

# **The Bioeconomy: A Primer**

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# **The Bioeconomy: A Primer**

The term bioeconomy refers to the share of the economy based on products, services, and processes derived from biological resources (e.g., plants and microorganisms). The bioeconomy is crosscutting, encompassing multiple sectors, in whole or in part (e.g., agriculture, textiles, chemicals, and energy). Many predict that the bioeconomy will be a key component of the future economy. Specifically, many view the development of and transition to predominantly a bioeconomy as a means to address grand challenges such as climate change, food security, energy independence, and environmental sustainability. Advancing the bioeconomy is also viewed as an opportunity to create new jobs and industries, improve human health through the development of new development.

### **SUMMARY**

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development of new drugs and diagnostics, and boost rural development. Some experts estimate the direct economic impact of bio-based products, services, and processes at up to \$4 trillion per year globally over the next 10 years.

U.S. competitiveness and leadership in the future global bioeconomy is uncertain. In 2012, the Office of Science and Technology Policy (OSTP) released a comprehensive vision for the U.S. bioeconomy. Progress on the goals and objectives outlined in the report remains unclear. Since 2016, the U.S. Department of Agriculture and the Department of Energy have led federal efforts on development of the U.S. bioeconomy. However, according to the International Advisory Council on Global Bioeconomy, such agencies have a "more agricultural and bioresources-based vision" than the crosscutting and comprehensive vision proposed by OSTP in 2012 (e.g., biomedicine, health, and biodefense are not emphasized). Organizations, including the National Academies of Sciences, Engineering, and Medicine, have recommended that the federal government develop and regularly update a comprehensive bioeconomy strategy to sustain and grow the U.S. bioeconomy. Other countries are adopting comprehensive policies and strategies to advance their bioeconomies. Such efforts have the potential to challenge United States leadership in biotechnology and other bioeconomy-related sectors that many view as critical to national security and economic competitiveness.

Congress may consider a number of issues regarding advancement of the U.S. bioeconomy, including the development and implementation of a national bioeconomy strategy, federal investments in bioeconomy-related research and development, expanding the bioeconomy workforce, promoting and furthering the development of regional bioeconomies, increasing both the market for bio-based products and services, as well as public awareness and acceptance of bio-based products and services.

Conversely, Congress may decide there is no need to restructure federal activities and policies, including some long-standing efforts (e.g., bio-based fuels or agricultural biotechnology), under a bioeconomy framework. Congress may decide to pursue bioeconomy-related policies through new or existing sector-specific efforts, or it may decide current policies and activities are sufficient.

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# Introduction

The bioeconomy is the portion of the economy based on products, services, and processes derived from biological resources (e.g., plants and microorganisms). Some predict that the future economy will be primarily a bioeconomy. According to the McKinsey Global Institute (MGI), "as much as 60 percent of the physical inputs to the global economy could, in principle, be produced biologically."<sup>1</sup> Such predictions are based, in part, on the advancement of our knowledge and understanding of the biological sciences. For example, humans have long bred plants and animals for desirable traits (e.g., higher yields, resistance to pests); however, we now understand the genetic basis for some of these traits and how information can be transmitted within cells and between generations. Not only can researchers read an organism's genetic code, they can edit it with a high-level of precision and create organisms with synthetic genomes.

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

- The substitution of renewable biomass or bio-based raw materials for fossil fuels in the production of energy, chemicals, and materials.
- An increase in crop and livestock production.
- Increased efficiency in the use of biomass and a reduction in waste.
- New drugs and diagnostics to improve human health.
- The creation of new jobs and industries.
- Boosting rural development.

According to the Organization for Economic Cooperation and Development (OECD), the potential benefits "will not become reality without attentive and active support from governments and the public at large."<sup>2</sup> Potential challenges associated with a transition to a bioeconomy and the successful development and commercialization of bioeconomy-related products and services include:

- ensuring policy coherence and alignment amongst the array of sectors involved;
- overcoming the "lock-in" or rigidness of existing production systems;
- ensuring equal access to bioeconomy-related products and services; and
- prompting consumer acceptance and demand.

Given concerns about U.S. competitiveness and national security associated with biotechnology—the use of cellular and biomolecular processes to develop technologies and processes—congressional interest in the bioeconomy and the potential it holds may grow. This report provides an overview of the bioeconomy, details the efforts of the United States and other selected nations pertaining to the bioeconomy (see **Appendix**), and offers policy considerations for strengthening the role of the United States in the global bioeconomy. The report does not examine the policies and programs of individual sectors that contribute to the bioeconomy (e.g.,

<sup>&</sup>lt;sup>1</sup> Michael Chui, Matthias Evers, and James Manyika, et al., *The Bio Revolution: Innovations Transforming Economies, Societies, and Our Lives*, McKinsey Global Institute, May 2020, p. vi.

<sup>&</sup>lt;sup>2</sup> Organization for Economic Cooperation and Development, *The Bioeconomy to 2030: Designing a Policy Agenda*, OECD Publishing, Paris, 2009, p. 3.

biofuels, biomanufacturing, pharmaceuticals, or agriculture), but instead discusses the bioeconomy from a macro level perspective.<sup>3</sup>

# Variability in the Scope of the Bioeconomy

There is no standard definition of the bioeconomy. The scope, emphasis, and definition of a nation's bioeconomy vary based on the country's technological capacity, natural resource base, and economic and trade policies. However, all nations with a definition of the bioeconomy view it as crosscutting, encompassing multiple sectors, in whole or in part (e.g., agriculture, textiles, chemicals, energy, and pharmaceuticals). The National Academies of Sciences, Engineering, and Medicine (NASEM) groups the variability observed in how a nation scopes or defines its bioeconomy into three categories or visions: (1) a biotechnology vision, (2) a bioresource vision, and (3) a bioecology vision. According to NASEM:

Under the biotechnology vision, activities in the bioeconomy center around generating scientific knowledge enabled by the purposeful manipulation of DNA, with production processes operating at the molecular level, the commercialization of such processes, and the development of new commercial products through biomanufacturing.

The bioresource vision involves the conversion of biomass and biological materials (e.g., crops, trees) into sources of power and/or new products, such as bio-plastics or biofuels.

The bioecology vision "highlights the importance of ecological processes that optimize the use of energy and nutrients, promote biodiversity, and avoid monocultures and soil degradation.<sup>4</sup>

These categories or visions, however, are not mutually exclusive. The box titled "Examples of Bioeconomy Definitions" presents definitions of the bioeconomy used by various countries and international organizations.

#### **Examples of Bioeconomy Definitions**

#### Brazil

The term bioeconomy refers to "the generation of innovative products and services based on the country's natural resources and ecosystem services."<sup>5</sup>

#### **European Union**

"The bioeconomy covers all sectors and systems that rely on biological resources (animals, plants, microorganisms and derived biomass, including organic waste), their functions and principles. It includes and interlinks: land and marine ecosystems and the services they provide; all primary production sectors that use and produce

<sup>&</sup>lt;sup>3</sup> More information on individual sectors that contribute to the bioeconomy can be found in other CRS reports. For example, see CRS Report R46737, *Agricultural Biotechnology: Overview, Regulation, and Selected Policy Issues*, by Genevieve K. Croft; CRS Report R43325, *The Renewable Fuel Standard (RFS): An Overview*, by Kelsi Bracmort; CRS Report R40529, *Biomass: Comparison of Definitions in Legislation*, by Kelsi Bracmort; and CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*, by Agata Bodie et al.

<sup>&</sup>lt;sup>4</sup> National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy*, The National Academies Press, Washington, DC, 2020, pp. 45, 48, https://www.nap.edu/catalog/25525/safeguarding-the-bioeconomy.

<sup>&</sup>lt;sup>5</sup> German Bioeconomy Council, *Bioeconomy Policy (Part III): Update Report of National Strategies around the World*, 2018, p. 32.

biological resources (agriculture, forestry, fisheries and aquaculture); and all economic and industrial sectors that use biological resources and processes to produce food, feed, bio-based products, energy and services."<sup>6</sup>

#### Germany

The Federal Government of Germany defines the bioeconomy as "the production, exploitation and use of biological resources, processes and systems to provide products, processes and services across all economic sectors within the framework of a future-oriented economy."<sup>7</sup>

#### Italy

The bioeconomy encompasses the integration of "the sustainable production of renewable biological resources and the conversion of these resources and waste streams into value-added products such as food, feed, bio-based products and bioenergy."<sup>8</sup>

#### Japan

The bioeconomy is a "concept that expands a sustainable and renewable circular economy and society by using biotechnology and renewable biological resources."<sup>9</sup> See "Sustainability and Creating a Circular Economy" below for further discussion.

#### South Africa

The South African bioeconomy definition refers to "activities that make use of bio-innovations, based on biological sources, materials and processes to generate sustainable economic, social and environmental development."<sup>10</sup>

#### United Nations, Food and Agriculture Organization (FAO)

FAO uses the definition of the bioeconomy adopted at the 2018 Global Bioeconomy Summit. "Bioeconomy is the production, utilization and conservation of biological resources, including related knowledge, science, technology, and innovation, to provide information, products, processes and services across all economic sectors aiming toward a sustainable economy."<sup>11</sup>

#### **United States**

A 2019 White House "Summit on America's Bioeconomy" stated "the bioeconomy represents the infrastructure, innovation, products, technology, and data derived from biologically-related processes and science that drive economic growth, improve public health, agricultural, and security benefits."<sup>12</sup>

# The Bioeconomy of the United States

The lack of an officially accepted definition for the U.S. bioeconomy complicates its analysis and decisionmaking. The characteristics of the U.S. bioeconomy consist of an emphasis on

<sup>&</sup>lt;sup>6</sup> European Commission, A Sustainable Bioeconomy for Europe: Strengthening the Connection Between Economy, Society and the Environment, 2018, p. 4.

<sup>&</sup>lt;sup>7</sup> International Advisory Council on Global Bioeconomy, *Global Bioeconomy Policy Report (IV): A Decade of Bioeconomy Policy Development around the World*, November 2020, p. 102.

<sup>&</sup>lt;sup>8</sup> Ibid., p. 116.

<sup>&</sup>lt;sup>9</sup> Ibid., p. 54.

<sup>&</sup>lt;sup>10</sup> Ibid., p. 25.

<sup>&</sup>lt;sup>11</sup> Marta Gomez San Juan, Anne Bogdanski and Olivier Dubois, *Towards Sustainable Bioeconomy: Lessons Learned from Case Studies*, Food and Agriculture Organization, United Nations, 2019, p. ix.

<sup>&</sup>lt;sup>12</sup> Office of Science and Technology Policy, *Summary of the 2019 White House Summit on America's Bioeconomy*, Washington, DC, October 7, 2019, p. 3.

biotechnology and innovation, the inclusion of biomedicine and health, and the application of the bioeconomy to defense and national security purposes (e.g., protecting against biological threats).<sup>13</sup>

In 2020, the NASEM proposed the following definition for the U.S. bioeconomy:

The U.S. bioeconomy is economic activity that is driven by research and innovation in the life sciences and biotechnology, and that is enabled by technological advances in engineering and in computing and information sciences.<sup>14</sup>

As estimated by the NASEM, the U.S. bioeconomy accounted for more than 5% of U.S. gross domestic product or \$959.2 billion in 2016.<sup>15</sup> The NASEM groups U.S. bioeconomy activities into three primary domains—agricultural, biomedical, and bioindustrial—in addition to "a cross-cutting category of tools, kits, and services" that advance biotechnology research and development (R&D) (see **Figure 1**).<sup>16</sup> The 2020 report also detailed industry sectors excluded from or included, wholly or in part, in NASEM's proposed definition (e.g., crop production and pharmaceuticals, see **Table 1**).

As indicated by NASEM, one of the principal differences between the scope of the U.S. bioeconomy and the bioeconomy of countries within the European Union (EU) and Japan is the treatment of primary sectors such as agriculture, fisheries, and forestry. In general, EU countries and Japan include these sectors wholly within their definition of the bioeconomy, while the United States includes only selected parts (e.g., genetically modified crops and crops produced for energy).<sup>17</sup> This difference reflects the U.S. view that biotechnology is a key driver of the bioeconomy. For example, the NASEM established biotechnology-focused criteria for inclusion of agricultural activities within the scope of its definition, including the use of genetic engineering when creating a strain or seed, among others (see **Figure 1**).<sup>18</sup> Additionally, the EU explicitly excludes health and medicine from the scope of the EU bioeconomy, while the United States and Japan include such sectors.<sup>19</sup>

NASEM indicates that there are advantages and disadvantages in adopting a broad versus narrow definition or scope of the bioeconomy. According to NASEM,

If one adopts a broad, highly inclusive definition, the bioeconomy is dominated by mature economic activities (e.g., manufacturing of wood furniture) that (as yet) involve neither applications of biological research or biotechnology nor the substitution of biological for petrochemical resources. Adopting a broader definition has the advantage of including the totality of such sectors as agriculture, forestry, wood manufacturing, and food processing. These sectors are already characterized and defined in national income accounts and recorded regularly in government statistics. This facilitates measurement, but measures of the bioeconomy heavily weighted toward such mature sectors may indicate that the bioeconomy is a shrinking share of economic activity, incomes, and wages over time.

<sup>&</sup>lt;sup>13</sup> International Advisory Council on Global Bioeconomy, *Global Bioeconomy Policy Report (IV): A Decade of Bioeconomy Policy Development around the World*, November 2020, p. 31.

<sup>&</sup>lt;sup>14</sup> National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy*, The National Academies Press, Washington, DC, 2020, pp. 58-66.

<sup>&</sup>lt;sup>15</sup> Ibid., p. 73.

<sup>&</sup>lt;sup>16</sup> Ibid., p. 6.

<sup>&</sup>lt;sup>17</sup> Ibid., pp. 53-58.

<sup>&</sup>lt;sup>18</sup> Ibid., p. 61.

<sup>&</sup>lt;sup>19</sup> International Advisory Council on Global Bioeconomy, *Global Bioeconomy Policy Report (IV): A Decade of Bioeconomy Policy Development around the World*, November 2020, p. 153.

In contrast, a narrower definition, based more on biological innovations, may be better equipped to track innovation and dynamism within mature sectors. For example, under a narrower definition of the bioeconomy, forestry may not be included. Yet, as adoption of future biotechnology applications progresses, activities within the forestry sector would increasingly be included in the bioeconomy. Likewise, innovations in cellular agriculture could bring more activities within livestock production or food processing under the umbrella of the bioeconomy.<sup>20</sup>

<sup>&</sup>lt;sup>20</sup> National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy*, The National Academies Press, Washington, DC, 2020, p. 56.

#### Figure 1. Definition and Primary Domains of U.S. Bioeconomy

As proposed by the National Academies of Science, Engineering, and Medicine



**Source:** Adapted from Figure 2-2, National Academies of Sciences, Engineering, and Medicine, Safeguarding the Bioeconomy, The National Academies Press, Washington, DC, 2020, p. 60.

| Wholly Included<br>Industries | Partially<br>Included<br>Industries   | Industries with Emerging<br>Activities That May Be<br>Included in the Future | Excluded Industries              |  |
|-------------------------------|---|--|----------------------------------|--|
| Pharmaceuticals               | Crop Production   | Livestock Production   | Beverages and Tobacco            |  |
| Biotechnology                 | Electricity   | Fisheries/Aquaculture  | Leather and Products             |  |
| Research and<br>Development   | Generation<br>Processed Food<br>Chemicals<br>Plastics and<br>Rubber<br>Other Physical,<br>Engineering and<br>Life Sciences<br>Research and<br>Development | Forestry<br>Mining (bioleaching)<br>Textiles                                 | Wood Manufacturing               |  |
|                               |   |  | Paper Products                   |  |
| Medical<br>Diagnostics        |   |  | Furniture Manufacturing          |  |
| Diagnostics                   |   |  | Apparel                          |  |
|                               |   |  | Health Care                      |  |
|                               |   |  | Druggists' Goods (wholesalers)   |  |
|                               |   |  | Agriculture Supplies (wholesale) |  |
|                               |   |  | Construction                     |  |
|                               |   |  | Water Treatment and Supply       |  |
|                               |   |  | Nature Tourism, Hunting, Fishing |  |

Table 1. Industries Included in or Excluded from the U.S. Bioeconomy

As proposed by the National Academies of Science, Engineering, and Medicine

**Source:** Adapted from Table 2-1, National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy*, The National Academies Press, Washington, DC, 2020, pp. 54-55.

**Notes:** The category "Industries with Emerging Activities That May Be Included in the Future" represents industries in which some, not all, activities are anticipated to be included.

### Federal Activity in the U.S. Bioeconomy

The following sections provide an overview and background on current and past federal activities associated with the bioeconomy. The sections are limited to activities that explicitly reference the term "bioeconomy" and are intended to be illustrative of executive branch and legislative actions in this area, without necessarily being comprehensive.

#### **Executive Branch**

In 2010, the Office of Budget and Management (OMB) and the Office of Science and Technology Policy (OSTP) included bioeconomy R&D among the Obama Administration's science and technology priorities for formulating the FY2012 budget. The OMB and OSTP memorandum stated that federal agencies should "support research to establish the foundations for a 21<sup>st</sup> century 'bio-economy.' Advances in biotechnology and improvements in our ability to design biological systems have the potential to address critical national needs in agriculture, energy, health, and the environment."<sup>21</sup>

In 2012, the Obama Administration released the *National Bioeconomy Blueprint* with the stated purpose of "lay[ing] out strategic objectives that will help realize the full potential of the U.S. bioeconomy."<sup>22</sup> According to the bioeconomy blueprint, "a bioeconomy is one based on the use

<sup>&</sup>lt;sup>21</sup> Peter R. Orszag and John P. Holdren, "Memorandum for the Heads of Executive Departments and Agencies, Subject: Science and Technology Priorities for the FY2012 Budget," Executive Office of the President, Office of Management and Budget, Washington, DC, July 21, 2010, https://obamawhitehouse.archives.gov/sites/default/files/ microsites/ostp/fy12-budget-guidance-memo.pdf.

<sup>&</sup>lt;sup>22</sup> White House, *National Bioeconomy Blueprint*, Washington, DC, April 2012, p. 2, https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/.

of research and innovation in the biological sciences to create economic activity and public benefit."<sup>23</sup> The bioeconomy blueprint included the following strategic objectives.

- Support for R&D investments to provide the foundation for the future U.S. bioeconomy.
- Facilitating the transition and commercialization of bio-inventions, including an increased focus on translational and regulatory sciences.
- Developing and reforming regulations to reduce barriers, increase the speed and predictability of regulatory processes, and reduce costs while protecting human and environmental health.
- Updating training programs and aligning academic institution incentives to address national workforce needs.
- Identifying and supporting the development of public-private partnerships and precompetitive collaborations.<sup>24</sup>

While the 2015 update of the Obama Administration's *American Innovation Strategy* highlighted the need for R&D investments to advance the bioeconomy, including efforts to promote the development of biotechnology tools and investments associated with bioenergy, the extent to which the 2012 bioeconomy blueprint was implemented is unclear. The federal government has not issued another government-wide strategy or vision for the bioeconomy since 2015.

As noted by the International Advisory Council on Global Bioeconomy, since 2016, the direction of the U.S. bioeconomy has been "marked by the more agricultural and bioresources-based vision put forth by individual federal agencies."<sup>25</sup> In particular, the U.S. Department of Agriculture (USDA) and the Department of Energy (DOE) have a long history of supporting R&D and policies in areas associated with the bioeconomy.

In 2016, the Biomass R&D Board,<sup>26</sup> an interagency group co-chaired by DOE and USDA and also including the Departments of Transportation, the Interior, and Defense, the Environmental Protection Agency, the National Science Foundation, and OSTP, released a *Federal Activities Report on the Bioeconomy* to "emphasize the significant potential for an even stronger U.S. bioeconomy through the production and use of biofuels, bioproducts, and biopower." The report outlined a vision for "expand[ing] the sustainable production and use of biomass," proposed a number of objectives for, and identified barriers to achieving such a vision. The report divided the objectives into the following areas.

- Use an integrated systems approach.
- Provide the science and technology needed to drive innovation.

national\_bioeconomy\_blueprint\_april\_2012.pdf.

<sup>&</sup>lt;sup>23</sup> Ibid., p. 7.

<sup>&</sup>lt;sup>24</sup> Ibid., pp. 2-5.

<sup>&</sup>lt;sup>25</sup> International Advisory Council on Global Bioeconomy, *Global Bioeconomy Policy Report (IV): A Decade of Bioeconomy Policy Development around the World*, November 2020, pp. 40-41.

<sup>&</sup>lt;sup>26</sup> P.L. 106-224 established the Biomass Research and Development Board "to coordinate programs within and among departments and agencies of the Federal Government for the purpose of promoting the use of bio-based industrial products." Per 7 U.S.C. §8108 the current duties of the Board include coordinating R&D activities related to biofuels and bio-based products between USDA and DOE and with other federal departments and agencies. For more information on the Biomass Research and Development Initiative, see CRS In Focus IF10288, *Overview of the 2018 Farm Bill Energy Title Programs*, by Kelsi Bracmort, and CRS Report R45943, *The Farm Bill Energy Title: An Overview and Funding History*, by Kelsi Bracmort.

- Create public and private collaborations to overcome barriers and accelerate deployment.
- Develop a workforce for the future bioeconomy.
- Understand and inform policy.

The identified barriers included:

- sustainably producing and accessing adequate, affordable feedstock;
- developing and applying innovative, cost-competitive conversion technologies;
- optimizing distribution infrastructure across the nation to allow movement of biomass and subsequent derivatives across the entire supply chain; and
- educating the consumer.<sup>27</sup>

Also in 2016, DOE released an update to its *Billion-Ton Bioeconomy* report, which modeled and detailed the availability of up to one billion tons of biomass resources per year in the United States. In addition, the report examined concerns about climate change impacts, logistical operations, environmental sustainability, and systems integration across the production, harvest, and conversion of biomass.<sup>28</sup> DOE's Bioenergy Technology Office (BETO) also published the *Strategic Plan for a Thriving and Sustainable Bioeconomy* in 2016. The strategic plan identified the following key opportunity areas.

- Enhancing the value proposition of bioenergy.
- Mobilizing the nation's biomass resources.
- Cultivating end use markets and customers.
- Expanding stakeholder engagement and collaboration.<sup>29</sup>

In 2019, the Biomass R&D Board—as a follow-on to the 2016 federal activities report—released an implementation framework for the bioeconomy. As described in the report, the purpose of the framework is to

serve as a guiding document for the BR&D Board member agencies to increase government accountability and efficiency, maximize interagency coordination on bioeconomy research and other activities, and accelerate innovative and sustainable technologies that harness the nation's biomass resources. The cutting-edge research and development (R&D) described in this Framework can advance technologies to provide a secure, reliable, affordable, and enduring supply of U.S. energy and products.

There has been great progress to date, but many opportunities remain to unlock the full potential of the U.S. bioeconomy. This Framework lays out activities that will help understand and mitigate technology uncertainty; leverage government, academic,

<sup>&</sup>lt;sup>27</sup> Biomass Research and Development Board, *Federal Activities Report on the Bioeconomy*, February 2016, https://www.energy.gov/sites/prod/files/2016/02/f30/farb\_2\_18\_16.pdf.

<sup>&</sup>lt;sup>28</sup> U.S. Department of Energy, 2016 Billion-Ton Report: Advancing Domestic Resources for a Thriving Bioeconomy, Volume 1: Economic Availability of Feedstocks, Oak Ridge, TN, July 2016, https://www.energy.gov/sites/prod/files/ 2016/12/f34/2016\_billion\_ton\_report\_12.2.16\_0.pdf; and U.S. Department of Energy, 2016 Billion-Ton Report: Advancing Domestic Resources for a Thriving Bioeconomy, Volume 2: Environmental Sustainability Effects of Select Scenarios from Volume 1, Oak Ridge, TN, January 2017, https://www.energy.gov/eere/bioenergy/downloads/2016billion-ton-report-volume-2-environmental-sustainability-effects.

<sup>&</sup>lt;sup>29</sup> Bioenergy Technologies Office, *Strategic Plan for a Thriving and Sustainable Bioeconomy*, U.S. Department of Energy, December 2016, https://www.energy.gov/sites/prod/files/2016/12/f34/ beto\_strategic\_plan\_december\_2016\_0.pdf.

industrial, and non-governmental resources and capabilities; stimulate public-private partnerships and investment; and generate technical information that can inform decision-makers and policymakers across complex value chains. No singular agency has the expertise for all aspects of the bioeconomy supply chain; it is only by leveraging the strengths of all BR&D Board agencies and external partners that technology challenges can be addressed.<sup>30</sup>

Also in 2019, the Trump Administration hosted a White House summit to discuss U.S. leadership in the bioeconomy and key opportunities and challenges. In remarks at the summit, Michael Kratsios, Chief Technology Officer of the United States, stated:

As we look to the future, this Administration is focusing in on three of the core issues that will affect the future of the Bioeconomy: infrastructure, talent, and data.

First, infrastructure. We need to identify what the most critical infrastructure is in the bioeconomy, what we do well, what we don't do well enough, and where there are bottlenecks that impede our innovation or put our security at risk.

Second is talent. We must not only train future innovators, but also determine how we can most successfully support our great research institutions and talent producers so that they have the resources and protection they need to thrive.

And third, we should explore how we can best protect our genetic and biological data while safeguarding the freedom necessary for a robust and growing bioeconomy. As the bioeconomy develops, we need to ensure it is rooted in American values and is always used for the benefit of the American people.<sup>31</sup>

Furthermore, OSTP issued a request for information on the bioeconomy seeking to "inform notable gaps, vulnerabilities, and areas to promote and protect in the U.S. Bioeconomy that may benefit from Federal government attention."<sup>32</sup> The Trump Administration also identified the bioeconomy as a key area of focus for federal R&D investments in both the FY2021 and FY2022 R&D budget priority memoranda issued by OMB and OSTP.<sup>33</sup> According to *STAT News*, the Trump Administration drafted, but never issued an executive order that would have directed OSTP and the National Security Council to co-chair an interagency committee tasked with creating a national bioeconomy strategy within 210 days, in addition to directing the Department of Homeland Security with deciding if the bioeconomy should be designated as a critical infrastructure sector.<sup>34</sup>

<sup>&</sup>lt;sup>30</sup> Biomass Research and Development Board, *The Bioeconomy Initiative: Implementation Framework*, U.S. Department of Agriculture, Washington, DC, March 5, 2019, p. vii, https://biomassboard.gov/sites/default/files/pdfs/Bioeconomy\_Initiative\_Implementation\_Framework\_FINAL.pdf.

<sup>&</sup>lt;sup>31</sup> Office of Science and Technology Policy, *Summary of the 2019 White House Summit on America's Bioeconomy*, Washington, DC, October 7, 2019, p. 7, https://trumpwhitehouse.archives.gov/wp-content/uploads/2019/10/Summary-of-White-House-Summit-on-Americas-Bioeconomy-October-2019.pdf.

<sup>&</sup>lt;sup>32</sup> Office of Science and Technology Policy, "Request for Information on the Bioeconomy," *Federal Register*, vol. 84, no. 175, p. 47561, September 10, 2019.

<sup>&</sup>lt;sup>33</sup> Russell T. Vought and Dr. Kelvin Droegemeir, "Memorandum for the Heads of Executive Departments and Agencies, Subject: Fiscal Year 2021," Administration Research and Development Budget Priorities Executive Office of the President, Washington, DC, August, 30, 2019, https://trumpwhitehouse.archives.gov/wp-content/uploads/2019/08/FY-21-RD-Budget-Priorities.pdf; and Russell T. Vought and Dr. Kelvin Droegemeir, "Memorandum for the Heads of Executive Departments and Agencies, Subject: Fiscal Year (FY) 2022 Administration Research and Development Budget Priorities and Cross-Cutting Actions," Executive Office of the President, Washington, DC, August, 14, 2020, https://trumpwhitehouse.archives.gov/wp-content/uploads/2020/08/M-20-29.pdf.

<sup>&</sup>lt;sup>34</sup> Nicholas Florko, "Abandoned Trump Order on the Bioeconomy Highlights a Path Forward for Biden—But with Mixed Reviews," *STAT News*, May 17, 2021.

In 2020, USDA released a report that included the bioeconomy among the agency's science priorities through 2025. USDA's objectives for the bioeconomy included the following.

- Promoting the development of enabling technologies for the sustainable, efficient, and profitable production of bio-based products from renewable agricultural and bioeconomic crops, including emerging supplemental and alternative crops.
- Developing a bioeconomy research roadmap that sets near-, mid-, and long-term goals and highlighting progress towards those goals annually.
- Developing knowledge and tools to design and optimize biorefining and processing systems that leverage economies of scale to promote bio-based product competition and market access.
- Generating, gathering, and synthesizing relevant data and scientific information to quantify and inform the valuation of bioeconomic ecosystems as well as societal and environmental costs, benefits, and services.<sup>35</sup>

Also in 2020, the Department of Health and Human Services (HHS) awarded \$51 million to the Advanced Regenerative Manufacturing Institute (ARMI) to establish "the nation's first Foundry for American Biotechnology." ARMI is a nonprofit organization and a Manufacturing USA Institute with the mission "to make practical the large-scale manufacturing of engineered tissues and tissue-related technologies, to benefit existing industries and grow new ones."<sup>36</sup> According to the press release, the foundry will "produce technological solutions that help the United States protect against and respond to health security threats, enhance daily medical care, and add to the U.S. bioeconomy."<sup>37</sup>

The Department of Defense awarded \$87 million in 2020 to establish the Bioindustrial Manufacturing and Design Ecosystem (BioMADE), a Manufacturing USA Institute. According to a press release, BioMADE

will examine and advance industry-wide standards, tools, and measurements; mature foundational technologies; foster a resilient bioindustrial manufacturing ecosystem; advance education and workforce development; and support the establishment and growth of supply chain intermediaries that are essential for a robust U.S. bioeconomy. Other important focus areas include challenges related to biosafety and security and ethical, legal, and societal considerations.<sup>38</sup>

According to the National Science Foundation (NSF), "as the U.S. envisions an expanding bioeconomy as a cornerstone of its industrial base, NSF is positioned to have a leading role in

<sup>&</sup>lt;sup>35</sup> U.S. Department of Agriculture, USDA Science Blueprint: A Roadmap for USDA Science from 2020 to 2025, Washington, DC, February 6, 2020, p. 26, https://www.usda.gov/sites/default/files/documents/usda-scienceblueprint.pdf.

<sup>&</sup>lt;sup>36</sup> Advanced Regenerative Manufacturing Institute, "Our Mission," https://www.armiusa.org/about-us. For more information on Manufacturing USA Institutes, see CRS Report R46703, *Manufacturing USA: Advanced Manufacturing Institutes and Network*, by John F. Sargent Jr.

<sup>&</sup>lt;sup>37</sup> Department of Health and Human Services, "HHS Pioneers First Foundry for American Biotechnology," press release, February 10, 2020, https://www.hhs.gov/about/news/2020/02/10/hhs-pioneers-first-foundry-for-american-biotechnology.html.

<sup>&</sup>lt;sup>38</sup> Department of Defense, "DOD Approves \$87 Million for Newest Bioindustrial Manufacturing Innovation Institute," press release, October 20, 2020, https://www.defense.gov/Newsroom/Releases/Release/Article/2388087/dod-approves-87-million-for-newest-bioindustrial-manufacturing-innovation-insti/.

shaping that vision across the federal sector."<sup>39</sup> NSF invests \$250 million annually in biotechnology and bioeconomy activities, including through the agency's Understanding the Rules of Life Big Idea initiative that supports foundational research "to better understand and predict, control, and ultimately design how living systems function."<sup>40</sup> NSF has also identified biotechnology as one of its five "industries of the future." NSF investments in biotechnology and the bioeconomy are concentrated in four priority areas: foundational research, infrastructure, workforce, and the translation of research results.

According to the National Institute of Standards and Technology (NIST), the agency's role in the bioeconomy is to provide "the measurement science, validated data, and standards development leadership to support the maturation of new biotechnologies into successful products."<sup>41</sup> A 2020 presentation by the agency to the Visiting Committee on Advanced Technology, the agency's advisory council, indicates \$30.5 million in support for bioeconomy R&D and other activities in FY2020.<sup>42</sup>

### Congress

The following sections describe legislation and congressional hearings that explicitly reference the term bioeconomy, as of the date of this report. The following should be considered illustrative and not comprehensive.

### Legislation

In 2005, Congress required the Secretary of Agriculture to award grants to regional bioeconomy development associations, agricultural or energy trade associations, or land-grant universities to support the growth and development of regional bioeconomies.<sup>43</sup>

In 2008, the conference report to the Food, Conservation, and Energy Act of 2008 (P.L. 110-234, the 2008 farm bill) stated:

The Managers encourage the Secretary [of Agriculture] to continue to allow and support efforts of regional consortiums of public institutions, including land grant universities and State departments of agriculture, to jointly support the bio-economy through research, extension and education activities.<sup>44</sup>

In 2017, P.L. 115-31, the Consolidated Appropriations Act, 2017, required the Director of National Intelligence to brief the congressional intelligence committees on a proposed plan to monitor advances in life sciences and biotechnology. Congress required the plan to include

<sup>&</sup>lt;sup>39</sup> National Science Foundation, "Advanced Biotechnology and Bioeconomy Research at NSF," https://www.nsf.gov/ bio/bioeconomy.jsp.

<sup>&</sup>lt;sup>40</sup> National Science Foundation, "Fact Sheet: American Leadership in Biotechnology," https://www.nsf.gov/news/ factsheets/Factsheet\_BioTech\_v04.pdf.

<sup>&</sup>lt;sup>41</sup> National Institute of Standards and Technology, "NIST's Role in the Bioeconomy," https://www.nist.gov/topics/ bioscience/nists-role-bioeconomy.

<sup>&</sup>lt;sup>42</sup> National Institute of Standards and Technology, "Engineering Biology," February 12, 2020, https://www.nist.gov/ system/files/documents/2020/02/11/

<sup>10.%20</sup>NIST%20VCAT%20Feb%202020%20EngBio%20Feb1120%20Updated.pdf.

<sup>&</sup>lt;sup>43</sup> 42 U.S.C. §16254.

<sup>&</sup>lt;sup>44</sup> U.S. Congress, House Committee on Agriculture, *Food, Conservation, and Energy Act of 2008*, conference report to accompany H.R. 2419, 110<sup>th</sup> Cong., 2<sup>nd</sup> sess., May 13, 2008, H.Rept. 110-627, p. 923.

An assessment of the current collection and analytical posture of the life sciences and biotechnology portfolio as it relates to United States competitiveness and the global bioeconomy, the risks and threats evolving with advances in genetic editing technologies, and the implications of such advances on future biodefense requirements.<sup>45</sup>

In 2018, the House report to H.R. 5952 (115<sup>th</sup> Congress), the Commerce, Justice, Science, and Related Agencies Appropriations Act, 2019, directed the Federal Bureau of Investigation (FBI) to provide the appropriations committee with a briefing on biotechnologies and FBI efforts to safeguard the bioeconomy.<sup>46</sup>

In the 116<sup>th</sup> Congress (2019-2020), some Members of Congress introduced a few pieces of legislation related to the bioeconomy. S. 3734, the Bioeconomy Research and Development Act of 2020, and a related bill, H.R. 4373, the Engineering Biology Research and Development Act of 2019, would have required OSTP to would establish a federal engineering biology research initiative, develop a national strategy for federal agency investments, and create a framework for interagency coordination. The legislation would also have required the National Science Foundation to sponsor a review by NASEM of the ethical, legal, environmental, and security issues related to engineering biology R&D, among other provisions.

H.R. 5685, the Securing American Leadership in Science and Technology Act of 2020, would have required the National Institute of Standards and Technology (NIST) within the Department of Commerce to support engineering biology R&D by improving measurement science and the development of standards for synthetic biology, in addition to developing and evaluating predictive models associated with engineered biological systems.

In March 2021, Representative Lucas introduced H.R. 2153 (117<sup>th</sup> Congress), the Securing American Leadership in Science and Technology Act of 2021 (identical to H.R. 5685 described above). In April 2021, Senator Markey introduced S. 1418 (117<sup>th</sup> Congress), the Bioeconomy Research and Development Act of 2021. S. 1418 is identical to S. 3734 (116<sup>th</sup> Congress) described above. On June 8, 2021, the Senate passed the United States Innovation and Competition Act of 2021 (S. 1260, 117<sup>th</sup> Congress) which included the Bioeconomy Research and Development Act of 2021 as Section 2217.

#### Hearings

The bioeconomy has been the focus of or a significant part of several congressional hearings. For example, in 2007, the Senate Committee on Agriculture, Nutrition, and Forestry held a hearing examining policy proposals related to energy and rural development for the 2008 farm bill.<sup>47</sup> The hearing included testimony from a representative of the North Central Bioeconomy Consortium, a 12-state collaborative effort that is no longer active, focused on policies that should be included in the 2008 farm bill to support the development of the bioeconomy. In 2017, the House Committee on Agriculture, Subcommittee on Commodity Exchanges, Energy, and Credit, discussed the bioeconomy as part of a series of hearings the committee held in preparation for the 2018 farm

<sup>&</sup>lt;sup>45</sup> P.L. 115-31

<sup>&</sup>lt;sup>46</sup> U.S. Congress, House Committee on Appropriations, *Commerce, Justice, Science, and Related Agencies Appropriations Bill, 2019*, report to accompany H.R. 5952, 115<sup>th</sup> Cong., 2<sup>nd</sup> sess., May 24, 2018, H.Rept. 115-704 (Washington: GPO, 2018), p. 40.

<sup>&</sup>lt;sup>47</sup> U.S. Congress, Senate Committee on Agriculture, Nutrition, and Forestry, *Farm Bill Proposals Relating to Farm and Rural Energy Issues and Rural Development*, 110<sup>th</sup> Cong., 1<sup>st</sup> sess., May 9, 2007, S. Hrg. 110-156 (Washington: GPO, 2007).

bill.<sup>48</sup> In 2019, the House Committee on Science, Space, and Technology held a hearing to review the opportunities and challenges associated with new and emerging biological innovations and their application in agriculture, energy, and manufacturing; to examine the status of U.S. leadership in engineering biology; and to receive testimony on the Engineering Biology Research and Development Act.<sup>49</sup> In addition, in 2019, the Senate Committee on Armed Services held a hearing on biological threats to the United States that included testimony on the role of the bioeconomy in national security.<sup>50</sup> In 2020, the Senate Committee on Commerce, Science, and Transportation held a hearing on "securing U.S. leadership in the bioeconomy."<sup>51</sup>

# **Policy Considerations**

The following sections describe issues for consideration regarding advancement of the U.S. bioeconomy. Congress may pursue all, some, or none of the areas described below.

### Development and Implementation of a National Strategy

Given the potential economic and societal opportunities provided by a robust U.S. bioeconomy, NASEM and others have recommended that the federal government develop and regularly update a national bioeconomy strategy.<sup>52</sup> In addition, due to the complexity of the bioeconomy, NASEM recommended that the federal government solicit input from industry, academia, and others regarding the goals and objectives of such a strategy. Some have also called for the establishment of a coordination body within the Executive Office of the President to oversee the development and implementation of a national bioeconomy strategy. For example, a policy proposal released by the Day One Project, an initiative of the Federation of American Scientists, calls for the creation of a National Bioeconomy Coordination Office that is "a joint mandate of the National Security Council (NSC) and the White House Office of Science and Technology Policy (OSTP) to work with federal agencies on bioeconomy priorities." It also recommended each federal agency with a role in the bioeconomy appoint a senior leader to assume responsibility for bioeconomy-related activities and efforts.<sup>53</sup> As detailed in the 2012 bioeconomy blueprint, at least 25 federal departments and agencies support biological R&D and have a potential role in promoting the U.S. bioeconomy (see box titled "Federal Departments and Agencies that Support Biological Research").

<sup>&</sup>lt;sup>48</sup> U.S. Congress, House Committee on Agriculture, *The Next Farm Bill*, 115<sup>th</sup> Cong., 1<sup>st</sup> sess., March, 9, 2017, Serial no. 115-3, Part 1 (Washington: GPO, 2018).

<sup>&</sup>lt;sup>49</sup> U.S. Congress, House Committee on Science, Space, and Technology, Subcommittee on Research and Technology, *Engineering Our Way to a Sustainable Bioeconomy*, 116<sup>th</sup> Cong., 1<sup>st</sup> sess., March 12, Serial no. 116-6 (Washington: GPO, 2019).

<sup>&</sup>lt;sup>50</sup> U.S. Congress, Senate Committee on Armed Services, Subcommittee on Emerging Threats and Capabilities, *Biological Threats to United States National Security*, 116<sup>th</sup> Cong., 1<sup>st</sup> sess., November 20, 2019, S. Hrg. 116-259 (Washington: GPO, 2020).

<sup>&</sup>lt;sup>51</sup> U.S. Congress, Senate Committee on Commerce, Science, and Transportation, Subcommittee on Science, Oceans, Fisheries, and Weather, *Securing U.S. Leadership in the Bioeconomy*, 116<sup>th</sup> Cong., 2<sup>nd</sup> sess., March 3, 2020.

<sup>&</sup>lt;sup>52</sup> National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy*, The National Academies Press, Washington, DC, 2020, pp. 347-351.

<sup>&</sup>lt;sup>53</sup> Alexander Titus, A National Bioeconomy Manufacturing and Innovation Initiative, Day One Project, December 2020, p. 4, https://9381c384-0c59-41d7-bbdf-62bbf54449a6.filesusr.com/ugd/ 14d834\_f2ddb9288684d0591389d437284bfa8.pdf.

### Federal Departments and Agencies that Support Biological Research

#### **Department of Agriculture**

- Agricultural Research Service
- National Institute of Food and Agriculture
- Forest Service
- **Department of Commerce**
- National Oceanic and Atmospheric Administration
- National Institute of Standards and Technology

#### **Department of Defense**

- Defense Advanced Research Projects Agency
- Defense Science and Technology Program
- Office of Naval Research
- U.S. Army Medical Research and Materiel Command
- Department of Energy
- Office of Science
- Office of Energy Efficiency and Renewable Energy
- Advanced Research Projects Agency-Energy

#### Department of Homeland Security

- Science and Technology Directorate
- **Department of the Interior**
- Fish and Wildlife Service
- U.S. Geological Survey

#### Environmental Protection Agency

#### **Department of Health and Human Services**

- Centers for Disease Control and Prevention
- Food and Drug Administration
- National Institutes of Health
- Assistant Secretary for Preparedness and Response
- National Aeronautics and Space Administration
- National Science Foundation
- Veteran Affairs Department
- United States Agency for International Development Smithsonian Institution
- Source: White House, National Bioeconomy Blueprint, Washington, DC, April 2012, p. 18.

Mechanisms to improve the coordination and governance of bioeconomy policies and activities across sectors are prominently featured in the bioeconomy strategies of other nations. In general, other nations tasked inter-governmental coordination groups with developing and implementing their country's bioeconomy strategy and ensuring policy coherence (i.e., resolving conflicts between goals). Some have also established advisory bodies-composed of outside experts-tasked with evaluating bioeconomy programs and policies and providing recommendations for improvement.

In 2012, OSTP released a comprehensive vision for the U.S. bioeconomy, but an implementation plan was not developed, and progress toward the goals and objectives outlined in the 2012 vision remains unclear. Since 2016, USDA and DOE, including through the Biomass R&D Board, have led federal efforts on development of the U.S. bioeconomy. As described by the International Advisory Council on Global Bioeconomy, such agencies have a "more agricultural and bioresources-based vision" than the one proposed in 2012 (i.e., biomedicine, health, and biodefense are not emphasized). In 2019, the agencies of the Biomass R&D Board, chaired by USDA and DOE, issued an implementation framework for the development of biofuels, biopower, and bioproducts from renewable biomass materials and waste.

Should Congress be interested in further supporting the U.S. bioeconomy, it may

consider establishing a high-level coordination body tasked with developing, implementing, and evaluating a comprehensive U.S. bioeconomy strategy. It could also continue to support a more decentralized framework that encourages sector specific programs and activities related to the bioeconomy. For example, it could support the "bioresource vision" of the Biomass R&D Board, in addition to strengthening bioeconomy objectives in biomedicine and health, and biodefense and national security through separate strategies, programs, or initiatives. Congress could also consider the development of a comprehensive bioeconomy strategy augmented by detailed sector

specific implementation plans or roadmaps. Existing interagency bodies (e.g., the Biomass R&D Board) could execute such roadmaps or Congress could establish new interagency groups that focus on certain sectors or aspects of the bioeconomy. Regardless of the approach, sustainment of bioeconomy policies and programs across presidential Administrations and Congresses will likely be necessary for maintaining U.S. leadership in the future bioeconomy. Ensuring long-term engagement, including the provision of sufficient resources, is often challenging.

In testimony before the Senate Committee on Armed Services in 2019, Dr. Tara O'Toole, Executive Vice President and Senior Fellow at In-Q-Tel and former Under Secretary for Science and Technology at the Department of Homeland Security, emphasized the role of biotechnology—generally considered a driver of the bioeconomy—in the future competitiveness of the U.S., stating:

Biology will prove equally transformative—Americans just do not see it yet. This is a problem because biotechnology is both a humanitarian and geopolitical necessity. Biotechnology will dramatically and literally reshape our lives and our world. It will also become a significant source of national power—economic, and in all likelihood military— as it creates entirely new possibilities, materials, and products. The question is whether our government can best position the United States to capitalize on this promise.<sup>54</sup>

NASEM and others have also recommended that the federal government improve its ability to measure the bioeconomy.<sup>55</sup> Relevant metrics are generally seen as critical to understanding the value of the U.S. bioeconomy, in addition to tracking progress and assessing the impact of policies. Metrics could also be useful in comparing the U.S. bioeconomy with other nations. Standardizing such metrics would be challenging given differences among national definitions, but they could still serve as useful benchmarks.

## Investment in R&D

Many experts call for increased federal investment in R&D to maintain U.S. leadership in the bioeconomy. In general, experts highlight the life sciences, computing and information sciences, engineering, and biotechnology for increased support. Many also emphasize the convergence of such disciplines. In one example, the Engineering Biology Research Consortium (EBRC), a nonprofit, public-private partnership, has released a series of roadmaps that identify high-priority research areas in engineering or synthetic biology (see box titled "What is Synthetic Biology?"). According to EBRC, the aim of the effort is "to guide better-coordinated efforts throughout the U.S. government to

### What Is Synthetic Biology?

Synthetic biology is a component of biotechnology. Specifically, synthetic biology is a field of science that involves redesigning organisms for useful purposes by engineering them to have new abilities. Synthetic biology focuses on the design and construction of core components (parts of enzymes, genetic circuits, metabolic pathways, etc.) that can be modeled, understood, and fine-tuned to meet specific performance criteria, in addition to being assembled into larger integrated systems to solve specific problems.

Sources: National Human Genome Research Institute, "Synthetic Biology," https://www.genome.gov/aboutgenomics/policy-issues/Synthetic-Biology and Engineering Biology Research Consortium, "What is Synthetic/Engineering Biology?," https://ebrc.org/whatis-synbio/.

<sup>&</sup>lt;sup>54</sup> U.S. Congress, Senate Committee on Armed Services, Subcommittee on Emerging Threats and Capabilities, *Biological Threats to United States National Security*, 116<sup>th</sup> Cong., 1<sup>st</sup> sess., November 20, 2019, S. Hrg. 116-259 (Washington: GPO, 2020), p. 20.

<sup>&</sup>lt;sup>55</sup> National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy*, The National Academies Press, Washington, DC, 2020, pp. 341-346.

fund and expand engineering biology research, to engage new stakeholders, and to inform the research and scientific support community about the challenges and potential of the engineering biology field."<sup>56</sup>

According to the American Association of Universities,

Equally important to ensuring substantive federal investments to support the U.S. bioeconomy is maintaining a mechanism that provides predictable, consistent, and sustained funding. The Congressional appropriations process continues to labor to pass the required annual appropriations measures by the end of each fiscal year.<sup>57</sup>

Beyond investments in basic and applied research in areas deemed critical to advancing the bioeconomy, some are calling for improvements in bioeconomy-related R&D infrastructure, including biomanufacturing platforms and pilot facilities.<sup>58</sup> According to a report by the OECD, support for translational R&D seems to be particularly important for advancing the adoption and commercialization of health-related innovations.<sup>59</sup> Additionally, given the growing importance of "big data" to scientific discovery, a number of experts have recommended improvements in the management of and access to biological data. For example, the Information Technology and Innovation Foundation recommends that Congress create "a National Health Research Data Exchange to improve the collection and sharing of patient medical data for research purposes."<sup>60</sup> A proposal by the Day One Project recommends the creation of a "National Biological Data Collective…to provide a resource from which small- and medium-sized businesses applying the tools of artificial intelligence can draw [on] to develop new products, therapies, and capabilities for the bioeconomy."<sup>61</sup> The Trump Administration also highlighted the importance of biological data, including consideration of data security and ethical use during its 2019 summit on the bioeconomy.

As indicated in a 2017 report by the NASEM, "the profusion of biotechnology products over the next 5–10 years has the potential to overwhelm the U.S. regulatory system, which may be exacerbated by a disconnect between research in regulatory science and expected uses of future biotechnology products." To address this concern NASEM recommended:

The National Science Foundation, the U.S. Department of Defense, the U.S. Department of Energy, the National Institute of Standards and Technology, and other agencies that fund biotechnology research with the potential to lead to new biotechnology products should

<sup>&</sup>lt;sup>56</sup> Engineering Biology Research Consortium, "Research Roadmapping," https://ebrc.org/focus-areas/roadmapping/.

<sup>&</sup>lt;sup>57</sup> Mary Sue Coleman, President, Association of American Universities, *Comments Submitted in Response to White House Office of Science and Technology Request for Information on the Bioeconomy*, October 22, 2019, p. 2, https://www.aau.edu/sites/default/files/AAU-Files/Key-Issues/Innovation-Competitiveness/AAU-response-OSTP-RFI-Bioeconomy.pdf.

<sup>&</sup>lt;sup>58</sup> Martin Borowiecki and James Philp, *Policy Initiatives for Health and the Bioeconomy*, Organisation for Economic Cooperation and Development, OECD Science, Technology, and Industry Policy Papers, No. 83, Paris, October 2019, https://www.oecd-ilibrary.org/science-and-technology/policy-initiatives-for-health-and-the-bioeconomy\_9d98177b-en.

<sup>&</sup>lt;sup>59</sup> Ibid. According to the National Center for Advancing Translation Science, translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public—from diagnostics and therapeutics to medical procedures and behavioral changes.

<sup>&</sup>lt;sup>60</sup> Information Technology and Innovation Foundation, *Comments by the Information Technology and Innovation Foundation*, October 15, 2019, p. 7, http://www2.itif.org/2019-comments-ostp-bioeconomy.pdf.

<sup>&</sup>lt;sup>61</sup> Alexander Titus, A National Bioeconomy Manufacturing and Innovation Initiative, Day One Project, December 2020, p. 8.

increase their investments in regulatory science and link research and education activities to regulatory-science activities. $^{62}$ 

Congress may find that a more holistic view of its investments in and oversight of biological research, infrastructure, and data is necessary. As noted above, at least 25 federal agencies and departments support biological research and development. The jurisdiction of such agencies spans multiple congressional committees, which may make coordination, oversight, and coherence of bioeconomy policies and investments more challenging.

### **Promotion of Regional Efforts**

In order to have ready access to biological resources (e.g., crops, forests), implementation of many aspects of the bioeconomy will occur at the regional scale and involve rural communities. Policies to encourage the development of bioeconomy clusters and regions, including resources for planning and the creation of networks that facilitate collaboration between diverse stakeholders, including firms from divergent sectors and small businesses, are common.

More than 130 federal programs support economic development activities.<sup>63</sup> The nature and scope of such programs vary; however, a few programs may be of particular interest as they relate to the bioeconomy and regional development. For example, the Build to Scale program (formerly Regional Innovation Strategies) within the Department of Commerce's Economic Development Administration (EDA) awards grants to develop and support regional innovation initiatives and the Small Business Administration (SBA) supports regional development efforts through its Regional Innovation Clusters program. Congress appropriated \$38 million to the Build to Scale program and \$6 million to the Regional Innovation Clusters program in FY2021.<sup>64</sup> Both programs have awarded grants to regional efforts in areas that would fall under the bioeconomy. As it relates to rural development, USDA's Rural Business Development Grants program supports technology-based economic development, feasibility studies and business plans, leadership and entrepreneur training, and rural business incubators, among other activities.<sup>65</sup> Congress appropriated \$37 million to the Rural Business Development Grants program in FY2021.<sup>66</sup>

It is unclear if existing programs and efforts to support regional innovation and technology-based economic development, including in rural areas, are sufficient to advance the bioeconomy. Congress may examine the size, scope, effectiveness, and synergy of existing programs, in

<sup>&</sup>lt;sup>62</sup> National Academies of Sciences, Engineering, and Medicine, *Preparing for Future Products of Biotechnology*, The National Academies Press, Washington, DC, 2017, pp. 13-14, https://www.nap.edu/catalog/24605/preparing-for-future-products-of-biotechnology.

<sup>&</sup>lt;sup>63</sup> For more information see, CRS Report R46683, *Federal Resources for State and Local Economic Development*, by Julie M. Lawhorn.

<sup>&</sup>lt;sup>64</sup> "Explanatory Statement Submitted by Mrs. Lowey, Chairwoman of the House Committee on Appropriations Regarding H.R. 133, Consolidated Appropriations Act, 2021 (Division B—Commerce, Justice, Science, and Related Agencies Appropriations Act, 2021)," *Congressional Record*, vol. 166, p. H7922 and "Explanatory Statement Submitted by Mrs. Lowey, Chairwoman of the House Committee on Appropriations Regarding H.R. 133, Consolidated Appropriations Act, 2021 (Division E—Financial Services and General Government Appropriations Act, 2021)," *Congressional Record*, vol. 166, p. H8444.

<sup>&</sup>lt;sup>65</sup> For more information, see CRS Report R46235, *Rural Development Provisions in the 2018 Farm Bill (P.L. 115-334)*, by Alyssa R. Casey.

<sup>&</sup>lt;sup>66</sup> "Explanatory Statement Submitted by Mrs. Lowey, Chairwoman of the House Committee on Appropriations Regarding H.R. 133, Consolidated Appropriations Act, 2021 (Division A—Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2021)," *Congressional Record*, vol. 166, p. H7989.

addition the possibility of creating new programs or modifying existing programs to promote regional bioeconomy efforts.

### **Creating a Market for Bio-Based Products**

According to an analysis by the OECD, bioeconomy-related policies focus primarily on supplyside or technology push measures (i.e., support for R&D and demonstration efforts). The OECD indicates that a shift to "a bio-based economy will likely require a balance of more demand-side [or market pull] measures in order to help ensure a market for innovative products" (see **Table** 2).<sup>67</sup>

In particular, they emphasize the importance of public procurement in helping to create a market for bio-based products. The OECD recognized the USDA's BioPreferred Program as the most advanced effort in this regard. The BioPreferred Program—initially established in the 2002 farm bill and reauthorized and amended by Congress in the 2018 farm bill—requires federal agencies and contractors to give purchasing preferences to bio-based products.<sup>68</sup> Specifically, USDA is required to identify eligible product categories and to specify the minimum bio-based content required for each category. Currently, there are 139 product categories and approximately 14,000 bio-based products under the program. In addition to the federal purchasing requirements, the BioPreferred Program also includes a voluntary labeling initiative in which a business can display a "USDA Certified Biobased Product label" on a product that meets USDA criteria.<sup>69</sup> Despite the relative success of the program, the NASEM identified some areas for improvement. NASEM stated:

Although the Farm Bill mandates that federal agencies and contractors purchase biobased products when doing so does not impose cost or performance penalties, no regular report is available through which to understand the progress or scale of biobased procurement. Updating the reporting mechanisms involved in the federal procurement of biobased products, setting procurement targets, and increasing funding for the program to enable increased awareness and standardized reporting—such as a realtime public-facing dashboard to report federal progress in biobased procurement—would go a long way toward stimulating the bioeconomy and supporting jobs in rural areas where many source materials are concentrated.<sup>70</sup>

<sup>&</sup>lt;sup>67</sup> Organization for Economic Cooperation and Development, *Innovation Ecosystems in the Bioeconomy*, OECD Science and Technology Policy Papers, No. 76, OECD Publishing, Paris, September 2019.

<sup>&</sup>lt;sup>68</sup> For more information see, CRS Report R45943, *The Farm Bill Energy Title: An Overview and Funding History*, by Kelsi Bracmort.

<sup>&</sup>lt;sup>69</sup> U.S. Department of Agriculture, "What is BioPreferred?," https://www.biopreferred.gov/BioPreferred/faces/pages/AboutBioPreferred.xhtml.

<sup>&</sup>lt;sup>70</sup> National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy*, The National Academies Press, Washington, DC, 2020, pp. 351.

| Supply-Side/Technology Push        | Demand-Side/Market Pull                             | Crosscutting                          |
|------------------------------------|---|---------------------------------------|
| Local access to feedstocks         | Targets and quotas                                  | Standards and norms                   |
| International access to feedstocks | Mandates and bans                                   | Certification                         |
| R&D subsidy                        | Public procurement                                  | Skills and education                  |
| Pilot and demonstrator support     | Labels and raising awareness                        | Regional clusters                     |
| Flagship financial support         | Direct financial support for bio-<br>based products | Public acceptance                     |
| Tax incentives for industrial R&D  | Tax incentives for bio-based products               | Metrics, definitions, and terminology |
| Improved investment conditions     | Incentives related to greenhouse gas emissions      |                                       |
| Technology clusters                | Taxes on fossil carbon                              |                                       |
| Governance and regulation          | Removing fossil fuel subsidies                      |                                       |

 Table 2. OECD Identified Policy Measures for Creating a Bioeconomy

 Innovation Ecosystem

**Source:** Adapted from Organization for Economic Cooperation and Development, *Innovation Ecosystems in the Bioeconomy*, OECD Science and Technology Policy Papers, No. 76, OECD Publishing, Paris, September 2019, p. 53.

Note: Italicized policy measures are those more frequently cited in the case studies examined by the OECD.

## **Developing a Bioeconomy Workforce**

There is broad consensus that access to a skilled workforce is essential to advancing the bioeconomy. Given the role that the convergence of disciplines—life sciences, engineering, and computer sciences—has played in the progress of biological innovation, it is also clear that bioeconomy education and training should be multidisciplinary in nature. However, as noted by the OECD, "the long-standing conundrum of multidisciplinary education is the need for both breadth and depth to graduate people with problem-solving abilities."<sup>71</sup> Additionally, according to the OECD, the bioeconomy workforce needs more undergraduates than doctorates.

Many reports discuss the need to increase science, technology, engineering, and mathematics (STEM) literacy and the number of STEM graduates in the U.S. to meet 21<sup>st</sup> century workforce needs, including the bioeconomy.<sup>72</sup> For example, in 2018, the White House released *Charting a Course for Success: America's Strategy for STEM Education*, which "presents the Federal Government's five-year strategic plan for STEM education."<sup>73</sup>

As it relates specifically to the bioeconomy, NASEM found that training and workforce development efforts have occurred predominantly in the areas of synthetic biology and biotechnology, with a few programs in bioprocessing, and that in contrast, there are a number of

<sup>&</sup>lt;sup>71</sup> Organization for Economic Cooperation and Development, *Innovation Ecosystems in the Bioeconomy*, OECD Science and Technology Policy Papers, No. 76, OECD Publishing, Paris, September 2019, p. 64.

<sup>&</sup>lt;sup>72</sup> For more information on STEM education, see CRS Report R45223, *Science, Technology, Engineering, and Mathematics (STEM) Education: An Overview*, by Boris Granovskiy.

<sup>&</sup>lt;sup>73</sup> Committee on STEM Education, National Science and Technology Council, *Charting a Course for Success: America's Strategy for STEM Education*, Executive Office of the President, Washington, DC, December 2018, https://trumpwhitehouse.archives.gov/wp-content/uploads/2018/12/STEM-Education-Strategic-Plan-2018.pdf.

European programs focused specifically on bioeconomy training at the masters and doctorate levels. NASEM recommended that bioeconomy training and workforce development occur at all levels and that it "should be a high priority for future public investment."<sup>74</sup>

In addition, the Biomass R&D Board noted the need for improved analysis and modeling to understand "workforce availability and development (both pertaining to geographic distribution and having the prerequisite skills)" to support the expansion of the bioeconomy.<sup>75</sup> Congress may examine federal investments in bioeconomy training, education, and workforce development and the progress of the federal government in attaining the goals outlined in its strategic plan on STEM education.

## **Public Engagement and Acceptance**

According to the McKinsey Global Institute:

In the next decade, more than 50 percent of the total potential impact [of bio innovations] could hinge on consumer, societal, and regulatory acceptance, rising to about 70 percent over the next two decades. Effective mechanisms to govern use, such as societal norms or regulations, will be needed to persuade society that innovations that bring benefits but may be risky and cause discomfort are being pursued safely. Today, policies to govern use vary significantly among countries with different value systems.<sup>76</sup>

Due to the significance of public acceptance, a number of countries are pursuing public engagement and awareness activities and policies. For example, the European Commission has supported more than 70 projects and initiatives to increase awareness and support for, in addition to identifying challenges and opportunities associated with, transitioning to a bioeconomy<sup>77</sup>

In a 2017 study, the NASEM recommended that federal agencies invest in new methods of understanding the ethical, legal, and societal implications (ELSI) of future biotechnology products. NASEM noted that ELSI research associated with biotechnology represented less than 1 percent of the total investment in biotechnology research between 2008 and 2015.<sup>78</sup> Congress may = conduct additional oversight on federal efforts to enhance public awareness and acceptance of bio-based products and services. Congress may also consider the level of resources allocated toward ELSI-related research across federal agencies, in addition to the coordination of such efforts.

## **International Collaboration**

Most bioeconomy-related policies and strategies focus at the national level with some exceptions (e.g., the European Union). According to the International Advisory Council on Global Bioeconomy, references to and promotion of international collaboration generally emphasize cooperation between research institutions and the removal of trade barriers with "far less

<sup>&</sup>lt;sup>74</sup> National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy*, The National Academies Press, Washington, DC, 2020, pp. 205, 353.

<sup>&</sup>lt;sup>75</sup> Biomass Research and Development Board, *The Bioeconomy Initiative: Implementation Framework*, U.S. Department of Agriculture, Washington, DC, March 5, 2019, pp.44-45.

<sup>&</sup>lt;sup>76</sup> Michael Chui, Matthias Evers, and James Manyika, et al., *The Bio Revolution: Innovations Transforming Economies, Societies, and Our Lives*, McKinsey Global Institute, May 2020, pp. 22-23.

<sup>&</sup>lt;sup>77</sup> The European Bioeconomy Network, https://eubionet.eu/.

<sup>&</sup>lt;sup>78</sup> National Academies of Sciences, Engineering, and Medicine, *Preparing for Future Products of Biotechnology*, The National Academies Press, Washington, DC, 2017, p. 185.

discussion about issues relating to the global interconnectedness of the bioeconomy, biomass resources, value-added chains, and technologies with international division of labor."<sup>79</sup>

A recent study by researchers from the Stockholm Environment Institute explored the role some international institutions and processes have taken on or could take on related to global governance associated with the bioeconomy. The authors suggested a number of options for international collaboration, including focusing collaboration on less controversial issues such as research and innovation or standardization, monitoring, and verification of bio-based products. Collaboration on such issues may level the playing field as it relates to international competition in the bioeconomy.<sup>80</sup>

In the United States, some states have engaged in bilateral collaborations. For example, Maine and Michigan both signed memoranda of understanding (MOUs) with the government of Finland to develop joint efforts and cooperate in the forest bioeconomy.<sup>81</sup> Michigan's MOU also outlined cooperation in the areas of battery technology, energy storage, and the automotive industry, among others. Congress may examine the state of international collaboration on the bioeconomy and the need for congressional direction in this regard.

## Sustainability and Creating a Circular Economy

A number of nations, especially those in the European Union are increasingly connecting their bioeconomy strategies and policies to action plans associated with creating a more sustainable and circular economy (see **Appendix**). According to the European Parliamentary Research Service,

Unlike the traditional linear economic model based on a 'take-make-consume-throw away' pattern, a circular economy is based on sharing, leasing, reuse, repair, refurbishment and recycling, in an (almost) closed loop, where products and the materials they contain are highly valued. In practice, it implies reducing waste to a minimum.<sup>82</sup>

Many countries see a connection between the bioeconomy and a circular economy as a means to address a number of the Sustainable Development Goals (SDGs). In 2015, 193 countries, including the United States, adopted the SDGs as part of the 2030 Agenda for Sustainable Development. The SDGs include ensuring sustainable consumption and production patterns, taking urgent action to combat climate change and its impacts, and ensuring access to affordable, reliable, sustainable and modern energy for all, among others.<sup>83</sup> In 2021, the Food and Agriculture

<sup>&</sup>lt;sup>79</sup> International Advisory Council on Global Bioeconomy, *Global Bioeconomy Policy Report (IV): A Decade of Bioeconomy Policy Development around the World*, November 2020, pp. 161-162.

<sup>&</sup>lt;sup>80</sup> Stefan Bößner, Francis X. Johnson, and Zoha Shawoo, "Governing the Bioeconomy: What Role for International Institutions?," *Sustainability*, vol. 13, no. 1 (2021), https://www.mdpi.com/2071-1050/13/1/286/htm.

<sup>&</sup>lt;sup>81</sup> "Memorandum of Understanding Between the Ministry of Economic Affairs and Employment of Finland and the State of Michigan Concerning Cooperation on Clean Technologies," https://www.michiganbusiness.org/4af068/ globalassets/documents/mous/mou-signing-between-state-of-michigan-and-finland-concerning-clean-technologies-2020, and "Memorandum of Understanding Concerning Cooperation in Forestry Between the Ministry of Agriculture and Forestry of Finland and Maine Department of Agriculture, Conservation, and Forestry," https://www.maine.gov/ governor/mills/sites/maine.gov.governor.mills/files/inline-files/Maine%20and%20Finland%20MOU.pdf.

<sup>&</sup>lt;sup>82</sup> Didier Bourguignon, *Closing the Loop New Circular Economy Package*, European Parliamentary Research Service, January 2016, p. 1, https://www.europarl.europa.eu/RegData/etudes/BRIE/2016/573899/ EPRS\_BRI(2016)573899\_EN.pdf.

<sup>&</sup>lt;sup>83</sup> As described by the United Nations, the 2030 Agenda for Sustainable Development, adopted by all United Nations Member States in 2015, "provides a shared blueprint for peace and prosperity for people and the planet, now and into the future. At its heart are the 17 Sustainable Development Goals (SDGs), which are an urgent call for action by all countries—developed and developing—in a global partnership. They recognize that ending poverty and other

Organization of the United Nations (FAO) released a set of principles and criteria with the aim of ensuring that the "bioeconomy, when implemented correctly, can benefit individual communities and the global environment in ways that are in line with the SDGs."<sup>84</sup> FAO's principles are that a sustainable bioeconomy should:

- support food security and nutrition at all levels;
- ensure that natural resources are conserved, protected, and enhanced;
- support competitive and inclusive economic growth;
- make communities healthier, more sustainable, and harness social and ecosystem resilience;
- rely on improved efficiency in the use of resources and biomass;
- be underpinned by responsible and effective governance mechanisms;
- make good use of existing relevant knowledge and proven sound technologies and good practices, and where appropriate, promote research and innovations;
- use and promote sustainable trade and market practices;
- address societal needs and encourage sustainable consumption; and
- promote cooperation, collaboration, and sharing between interested and concerned stakeholders in all relevant domains and at all relevant levels.

Congress may consider the degree to which U.S. bioeconomy policies and activities can or should be tied to and aligned with achieving the SDGs. Additionally, while the use of waste material as a feedstock is central to a circular economy there are often challenges to its use. For example, a 2020 workshop hosted by DOE, titled "Advancing the Bioeconomy: From Waste to Conversion-Ready Feedstocks," found that the variability of municipal solid waste streams poses a significant challenge for downstream conversion and detailed characterization and compositional data are lacking to understand and manage such variability.<sup>85</sup> Congress may examine any regulatory impediments or other barriers to creating a circular economy.

# **Concluding Remarks**

The crosscutting nature of the bioeconomy, in addition to the diversity of potential benefits associated with its growth and advancement offer a number of reasons for increased congressional interest in bioeconomy policies. Some may view support for and promotion of the bioeconomy as a way to accelerate post-COVID-19 economic recovery and advance public health. Others may be more interested in the environmental benefits associated with a transition away from fossil fuels. Still others may focus on the potential for rural development. The crosscutting nature of the bioeconomy also poses potential challenges to effective policymaking, including the harmonization of policies and coherent governance. Moreover, it likely means that

deprivations must go hand-in-hand with strategies that improve health and education, reduce inequality, and spur economic growth—all while tackling climate change and working to preserve our oceans and forests." For more information, see https://sdgs.un.org/goals and CRS In Focus IF10249, *The Post-2015 Global Development Agenda*, by Marian L. Lawson.

<sup>&</sup>lt;sup>84</sup> Food and Agriculture Organization of the United Nations, *Aspirational Principles and Criteria for a Sustainable Bioeconomy*, Rome, 2021, p. 3.

<sup>&</sup>lt;sup>85</sup> U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, "Advancing the Bioeconomy: From Waste to Conversion-Ready Feedstocks Workshop Summary Report," February 2020, p. 27, https://www.energy.gov/sites/prod/files/2021/02/f82/beto-municipal-solid-waste-report.pdf.

the growth and success of the U.S. bioeconomy will depend, in part, on effective public-private partnerships in research, innovation, education, and workforce development. Transitioning to a bio-based economy would take sustained commitment, including balancing short-term actions and long-term planning, removing barriers to such a transition, and creating the opportunity for radical innovation. As noted by the OECD,

Systemic change calls for policy making that allows both small and deep support. Vision has to be complemented with a strategy that can be converted to action. It requires action at multi-actor, multi-sector and multi-level, and geographically it is national, regional and local in its approach.<sup>86</sup>

Congress may decide there is no need to reorganize or group together federal activities, including some long-standing efforts, under a bioeconomy framework. It may decide to pursue bioeconomy-related policies through new or existing sector-specific focused efforts, or it may decide current policies and activities are sufficient. Regardless, other countries are adopting policies and strategies to advance their bioeconomies. Such efforts have the potential to challenge United States leadership in biotechnology and other bioeconomy-related sectors that many view as critical to national security and economic competitiveness. According to NASEM, "Internationally, the United States is the leader in the commercialization of advances in synthetic biology and continues to hold an advantage in terms of the education of new Ph.D.s in the life sciences. This position provides the basis for but no guarantee of future leadership in bioeconomy innovation."<sup>87</sup>

<sup>&</sup>lt;sup>86</sup> Organization for Economic Cooperation and Development, *Innovation Ecosystems in the Bioeconomy*, OECD Science and Technology Policy Papers, No. 76, OECD Publishing, Paris, September 2019, p. 8.

<sup>&</sup>lt;sup>87</sup> National Academies of Sciences, Engineering, and Medicine, *Safeguarding the Bioeconomy*, The National Academies Press, Washington, DC, 2020, p. 151.

# **Appendix. Bioeconomy Efforts of Select Countries**

Nearly 60 countries—spurred, in part, by the potential associated with growing the bioeconomy portion of their national economy (e.g., environmental benefits and economic growth)—have developed bioeconomy-related policies. The following sections provide high-level descriptions of the bioeconomy efforts of select countries.<sup>88</sup>

## China

In general, China does not use the term bioeconomy in its policy planning documents and strategies. Instead, multiple policy documents and strategies, including *Made in China 2025* and the *13<sup>th</sup> Five-Year Plan* for 2016 to 2020, refer to biotechnology, the biotech industry, or the bioindustry as priority areas for development and growth. In general, the terms biotechnology, biotech industry, and bioindustry describe activities within the areas of biomedicine, biomedical engineering, agriculture biotechnology, bio-based manufacturing, bioenergy, bio-based environmental protection, and biotechnology services—all areas that generally fall within the scope of the term bioeconomy. According to one estimate, China's bioeconomy amounted to \$700 billion in 2015.<sup>89</sup>

China first recognized the bioindustry as a priority area and contributor to the country's economy in 2006, this priority's importance has grown over the years. For example, in 2017, through the *13<sup>th</sup> Five-Year Bioindustry Development Plan*, China indicated that it wanted its bioindustry to reach between \$1.2 trillion and \$1.6 trillion by 2020 and account for more than 4% of the country's gross domestic product (GDP).<sup>90</sup> Additionally, China identified the biotech industry as one of five strategic emerging industries that together would account for more than 15% of the country's GDP by 2020. Specifically, as described in the *13<sup>th</sup> Five-Year National Strategic Emerging Industry Development Plan*, China seeks to "accelerate the pace of innovation and development of the biotech industry and foster new biotech economic drivers" by:

- building a new biopharmaceutical system;
- enhancing the development level of biomedical engineering;
- accelerating the industrialization of biotech agriculture;
- promoting the scaled application of biotech manufacturing;
- cultivating new forms of biological services; and
- creating models for the development of bioenergy.<sup>91</sup>

<sup>&</sup>lt;sup>88</sup> For more information on the bioeconomy strategies of various countries see International Advisory Council on Global Bioeconomy, *Global Bioeconomy Policy Report (IV): A Decade of Bioeconomy Policy Development around the World*, November 2020, https://gbs2020.net/wp-content/uploads/2020/11/GBS-2020\_Global-Bioeconomy-Policy-Report\_IV\_web.pdf.

<sup>&</sup>lt;sup>89</sup> Rob Carlson and Rik Wehbring, *Two Worlds Two Bioeconomies: The Impacts of Decoupling US-China Trade and Technology Transfer*, Johns Hopkins Applied Physics Laboratory, 2020, p. 6, https://www.jhuapl.edu/Content/documents/Carlson\_Wehbring-Biotech.pdf.

<sup>&</sup>lt;sup>90</sup> Organization for Economic Cooperation and Development, *Innovation Ecosystems in the Bioeconomy*, OECD Science and Technology Policy Papers, No. 76, OECD Publishing, Paris, September 2019, p. 25, https://www.oecd-ilibrary.org/deliver/e2e3d8a1-en.pdf?itemId=%2Fcontent%2Fpaper%2Fe2e3d8a1-en&mimeType=pdf.

<sup>&</sup>lt;sup>91</sup> People's Republic of China State Council, *Circular of the State Council on Issuing the National 13th Five-Year Plan for the Development of Strategic* translation by the Center for Security and Emerging Technology, November 2016, pp. 19-23, https://cset.georgetown.edu/research/national-13th-five-year-plan-for-the-development-of-strategic-emerging-

More recently, biotechnology is included as a strategic area in the 14<sup>th</sup> Five-Year Plan, which states China's plans to increase R&D spending by 7% annually through 2025.<sup>92</sup>

According to a 2019 report prepared for the U.S.-China Economic and Security Review Commission by Gryphon Scientific and the Rhodium Group:

China's biotech industry has grown rapidly over the past decade but still remains less than a tenth the size of the US biotech industry in terms of market size. China's biologics market is estimated at 30 to 40 billion yuan (\$4.7 to \$6.2 billion) and their agricultural biotech market is around \$8.1 billion, while estimates places those US markets at \$118 billion and \$110 billion, respectively. Overall, the US maintains a superior biotechnology innovation capacity through world-class research training and strong governmental support of R&D, but China is seeking to close that gap through its top-down government strategy and coordination, talent recruitment programs, high R&D spending across the industry, and capacity for high-tech R&D.<sup>93</sup>

### **European Union**

The European Union (EU) issued its first bioeconomy strategy in 2012, stating,

In order to cope with an increasing global population, rapid depletion of many resources, increasing environmental pressures and climate change, Europe needs to radically change its approach to production, consumption, processing, storage, recycling and disposal of biological resources. The Europe 2020 Strategy calls for a bioeconomy as a key element for smart and green growth in Europe. Advancements in bioeconomy research and innovation uptake will allow Europe to improve the management of its renewable biological resources and to open new and diversified markets in food and bio-based products. Establishing a bioeconomy in Europe holds a great potential: it can maintain and create economic growth and jobs in rural, coastal and industrial areas, reduce fossil fuel dependence and improve the economic and environmental sustainability of primary production and processing industries.<sup>94</sup>

In 2018, the EU updated its bioeconomy strategy<sup>95</sup> indicating that a renewed strategy will support the transition to a sustainable and circular bioeconomy, address wider EU priorities and policies (e.g., climate, innovation, food, and energy), and fulfill global commitments associated with the United Nations 2030 Agenda for Sustainable Development<sup>96</sup> and the Paris Agreement.<sup>97</sup>

industries/.

<sup>&</sup>lt;sup>92</sup> People's Republic of China, Outline of the People's Republic of China 14<sup>th</sup> Five-Year Plan for National Economic and Social Development and Long-Range Objectives for 2035, translation by the Center for Security and Emerging Technology, May 12, 2021, pp. 8, 10, https://cset.georgetown.edu/wp-content/uploads/ t0284\_14th\_Five\_Year\_Plan\_EN.pdf.

<sup>&</sup>lt;sup>93</sup> Gryphon Scientific, LLC and Rhodium Group, LLC, *China's Biotechnology Development: The Role of US and Other Foreign Engagement*, A report prepared for the U.S.-China Economic and Security Review Commission, February 14, 2019, p. 2, https://www.uscc.gov/sites/default/files/Research/US-China%20Biotech%20Report.pdf.

<sup>&</sup>lt;sup>94</sup> European Commission, Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions, *Innovating for Sustainable Growth: A Bioeconomy for Europe*, February 13, 2013, p. 2, https://ec.europa.eu/research/bioeconomy/pdf/official-strategy\_en.pdf.

<sup>&</sup>lt;sup>95</sup> European Commission, Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions, *A Sustainable Bioeconomy for Europe: Strengthening the Connection Between Economy, Society and the Environment*, October 11, 2018, https://op.europa.eu/en/publication-detail/-/publication/edace3e3-e189-11e8-b690-01aa75ed71a1/.

<sup>&</sup>lt;sup>96</sup> For more information, see https://sdgs.un.org/goals.

<sup>&</sup>lt;sup>97</sup> As described by the United Nations, the Paris Agreement is a legally binding international treaty on climate change,

Specifically, the updated strategy included actions to address three priorities: (1) strengthening and scaling up EU bio-based sectors and unlocking investments and markets; (2) deploying local bioeconomies rapidly across the whole of Europe; and (3) understanding the ecological boundaries of the bioeconomy. According to the EU, it invested approximately \$4.5 billion in the bioeconomy from 2014 to 2020 and plans to invest nearly \$12 billion between 2021 and 2027.<sup>98</sup>

### Germany

The German bioeconomy—estimated at about \$500 billion—is the largest in Europe.<sup>99</sup> Germany considers itself a leader in the bioeconomy, developing a national research strategy for the bioeconomy in 2010 and a policy strategy for the bioeconomy in 2013. In 2020, Germany published a comprehensive national strategy, combining research and policy goals from various documents into a single "coherent framework" that "lays the foundations for Germany to strengthen its role as a bioeconomy leader and to create the technology and jobs of tomorrow."<sup>100</sup>

Germany's 2020 bioeconomy strategy, as with other European nations, aligns with the bioeconomy goals and priorities of the European Union (EU) (discussed above). Similar to the 2018 EU Bioeconomy Strategy, the German strategy emphasizes sustainability and resilience. The German government defines the bioeconomy as "the production, exploitation and use of biological resources, processes and systems to provide products, processes and services across all economic sectors within the framework of a future-oriented economy."<sup>101</sup>

The German national strategy outlines two guidelines and six strategic goals. The guidelines are:

- harnessing biological knowledge and responsible innovation for sustainable, climate-neutral development; and
- using biogenic raw materials for a sustainable, circular economy.

The strategic goals are:

- develop bioeconomy solutions for the 2030 Agenda for Sustainable Development;
- recognize and harness the potential of the bioeconomy within ecological boundaries;
- enhance and apply biological knowledge;
- establish a sustainable raw material base for industry;
- promote Germany as the leading location for innovation in the bioeconomy; and

adopted by 196 countries on December 12, 2015, with the goal to limit global warming to below 2 degrees Celsius, compared to pre-industrial levels. For more information, see https://unfccc.int/process-and-meetings/the-paris-agreement/the-paris-agreement and CRS Report R46204, *The United Nations Framework Convention on Climate Change, the Kyoto Protocol, and the Paris Agreement: A Summary, by Jane A. Leggett.* 

<sup>&</sup>lt;sup>98</sup> European Commission, *Bioeconomy: the European Way to Use Our Natural Resources, Action Plan 2018*, October 2018, https://op.europa.eu/en/publication-detail/-/publication/775a2dc7-2a8b-11e9-8d04-01aa75ed71a1.

<sup>&</sup>lt;sup>99</sup> Assobiotec and Intesa Sanpaolo, *Bioeconomy in Europe*, 6<sup>th</sup> Edition, June 2020, https://assobiotec.federchimica.it/ docs/default-source/default-document-library/bioeconomia-executivesummary656353eb1efe40198f9258ada35ca85e.pdf?sfvrsn=d48dbd39\_0.

<sup>&</sup>lt;sup>100</sup> German Federal Ministry of Education and Research and Federal Ministry of Food and Agriculture, *National Bioeconomy Strategy*, The German Federal Government, January 2020, p. 4, https://www.bmbf.de/upload\_filestore/pub/BMBF\_Nationale\_Biooekonomiestrategie\_Langfassung\_eng.pdf.

<sup>&</sup>lt;sup>101</sup> Ibid., p. 10.

• involve society and strengthen national and international collaboration.<sup>102</sup>

In addition, Germany's strategy calls for the establishment of a new advisory board tasked with developing an implementation plan for the national strategy. Germany plans to invest more than \$4.3 billion towards the implementation of its bioeconomy strategy from 2020 to 2024. Of this total, about \$1.3 billion is to target bioeconomy-related research. From 2010 to 2016, the German government invested approximately \$2.9 billion on bioeconomy-related research.<sup>103</sup>

## Italy

Agriculture and food are at the center of the Italian bioeconomy—estimated at more than \$400 billion in 2018. Italy also considers forestry, fisheries and aquaculture, and bio-based industries (e.g. chemicals) as key components of the nation's bioeconomy.<sup>104</sup> In 2017, Italy developed a dedicated national bioeconomy strategy. In 2019, it released a revised strategy with the goal of increasing the performance of the Italian bioeconomy by 15% by 2030. Both strategies define the Italian bioeconomy as the integration of "the sustainable production of renewable biological resources and the conversion of these resources and waste streams into value-added products such as food, feed, bio-based products and bioenergy."<sup>105</sup>

The revised 2019 strategy created the National Bioeconomy Coordination Group (NBCG) and tasked it with ensuring "synergy between national, regional and local public administrations and the National Technology clusters operating in the bioeconomy," in addition to facilitating and monitoring the implementation of the bioeconomy strategy.<sup>106</sup> The NBCG released an implementation action plan in 2020. The action plan proposes to invest nearly \$700 million in the following areas:

- the creation of regional value chains and multi-purpose and multi-product biorefineries;
- establishing a market for the use of urban bio-waste and wastewater;
- reconversion of industrial sites;
- restoration of the marine ecosystem; and
- circular and sustainable agrifood chains.

It also seeks to address regulatory barriers at both the European and national level. Furthermore, the implementation action plan highlights what it asserts is the potential of a circular bioeconomy

<sup>&</sup>lt;sup>102</sup> Ibid., pp. 14-16.

<sup>&</sup>lt;sup>103</sup> International Advisory Council on Global Bioeconomy, *Global Bioeconomy Policy Report (IV): A Decade of Bioeconomy Policy Development around the World*, November 2020, p. 103.

<sup>&</sup>lt;sup>104</sup> Fabio Fava, Lucia Gardossi, and Patrizia Brigidi, et al., "The Bioeconomy in Italy and the New National Strategy for a More Competitive and Sustainable Country," *New BIOTECHNOLOGY*, vol. 61 (2021), pp. 124-136.

<sup>&</sup>lt;sup>105</sup> International Advisory Council on Global Bioeconomy, *Global Bioeconomy Policy Report (IV): A Decade of Bioeconomy Policy Development Around the World*, November 2020, pp. 114-120.

<sup>&</sup>lt;sup>106</sup> Italian National Committee for Biosafety, Biotechnology and Sciences of Life Presidency of the Council of Ministers, "National Bioeconomy Coordination Group Mandate," http://cnbbsv.palazzochigi.it/en/areas-of-work/bioeconomy/national-bioeconomy-coordination-body/mandate/.

in accelerating Italy's post-COVID-19 recovery.<sup>107</sup>From 2016 through 2020, Italy invested about \$600 million in bioeconomy research and innovation.<sup>108</sup>

## Japan

In 2019, Japan—the third largest economy in the world—issued its first bioeconomy strategy. The strategy builds, in part, on the country's long history of support for the production and industrial use of biomass. In 2020, Japan updated its bioeconomy strategy with an increased emphasis on biotechnology and biological data, in addition to recognizing the potential role of the bioeconomy in addressing and recovering from the coronavirus pandemic (e.g., developing measures against future public health crisis and building efficient supply chains). According to the International Advisory Council on Global Bioeconomy, the Japanese bioeconomy is "a concept that expands a sustainable and renewable circular economy and society by using biotechnology and renewable biological resources."<sup>109</sup> The strategy is crosscutting covering multiple sectors, including agriculture, industry, health, and medicine.

Five basic policies guide the Japanese strategy.

- The development of targeted market areas, roadmaps, and sustained commitment.
- Integration of biology with digital technologies.
- Promotion as an international hub.
- Coordination and enhancement of international strategies (e.g., standards development, trade policies).
- Responding to ethical, legal, and social implications.<sup>110</sup>

According to the strategy, these policies reflect knowledge gained from previous efforts.

The strategy also targets the following market areas.

- High-performance biomaterials.
- Bioplastics.
- A sustainable primary production system.
- Organic waste and wastewater treatment.
- Healthcare for lifestyle improvement, functional foods, and digital health.
- Industries related to biopharmaceuticals, regenerative medicine, cell therapy, and gene therapy.
- Bio-foundries, including bio-production of food products.
- Biological analysis, measurement, and experimentation.

<sup>109</sup> International Advisory Council on Global Bioeconomy, *Global Bioeconomy Policy Report (IV): A Decade of Bioeconomy Policy Development around the World*, November 2020, p. 54.
 <sup>110</sup> Ibid., p. 55.

<sup>&</sup>lt;sup>107</sup> Italian National Committee for Biosafety, Biotechnology and Sciences of Life Presidency of the Council of Ministers, *Implementation Action Plan (2020-2025) for the Italian Bioeconomy Strategy BIT II*, July 2020, http://cnbbsv.palazzochigi.it/media/2018/bitii\_implementationactionplan\_july2020-flg.pdf.

<sup>&</sup>lt;sup>108</sup> Fabio Fava, Lucia Gardossi, and Patrizia Brigidi, et al., "The Bioeconomy in Italy and the New National Strategy for a More Competitive and Sustainable Country," *New BIOTECHNOLOGY*, vol. 61 (2021), p. 132.

• Large-scale construction using wood and smart forestry.<sup>111</sup>

A Bioeconomy Taskforce, composed of the heads of innovation-related agencies and offices, is responsible for the implementation, monitoring, and evaluation of the bioeconomy strategy. Multiple agencies and offices are to provide funding and other support, but the level of investment is unclear. According to the strategy, Japan invested \$56.4 million in FY2019 for technology development related to the study and linking of biological data and for the demonstration of bio-production.<sup>112</sup>

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<sup>111</sup> Ibid.

<sup>&</sup>lt;sup>112</sup> Translation by German Tokyo Embassy of Decision of the Council for Integrated Innovation Strategy, Cabinet Office, *Bio-Strategy 2020: Basic Measures*, June 26, 2020, p. 7, https://www.dwih-tokyo.org/files/2020/10/bio2020\_honbun\_en\_rev-1.pdf.