White House Initiative to Advance the Bioeconomy, E.O. 14081: In Brief

October 5, 2022
Introduction

The bioeconomy is the portion of the economy based on products, services, and processes derived from biological resources (e.g., plants and microorganisms). According to the McKinsey Global Institute, “as much as 60 percent of the physical inputs to the global economy could, in principle, be produced biologically.”

Many experts view growing the bioeconomy as a means to address societal challenges such as climate change, food security, energy independence, and environmental sustainability. Potential benefits of growing the bioeconomy include

- substituting renewable biomass or bio-based raw materials for fossil fuels in the production of energy, chemicals, and materials;
- increasing crop and livestock production;
- increasing efficiency in the use of biomass and reducing waste;
- developing new drugs and diagnostics to improve human health;
- creating new jobs and industries; and
- boosting rural development.

According to the Organization for Economic Cooperation and Development (OECD), however, these potential benefits “will not become reality without attentive and active support from governments and the public at large.” Potential challenges associated with advancing the bioeconomy and successfully developing and commercializing bioeconomy-related products and services include

- the need for policy coherence amongst the array of sectors involved;
- the rigidity of existing production systems;
- land use change and feedstock availability;
- equitable access to bioeconomy-related products and services; and
- consumer acceptance and demand.

On September 12, 2022, President Biden issued Executive Order 14081, “Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy.” According to the White House, “global industry is on the cusp of an industrial revolution powered by biotechnology. Other countries are positioning themselves to become the world’s resource for biotechnology solutions and products.”

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1 For more information on the bioeconomy see, CRS Report R46881, The Bioeconomy: A Primer, by Marcy E. Gallo.
While the United States is currently the leader in biotechnology, U.S. competitiveness and leadership in the future global bioeconomy is uncertain. To address this concern, the National Academies of Sciences, Engineering, and Medicine (NASEM) recommended that the federal government develop and regularly update a comprehensive bioeconomy strategy to sustain and grow the U.S. bioeconomy. Congress may consider oversight associated with the Administration’s bioeconomy efforts, including whether the strategy and other activities called for by the executive order are sufficient or if there is a need to reorganize federal activities under a bioeconomy framework. Congress may consider whether to pursue bioeconomy-related policies through new or existing sector-specific focused efforts, or it may evaluate whether current policies and activities are sufficient.

This report provides an overview of the executive order, details supporting federal investments announced by the Administration, and offers some policy considerations for Congress regarding implementation of the executive order. For a broader discussion of the bioeconomy and synthetic biology/engineering biology see, CRS Report R46881, The Bioeconomy: A Primer, and CRS Report R47265, Synthetic/Engineering Biology: Issues for Congress.

Executive Order 14081

Executive Order 14081 prescribes a “whole-of-government approach to advance biotechnology and biomanufacturing towards innovative solutions in health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security.”

The stated goals and objectives of the executive order are to

(a) bolster and coordinate Federal investment in key research and development (R&D) areas of biotechnology and biomanufacturing in order to further societal goals;

(b) foster a biological data ecosystem that advances biotechnology and biomanufacturing innovation, while adhering to principles of security, privacy, and responsible conduct of research;

(c) improve and expand domestic biomanufacturing production capacity and processes, while also increasing piloting and prototyping efforts in biotechnology and biomanufacturing to accelerate the translation of basic research results into practice;

(d) boost sustainable biomass production and create climate-smart incentives for American agricultural producers and forest landowners;

(e) expand market opportunities for bioenergy and biobased products and services;

(f) train and support a diverse, skilled workforce and a next generation of leaders from diverse groups to advance biotechnology and biomanufacturing;

(g) clarify and streamline regulations in service of a science- and risk-based, predictable, efficient, and transparent system to support the safe use of products of biotechnology;

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(h) elevate biological risk management as a cornerstone of the life cycle of biotechnology and biomanufacturing R&D, including by providing for research and investment in applied biosafety and biosecurity innovation;

(i) promote standards, establish metrics, and develop systems to grow and assess the state of the bioeconomy; to better inform policy, decision-making, and investments in the bioeconomy; and to ensure equitable and ethical development of the bioeconomy;

(j) secure and protect the United States bioeconomy by adopting a forward-looking, proactive approach to assessing and anticipating threats, risks, and potential vulnerabilities (including digital intrusion, manipulation, and exfiltration efforts by foreign adversaries), and by partnering with the private sector and other relevant stakeholders to jointly mitigate risks to protect technology leadership and economic competitiveness; and

(k) engage the international community to enhance biotechnology R&D cooperation in a way that is consistent with United States principles and values and that promotes best practices for safe and secure biotechnology and biomanufacturing research, innovation, and product development and use.  

The Assistant to the President for National Security Affairs, in consultation with the Assistant to the President for Economic Policy and the Director of the Office of Science and Technology Policy (OSTP), is tasked with coordinating the overall effort, which is referred to as the National Biotechnology and Biomanufacturing Initiative.

The executive order requires a number of actions over the near and mid-term (see Table 1). Some of the prescribed actions seem consistent with Title IV of Division B of P.L. 117-167 (commonly known as the CHIPS and Science Act), which directs the President, through OSTP, to implement a National Engineering Biology Research and Development Initiative to “advance societal well-being, national security, sustainability, and economic productivity and competitiveness” (Section 10402). The statutory goals of the National Engineering Biology Research and Development Initiative include advancing research and biomanufacturing in engineering biology, including through the support of social, behavioral, economic, and risk research; accelerating the translation and commercialization of such research; and improving interagency planning and coordination of research programs.

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<td>Sec. 3. Harnessing Biotechnology and Biomanufacturing R&amp;D to Further Societal Goals</td>
<td>Requires each of the Secretaries of Health and Human Services (HHS), Energy, Agriculture, and Commerce, and the Director of the National Science Foundation (NSF) to submit a report to the President that identifies high-priority basic research and technology development needs to advance biotechnology and biomanufacturing and provides recommendations for actions to enhance biosafety and biosecurity to reduce risk throughout the biotechnology R&amp;D and biomanufacturing lifecycles.</td>
<td>March 11, 2023</td>
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9 E.O. 14801.
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<td>Sec. 4. Data for the Bioeconomy</td>
<td>Requires the OSTP Director, in coordination with the OMB Director and the heads of appropriate agencies, and in consultation with external stakeholders, to issue a report that identifies the data types and sources that are most critical to drive advances in health, climate, energy, food, agriculture, and biomanufacturing, as well as other bioeconomy-related R&amp;D, along with any data gaps; sets forth a plan to fill any data gaps and make new and existing public data findable, accessible, interoperable, and reusable in ways that are equitable, standardized, secure, and transparent; identifies security, privacy, and other risks and provides a data-protection plan to mitigate such risks; and outlines federal resources, legal authorities, and actions needed to support the Data Initiative required by the E.O.</td>
<td>May 10, 2023</td>
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<td>Sec. 5. Building a Vibrant Biomanufacturing Ecosystem</td>
<td>Requires the APNSA and the APEP, in coordination with the Secretaries of Defense, Agriculture, Commerce, HHS, and Energy, and the NSF Director and the Administrator of the National Aeronautics and Space Administration (NASA), to develop a strategy that identifies policy recommendations to expand domestic biomanufacturing capacity for products spanning the health, energy, agriculture, and industrial sectors, with a focus on advancing equity, improving biomanufacturing processes, and connecting relevant infrastructure; actions to mitigate risks posed by foreign adversary involvement in the biomanufacturing supply chain; and actions to enhance biosafety, biosecurity, and cybersecurity in new and existing infrastructure.</td>
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<td>Requires the Secretary of Agriculture, in consultation with the heads of appropriate agencies, to submit a plan to the President to support the resilience of the United States biomass supply chain for domestic biomanufacturing and bio-based product manufacturing, while also advancing food security, environmental sustainability, and the needs of underserved communities.</td>
<td>September 12, 2023</td>
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<td>Requires the Secretary of Homeland Security, in coordination with the heads of appropriate agencies, to provide the APNSA with vulnerability assessments of the critical infrastructure and national critical functions associated with the bioeconomy and enhance coordination with industry on threat information sharing, vulnerability disclosure, and risk mitigation for cybersecurity and infrastructure risks to the United States bioeconomy.</td>
<td>March 11, 2023</td>
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<td>Requires any federal agency that is using federal funds for procurement that has not yet established a bio-based procurement program as required by 7 U.S.C. §8102 to do so.</td>
<td>September 12, 2023</td>
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<td>Requires all appropriate staff of procuring agencies, including contracting officers, purchase card managers, and purchase card holders to complete training on bio-based product purchasing.</td>
<td>September 12, 2024</td>
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<td>Requires procuring agencies to report specified data on the procurement of bio-based products (i.e., number and dollar value of contracts) to the OMB Director.</td>
<td>March 11, 2023 and annually thereafter</td>
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<td>Requires the OMB Director to publish bio-based procurement information and to issue scorecards to encourage increased bio-based purchasing.</td>
<td>September 12, 2023 and annually thereafter</td>
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<td>Requires procuring agencies to report to the Secretary of Agriculture specific categories of bio-based products that are unavailable to meet their procurement needs. Requires the Secretary of Agriculture to publish such information.</td>
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<td>Requires the Secretaries of Commerce, Labor, and Education, the APDP, the OSTP Director, and the NSF Director to produce and make publicly available a plan to coordinate and use relevant federal education and training programs, while also recommending new efforts to promote multi-disciplinary education programs.</td>
<td>March 31, 2023</td>
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<td>Requires federal agencies that support relevant federal education and training programs identified in the plan described above to report to the President on measures taken and resources allocated pursuant to the plan.</td>
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<td>Sec. 8. Biotechnology Regulation Clarity and Efficiency</td>
<td>Requires the Secretary of Agriculture, the Administrator of the Environmental Protection Agency (EPA), and the Commissioner of Food and Drugs (FDA), in coordination with the OMB Director, the ADPD, and the OSTP Director, to identify areas of ambiguity, gaps, or uncertainties in the January 2017 Update to the Coordinated Framework for the Regulation of Biotechnology or in the policy changes made pursuant to Executive Order 13874, including by engaging with developers and external stakeholders, and through horizon scanning for novel products of biotechnology. Requires the Secretary of Agriculture, the EPA Administrator, and the FDA Commissioner to provide to the general public plain-language information regarding the regulatory roles, responsibilities, and processes of each agency. Requires the Secretary of Agriculture, the EPA Administrator, and the FDA Commissioner to provide a plan to the OMB Director, the ADPD, and the OSTP Director with processes and timelines to implement regulatory reform. Requires the Secretary of Agriculture, the EPA Administrator, and the FDA Commissioner to build on the Unified Website for Biotechnology Regulation developed pursuant to Executive Order 13874 by including on the website the required plain-language information described above.</td>
<td>March 11, 2023</td>
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<td>Sec. 9. Reducing Risk by Advancing Biosafety and Biosecurity</td>
<td>Requires the Secretaries of HHS and Homeland Security, in coordination with agencies that fund, conduct, or sponsor life sciences research, to produce a plan for biosafety and biosecurity for the bioeconomy. Requires agencies that fund, conduct, or sponsor life sciences research to report to the APNSA on efforts to achieve the objectives of the Biosafety and Biosecurity Innovation Initiative required by the E.O.</td>
<td>March 11, 2023</td>
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<td>Sec. 10. Measuring the Bioeconomy</td>
<td>Requires the Director of the National Institute of Standards and Technology, in consultation with other agencies and stakeholders, to create and make publicly available a lexicon for the bioeconomy. Requires the Bureau of Economic Analysis (in the Department of Commerce) to assess the feasibility, scope, and costs of developing a national measurement of the economic contributions of the bioeconomy. Requires the establishment of an interagency technical working group (ITWG) chaired by the Chief Statistician of the United States to improve and enhance federal statistical data collection designed to characterize the economic value of the United States bioeconomy.</td>
<td>December 11, 2022</td>
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<td>September 12, 2023 and annually thereafter for a period of 3 years</td>
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<td>Requires the ITWG to recommend bioeconomy-related revisions to the North American Industry Classification System (NAICS) and the North American Product Classification System (NAPCS) to the Economic Classification Policy Committee.</td>
<td>September 12, 2023</td>
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<td>Requires the ITWG to provide a report to the Chief Statistician of the United States describing the federal statistical collections of information that take advantage of bioeconomy-related NAICS and NAPCS codes, and recommending the implementation of any bioeconomy-related changes as part of the 2022 revisions of the NAICS and NAPCS.</td>
<td>March 12, 2024</td>
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<td>Requires the Director of National Intelligence (DNI) to provide the APNSA with classified assessments on the threats to U.S. national and economic security posed by foreign adversary development and application of biomanufacturing; and on foreign adversary means of, and intended usages related to, acquisition of U.S. biotechnologies, biological data, and proprietary or precompetitive information.</td>
<td>May 10, 2023</td>
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<td>Requires the APNSA, in coordination with heads of relevant agencies, to develop and finalize a plan to mitigate risk to the U.S. bioeconomy.</td>
<td>September 7, 2023</td>
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<td>Requires the OSTP Director, in coordination with the Secretary of Defense, the Attorney General, the Secretaries of HHS, Energy, and Homeland Security, the DNI, the NASA Administrator, and the Administrator of General Services, to review the national security implications of existing requirements related to federal procurement and recommend updates to those requirements. The aim of the required recommendations is to standardize pre-award data collection to enable due diligence review of conflict of interest; conflict of commitment; foreign ownership, control, or influence; or other potential national security concerns.</td>
<td>September 12, 2023</td>
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<td>Requires the Secretary of State, in coordination with the USTR and the heads of other relevant agencies, to submit a plan to the APNSA to promote and protect the U.S. and global bioeconomy.</td>
<td>March 11, 2023</td>
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**Notes:**
- E.O. 14801 requires a number of actions without a defined deliverable or deadline. For example, the Secretary of Homeland Security, in coordination with the Secretaries of Defense, Agriculture, Commerce, HHS, and Energy, and the OMB Director, is required to identify and recommend relevant cybersecurity best practices for biological data stored on federal government information systems. Actions without deliverables or defined deadlines are not listed in the table.
  
  
  
c. The Unified Website for Biotechnology Regulation is available at https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/.
Federal Investments Associated with E.O. 14801

On September 14, 2022, the White House hosted a summit led by the National Security Advisor, Jake Sullivan; the Director of the National Economic Council, Brian Deese; and the acting OSTP Director, Alondra Nelson, to announce federal agency investments and actions in support of the National Biotechnology and Biomanufacturing Initiative created by E.O. 14801. According to the White House, the more than $2 billion in funding for the Initiative will “lower prices, create good jobs, strengthen supply chains, improve health outcomes, and reduce carbon emissions.”

The federal funding highlighted at the summit included previously announced and future investments in support of the initiative.

Previously announced investments include:

- $500 million from the U.S. Department of Agriculture (USDA) to support independent, innovative, and sustainable American fertilizer production;
- $32 million from USDA for wood innovation and community wood grants;
- $178 million from the Department of Energy (DOE) to advance innovative research efforts in biotechnology, bioproducts, and biomaterials;
- $68 million from USDA to train the next generation of research and education professionals; and

Future investments are planned to include:

- $40 million from the Department of Health and Human Services (HHS) to expand biomanufacturing of active pharmaceutical ingredients, antibiotics, and key starting materials to produce essential medications;
- $270 million from the Department of Defense (DOD) over five years for the Tri-Service Biotechnology for a Resilient Supply Chain program;
- $1 billion from DOD over five years to catalyze the establishment of a domestic biomanufacturing industrial base;
- $200 million from DOD to support biosecurity- and cybersecurity- related efforts associated with the biomanufacturing industrial base;
- Up to $100 million from DOE for R&D on conversion of biomass to fuels and chemicals;

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11 The White House Summit highlighted some agency actions and activities without mentioning federal funds associated with such activities.

12 Only federal activities with an identified dollar amount are included.

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- $60 million from DOE to de-risk and scale up biotechnology products and biomanufacturing and support the commercialization of biorefineries;
- $10 million from USDA for the Bio-product Pilot Program which seeks to support scale up activities and studies on the benefits of bio-based products;
- $14 million from the National Institute of Standards and Technology for R&D to develop measurement technologies, standards, and data for the U.S. bioeconomy;
- $20 million from DOE’s National Nuclear Security Administration for a bioassurance program to advance U.S. capabilities to anticipate, assess, detect, and mitigate biological threats; and
- $20 million from the National Science Foundation (NSF) for a biosciences data center to increase understanding of living systems at small scales.14

The executive order requires federal agencies and offices within the Executive Office of the President to complete analyses that may, in part, identify current and future investment needs (see Table 1). For example, the Secretaries of HHS, DOE, USDA, and Commerce, and the NSF Director are required to submit a report to the President that identifies high-priority basic research and technology development needs to advance biotechnology and biomanufacturing. Federal agencies are also required to recommend actions that would enhance biosafety and biosecurity and reduce risks throughout the biotechnology R&D and biomanufacturing lifecycles. In addition, the OMB Director, in consultation with the heads of appropriate agencies, is tasked with performing a budget crosscut to identify existing levels of agency spending on biotechnology- and biomanufacturing-related activities to inform the development of the implementation plan described in the executive order.

These and other deliverables set forth in Table 1 may impact future agency budget requests and appropriations. The totality of future investments associated with E.O. 14081 could be subject to additional analysis once budget requests are submitted and appropriations are enacted.

Policy Considerations

The crosscutting nature of the bioeconomy poses potential challenges to effective policymaking, including the harmonization of policies and coherent governance. While the National Biotechnology and Biomanufacturing Initiative created by E.O. 14081 would appear to respond to calls for a comprehensive strategy for advancing the U.S. bioeconomy, Congress may consider several questions regarding implementation of the executive order:

- Given the potential benefits of advancing the U.S. bioeconomy, should aspects of the executive order be codified?
- The executive order requires the development of a budget crosscut “to identify existing levels of agency spending on biotechnology- and biomanufacturing-related activities to inform the development of the implementation plan.” What is the appropriate level of funding to support and advance the U.S. bioeconomy?
- Does the executive order sufficiently address the R&D coordination and other activities required by Title IV of Division B of P.L. 117-167, the CHIPS and Science Act?

14 Ibid.
• How do the activities of the executive order align with existing laws and policies? Is there a duplication of efforts? Can existing laws and policies be leveraged in support of the bioeconomy? If so, how?

• Many of the stated goals of the executive order (e.g., “developing innovative solutions in health, climate change, energy”) align with the expertise and regulatory authority of the Environmental Protection Agency (EPA). EPA is mentioned in a portion of the executive order focused on clarifying the regulation of biotechnologies. What role, if any, should EPA’s Office of Research and Development have in the R&D activities of the executive order, including biosafety and biosecurity research?

• The executive order requires the Secretaries of HHS and Homeland Security, in coordination with agencies that fund, conduct, or sponsor life sciences research, to produce a plan for biosafety and biosecurity for the bioeconomy. How will “biosafety and biosecurity” be defined? How will the scope of the definition impact which federal agencies are involved in developing the required plan? What gaps exist in biosafety and biosecurity R&D? To what extent, if any, will impacts to the environment, including ecosystem services, and their subsequent impact on human health, be considered? Should outside experts be engaged in developing the biosafety and biosecurity plan? If so, how?

• The executive order requires the USDA Secretary, the EPA Administrator, and the FDA Commissioner to identify “areas of ambiguity” within the regulatory framework for biotechnology products and to provide updates over the next four years on any gaps in statutory authority that should be addressed to improve the clarity and efficiency of regulating such products. Beyond potential statutory changes, what, if any, mechanisms should be put in place to streamline and clarify the regulation of future biotechnology products? Should a regulatory review and assessment occur periodically beyond the four-year period required by the executive order? Should outside experts or stakeholders be engaged in these periodic reviews? If so, how?

• According to NASEM, science education is crucial for the future workforce and the pursuit of living-wage jobs but “is not the national priority it needs to be.”

The executive order appears to focus its efforts on expanding biotechnology and biomanufacturing training and education within higher education. What changes, if any, are needed to improve K-12 science education to prepare students for the biotechnology and biomanufacturing workforce?

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