to track the bioeconomy.

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