The U.S. Bioeconomy Policy Landscape

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Executive Summary

The U.S. bioeconomy has emerged as one of the most durable bipartisan priorities in Congress over the past several years. Estimated to contribute over $210 billion to GDP and support more than 644,000 domestic jobs, the bioeconomy has advanced from a specialized science policy domain to a core pillar of U.S. economic competitiveness, national security, and industrial strategy.

This shift is driven by a convergence of structural forces: intensifying geopolitical competition with China in advanced biomanufacturing, vulnerabilities exposed by COVID-19-related supply chain disruptions, and the accelerating convergence of artificial intelligence with biological science and engineering. Together, these dynamics have reframed biotechnology not only as a driver of innovation, but as critical infrastructure for economic resilience and defense readiness. Policymakers across party lines view leadership in biotechnology as essential to sustaining U.S. competitive advantage.

At the federal level, a coordinated policy architecture is taking shape, though it remains in an early stage of integration. Key developments include the establishment of the National Biotechnology and Biomanufacturing Coordination Office (NBBCO), designed to improve cross-agency alignment across USDA, FDA, EPA, DOE, and DoD. Legislative initiatives such as the Biobased Materials Investment and Production Act, Ag BIO Act, and the Farm to Fly Act signal growing momentum to expand domestic bio-based markets in manufacturing, agriculture, and sustainable fuels. These efforts are complemented by significant federal financing tools, including DOE loan guarantees, USDA Section 9003 Biorefinery Assistance Program funding, and clean energy and sustainable fuels incentives embedded in the Inflation Reduction Act (IRA).

Importantly, federal industrial policy is increasingly focused on bridging the “scale-up gap” in biotechnology commercialization. Programs supporting pilot- and demonstration-scale infrastructure, along with public-private consortia such as BioMADE, are intended to accelerate the transition from laboratory innovation to commercial biomanufacturing capacity. At the same time, national strategy documents and commissions — including the National Security Commission on Emerging Biotechnology (NSCEB) — have elevated biotechnology as a strategic domain comparable to semiconductors or advanced energy systems, particularly in the context of defense readiness and supply chain security.

Across these federal efforts, policymakers are converging around six primary policy domains:

1. **Federal coordination** — Reducing fragmentation across agencies and aligning biotechnology policy through a centralized coordination office.
2. **China de-risking and supply chain security** — Combining defensive measures (e.g., BIOSECURE Act proposals) with offensive investments in domestic capacity.

3. **Regulatory modernization** — Updating the fragmented Coordinated Framework for Biotechnology Regulation (largely unchanged since 1986) to better accommodate novel bioengineered products and AI-enabled discovery systems.
4. **Financing and scaling** — Addressing persistent, long development timelines collide with short-term private capital expectations.
5. **Agricultural biotechnology** — Positioning bio-based innovation in agriculture as both an economic development tool and a national security imperative tied to food system resilience and export competitiveness.
6. **AI–biotechnology convergence** — Recognizing the accelerating impact of artificial intelligence on biological discovery, process optimization, and biomanufacturing scale-up.

The bipartisan durability of this policy agenda is notable. The bioeconomy's political coalition spans multiple, overlapping priorities: national security concerns regarding dependence on Chinese biomanufacturing; rural and agricultural economic development opportunities; supply chain reshoring imperatives following COVID-19 disruptions; and defense modernization priorities emphasizing bio-based materials, fuels, and resilience.

As Senator Joni Ernst has argued, dependence on foreign biomanufacturing presents a strategic vulnerability, while Senator Todd Young and others have elevated the importance of biotechnology's role in sustaining U.S. military advantage. Advancing the bioeconomy has also experienced continuity across administrations — from Obama-era bioeconomy initiatives, through the Trump Administration's 2019 White House summit, to the Biden Administration's 2022 Executive Order on advancing biotechnology and biomanufacturing, to the September 23, 2025, Trump White House issued Memorandum for the Heads of Executive Departments and Agencies (M-25-34 / NSTM-2), recognizing biomanufacturing as a strategic national capability:

> "The United States holds the resources to lead the world in producing next-generation bio-manufactured products. Feedstocks from America's heartland and novel biological processes can be used to secure our supply chains, create jobs, and build scalable and universal manufacturing capacity. Agencies should support innovation in modular and scalable biological platforms and ensure that promising technologies have clear lab-to-market pathways by leveraging lab and biofoundry infrastructure."

At the state level, policy innovation is increasingly complementing federal strategy, with states competing to establish regional bioeconomy hubs and commercialization ecosystems. Massachusetts continues to anchor the life sciences sector through sustained public investment in research infrastructure and workforce development. California has expanded its leadership in synthetic biology, climate biotech, and venture capital-backed biomanufacturing. North Carolina has strengthened its biotechnology corridor through a combination of university-linked research parks and manufacturing incentives. In the Midwest, states such as Iowa,

Nebraska, Minnesota, and Illinois are leveraging agricultural feedstocks to build next-generation biomanufacturing and bioindustrial platforms, often tied directly to corn, soybean, and other commodity value chains. Texas, meanwhile, is emerging as a hybrid energy–biotech hub, particularly in sustainable fuels and industrial bioprocessing.

These state-level strategies are increasingly reinforced by federal place-based initiatives, including the Regional Technology and Innovation Hub program and investments in advanced manufacturing ecosystems. Manufacturing innovation institutes such as BioMADE play a critical bridging role by connecting federal priorities with regional execution capacity, particularly in scaling pilot technologies into commercially viable production systems.

Taken together, the policy landscape reflects a rapidly converging ecosystem in which federal strategy, congressional action, industrial policy tools, and state-level innovation strategies are increasingly aligned.

However, despite meaningful progress, significant gaps remain across regulatory modernization, scale-up financing, workforce development, and coordinated infrastructure investment. Addressing these gaps will be essential to fully realizing the U.S. bioeconomy's potential as a driver of long-term economic prosperity, national security, and industrial leadership.

Congressional Leadership and Strategy

National Security Commission on Emerging Biotechnology (NSCEB)

The most important institutional development for advancing the bioeconomy is the National Security Commission on Emerging Biotechnology (NSCEB), the central organizing force driving bipartisan bioeconomy policy.

Established by Congress in Section 1091 of the FY2022 National Defense Authorization Act, the NSCEB was charged with "carrying out a review of advances in emerging biotechnology and associated technologies," evaluating the strategic competition between the United States and China, and examining the convergence of AI and biotechnology.

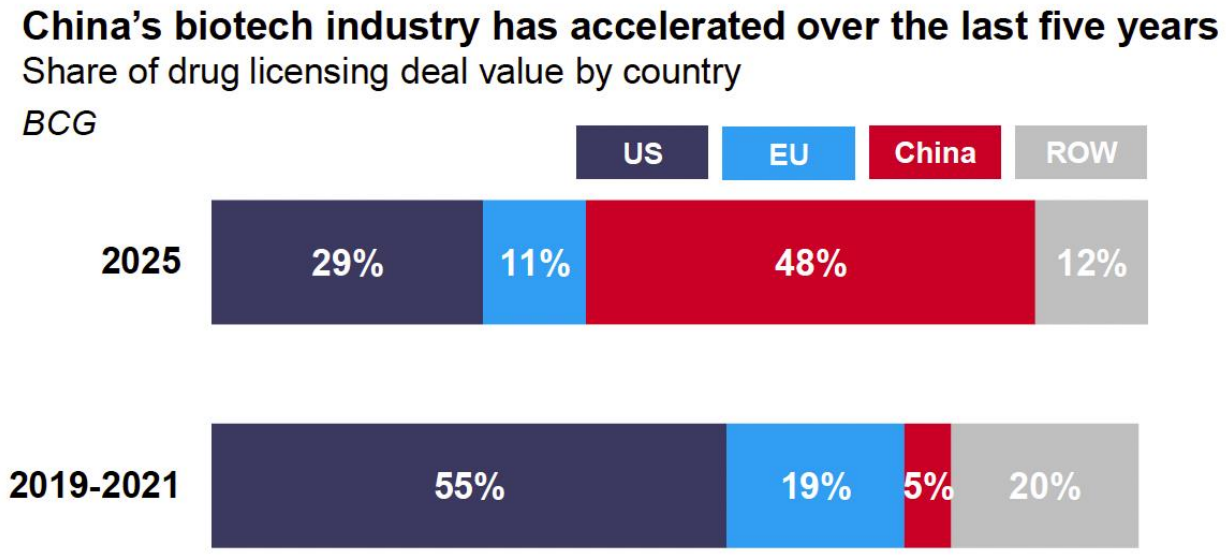
The bipartisan Commission is composed of Congressionally-appointed Commissioners with members from both the Senate and the House of Representatives, as well as experts from industry, academia, and government. The Commission's four Congressional commissioners are Senator Todd Young (R-IN), Senator Alex Padilla (D-CA), Representative Stephanie Bice (R-OK), and Representative Ro Khanna (D-CA).

In April 2025, the Commission delivered its final report to Congress, "Charting the Future of Biotechnology," outlining 49 recommendations aimed at accelerating biotechnology innovation and scaling the U.S. biomanufacturing base, reinforcing the bioeconomy as a strategic pillar of national security and economic competitiveness.

The Commission's report identified a six pillar framework for its recommendations:

1. **National coordination and governance** — Strengthening federal leadership and aligning agency efforts across the bioeconomy.
2. **Innovation and R&D leadership** — Expanding sustained investment in biotechnology discovery and translational science.
3. **Biomanufacturing scale-up capacity** — Building domestic infrastructure to move from lab breakthroughs to commercial production.
4. **Workforce and talent development** — Expanding education, training, and career pathways for a biotechnology-enabled economy.
5. **Regulatory modernization** — Updating and streamlining regulatory systems to keep pace with emerging biotech and AI-enabled tools.
6. **National security and supply chain resilience** — Securing critical bio-based supply chains, expanding global partnerships, and reducing strategic dependencies on adversarial nations.

The report concluded China is quickly ascending to biotechnology dominance, having made biotechnology a strategic priority for 20 years — and the United States must take swift action in the next three years, or risk falling behind in a way from which it may never recover. The report documented that 79 percent of U.S. pharmaceutical companies now depend on Chinese contract firms for manufacturing — a supply chain vulnerability that resonates with both Republican national security hawks and Democratic industrial policy advocates.



The report recommends a minimum U.S. investment of $15 billion over the next five years on emerging biotechnology and setting up a national coordinating office to optimize and coordinate the federal government's response to advancing the bioeconomy.

Promisingly, roughly half of the Commission's final recommendations have been introduced in Congress through standalone legislation and broader policy vehicles. More than a dozen (17) provisions aligned with the Commission's priorities have been enacted or partially implemented through the National Defense Authorization Act for Fiscal Year 2026, including measures to strengthen biotechnology leadership within the Department of Defense and the intelligence community, enhance supply chain security, and expand domestic biomanufacturing capacity.

Importantly, the NSCEB's April 2025 final report explicitly recommends the development of a comprehensive national bioeconomy strategy. Legislation such as the National Biotechnology Initiative Act (S.1387/H.R.2756), currently before Congress, including consideration in the Senate Committee on Health, Education, Labor, and Pensions and relevant House committees of jurisdiction, would operationalize these recommendations by institutionalizing interagency coordination through a National Biotechnology Coordination Office. Congressional action, therefore, represents the primary near-term pathway for formalizing and sustaining these strategic commitments at the federal level.

In short, while several of the Commission's most consequential proposals are still being implanted, the pace and breadth of legislative uptake of the NSCEB's recommendations underscore growing bipartisan consensus that biotechnology is a strategic domain of global competition.

A Snapshot of NSCEB Impact

Category	Key Development	Timeframe	What Changed / Was Proposed	Impact / Significance
Establishment	Created by the National Defense Authorization Act for Fiscal Year 2022	December 2021 (FY22 NDAA enacted)	Congress established the National Security Commission on Emerging Biotechnology(NSCEB) to assess biotech's role in national security and competitiveness	Elevated biotechnology to a core national security priority
Commission Operations	NSCEB research, hearings, and stakeholder engagement	2022–2024	Conducted studies, convened experts across government, industry, and academia	Built the analytical foundation for national biotech strategy
Final Report Issued	April 2025 report (49 recommendations)	Apr-25	Comprehensive strategy across investment, coordination, workforce, defense, and supply chains	Reframed biotech as a geopolitical and economic competition domain
Strategic Framework	Six-pillar national strategy concept	Apr-25	Whole-of-government approach spanning innovation, defense, workforce, and global alliances	Provided a coherent policy architecture for federal action
Legislative Translation Begins	Initial bills introduced reflecting NSCEB recommendations	Mid–Late 2025	Recommendations translated into standalone bills and legislative packages (e.g., coordination, agriculture, biosecurity)	Demonstrated rapid policy uptake for a federal commission
Major Coordination Proposal	National Biotechnology Initiative Act introduced (S.1387 / H.R.2756)	2025 (introduced); March 19, 2026 (Senate HELP hearing)	Proposed White House–level coordination office and agency leadership roles	Signals shift toward a centralized national biotech strategy
NDAA Implementation	Biotechnology provisions enacted in the National Defense Authorization Act (NDAA) for Fiscal Year 2026	Dec-25	~17 provisions aligned with NSCEB (leadership, supply chains, intelligence, biomanufacturing)	Marks early execution of NSCEB recommendations into law
Intelligence & Threat Provisions	Biotech threat reporting and IC engagement	2025–2026 (via NDAA & IAA pathways)	Required assessments of biotech threats, gaps, and expert engagement	Strengthened biosecurity and threat awareness
Industrial Base Focus	Biomanufacturing and supply chain provisions	2025–2026	Policies to expand domestic production and reduce reliance on foreign sources	Links biotech to industrial policy and reshoring efforts
Workforce & Talent Pipeline	Workforce strategy proposals	2025–present (legislative + policy development)	Expansion of biotech education, training, and talent programs	Addresses key constraint on scaling the bioeconomy
Ongoing Legislative Activity	Additional bills and policy proposals advancing	2025–2026 (ongoing)	~20–25 recommendations introduced; others under development	Reflects sustained bipartisan momentum

Key Federal Legislative Proposals

The Biobased Materials Investment and Production Act (March 2026)

The Biobased Materials Investment and Production Act (introduced March 27, 2026, by Reps. Michelle Fischbach and Nikki Budzinski) is the first bipartisan proposal to apply a CHIPS Act / Inflation Reduction Act-style tax credit framework to the U.S. biobased materials sector. The proposed bill addresses a key policy gap: while federal incentives have accelerated biofuels, many everyday products — such as plastics, packaging, and industrial chemicals — still rely heavily on foreign petroleum inputs.

The bill would allow companies using American-grown biomass to manufacture renewable materials to choose between two incentive pathways: (1) a 30 percent investment tax credit for constructing or retrofitting production facilities, or (2) a production tax credit of $0.10 per pound of qualifying renewable materials produced and sold, capped at $10 million annually. This dual-option structure mirrors the successful incentive models used in semiconductors and clean energy, giving businesses flexibility based on whether they are more capital-intensive or production-driven.

If enacted, the legislation could lower upfront project costs, improve plant economics, attract private investment, strengthen domestic supply chains, and accelerate commercialization of renewable chemicals and advanced materials. This bill also creates a template for expanding CHIPS- and IRA-style incentives across broader biomanufacturing sectors — including sustainable aviation fuel (SAF), renewable chemicals, and industrial biotechnology — helping build a more competitive U.S. bioeconomy.

Renewable Chemicals Act (2026)

Senators Coons (D-DE) and Ricketts (R-NE) introduced this bill providing a targeted tax credit for qualifying renewable chemicals or an investment tax credit for renewable chemical production facilities, incentivizing bio-based alternatives to fossil-derived chemicals. Eligible chemicals must be at least 95 percent biobased content and utilize the USDA Certified Biobased Product label.

National Biotechnology Initiative Act (2025)

Introduced jointly by Senators Young (R-IN) and Padilla (D-CA), and Representatives Bice (R-OK) and Khanna (D-CA), and noted above in the NSCEB section, this bill would establish a National Biotechnology Coordination Office within the Executive Office of the President to lead and coordinate federal biotechnology efforts and set in motion a whole-of-government

approach to advancing biotechnology for U.S. national security, economic productivity, and competitiveness.

BIOSECURE Act (signed into law, December 2025)

Originally introduced in January 2024 by Representatives Krishnamoorthi (D-IL) and Gallagher (R-WI), the House passed the BIOSECURE Act by a vote of 306 to 81 during "China Week" in September 2024, prohibiting federal agencies from procuring equipment or services from "biotechnology companies of concern." After a rocky path — it was cut from the FY2025 NDAA at the last minute — the BIOSECURE Act was ultimately included in the FY2026 National Defense Authorization Act, signed into law on December 18, 2025.

Biomanufacturing and Jobs Act (2025)

Senators Klobuchar (D-MN), Slotkin (D-MI), Ernst (R-IA), and Ricketts (R-NE) introduced this bill to strengthen USDA's BioPreferred program, which promotes the use of domestic biobased products derived from renewable agricultural materials, creating new markets for farmers while reducing dependence on fossil fuels.

Agricultural Biorefinery Innovation and Opportunity (Ag BIO) Act (2025)

Senators Klobuchar (D-MN) and Moran (R-KS) introduced this legislation to update the loan guarantee program and restore a grant program supporting public-private partnership investment in biorefineries, renewable chemicals, and biobased products.

The Agricultural Biorefinery Innovation and Opportunity (Ag BIO) Act of 2025

The Ag BIO Act, introduced by Senators Klobuchar (D-MN) and Moran (R-KS) and its House companion led by Representatives Nunn (R-IA) and Budzinski (D-IL), seeks to modernize USDA’s Section 9003 Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program. The legislation would streamline and expand loan guarantees, reestablish a grant program for pilot- and demonstration-scale facilities, and provide up to $100 million in mandatory funding over five years, including cost-share grants covering up to 60 percent of project costs. Designed to address the biomanufacturing “scale-up gap,” the bill aims to accelerate commercialization of biofuels, renewable chemicals, and biobased products while strengthening domestic supply chains and rural economic development. The legislation was introduced in both chambers and referred to committee but has not yet been enacted.

The Farm to Fly Act of 2025

The Farm to Fly Act focuses on accelerating the production and use of sustainable aviation fuels (SAF). It expands USDA eligibility for SAF projects, standardizes SAF definitions, and fosters interagency collaboration to streamline development and deployment. While the bill does not specify a funding amount, it directs the USDA to integrate SAF into its bioenergy programs, thereby creating new markets for American farmers and strengthening domestic energy resources.

Congressional Caucuses and Oversight

The BIOTech Caucus

Launched in June 2025, the bipartisan BIOTech Caucus is co-chaired by Reps. Chrissy Houlahan (D-PA) and Stephanie Bice (R-OK). The caucus elevates biotechnology as a strategic national priority with a focus on:

- **Biosecurity**. Federal investments to defend against natural and engineered threats.
- **Innovation**. Streamlining regulatory pathways, fostering public–private partnerships, and enabling rapid commercialization.
- **Economic Opportunity**. Supporting job creation, rural development, and global problem-solving in health, agriculture, and climate.

Vice-Chairs include Reps. Ro Khanna (D-CA), Gus Bilirakis (R-FL), Jake Auchincloss (D-MA), and Pete Sessions (R-TX). The caucus is expanding its membership and begun endorsing bipartisan legislation aligned with recommendations from the NSCEB's April 2025 report, signaling a shift from convening and education toward active legislative coordination.

State and regional bioscience caucuses, including those in Michigan and North Carolina, continue to complement these federal efforts by reinforcing localized innovation ecosystems.

Workforce & Education Policy

A skilled and scalable workforce is a foundational constraint and enabler for U.S. bioeconomy growth. Federal programs spanning NSF biotechnology and convergent engineering research, DOE biomanufacturing and clean energy workforce initiatives, and USDA extension and rural development programs collectively support talent development across the bioeconomy value chain. These efforts are increasingly complemented by industry-led partnerships such as BioMADE and regional biomanufacturing consortia, which focus on hands-on training, pilot-scale facility experience, and employer-driven credentialing. Despite this expanding ecosystem, persistent workforce gaps remain — particularly in biomanufacturing technicians,

process engineers, and regulatory and quality assurance professionals — at a time when synthetic biology and industrial biotechnology sectors are expected to experience sustained rapid growth through the end of the decade.

Federal Financial Tools Enhance Private-sector Investment

Department of Energy (DOE) Loan Programs Office

The DOE's Loan Programs Office (LPO) provides critical financing for large-scale energy projects, including bioenergy and advanced fuels, which are central to expanding the U.S. bioeconomy. Loan guarantees reduce investment risk for private developers scaling up biorefineries and sustainable aviation fuel (SAF) facilities.

Treasury’s Inflation Reduction Act (IRA) Incentives

IRA tax credits, including Section 45Z for SAF, provide per-gallon incentives for low-carbon fuels, directly supporting bio-based fuel production. The One Big Beautiful Bill Act (signed July 4, 2025) materially amended Section 45Z. Key changes, effective January 1, 2026: the SAF-specific credit rate has been reduced from $1.75/gallon to $1.00/gallon (now equal to the rate for non-SAF transportation fuels); the credit has been extended through December 31, 2029 (previously 2027); feedstocks must be sourced from the United States, Mexico, or Canada only; and negative emissions rates are prohibited, with the sole exception of animal manure feedstocks. The prevailing wage and apprenticeship requirements for accessing higher credits remain in place, continuing to drive U.S. workforce participation in bioeconomy sectors.

USDA Loan Guarantees: Biorefinery, Renewable Chemical, and Biobased Product Assistance Programs

USDA Section 9003 Loan Guarantees support the development, construction, retrofitting, and commercialization of facilities producing advanced biofuels, renewable chemicals, and biobased products. The program can provide loan guarantees of up to $250 million per project, helping reduce financing risk for lenders and enabling companies to scale emerging bio-based technologies from pilot stage to commercial production. Program availability depends on USDA funding authority and application windows

A Snapshot of Federal Policies and Programs Advancing the U.S. Bioeconomy

Bill/Department	Updated Policy Implications for the Bioeconomy
Farm Bill	Continues to be the core legislative platform supporting energy crops, biomass feedstocks, rural development, conservation incentives, and renewable fuel infrastructure. Programs such as BCAP, REAP, and rural energy initiatives can help expand domestic feedstock supply and lower costs for biorefineries and bio-based manufacturers. Reauthorization timing and funding levels will shape future sector growth.
USDA	Administers financing and commercialization programs including the Section 9003 Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program, which can provide loan guarantees of up to $250 million for eligible projects. USDA also supports grants, technical assistance, procurement of biobased products (BioPreferred), and rural development initiatives that help scale pilot and first-commercial facilities.
DOE	Supports commercialization through the Loan Programs Office (LPO), Bioenergy Technologies Office (BETO), ARPA-E, and national labs. DOE funds R&D, demonstration, and scale-up of advanced biofuels, carbon utilization, industrial biotechnology, renewable chemicals, and SAF pathways. Plays a critical role in bridging innovation from lab to market.
Department of Defense (DoD)	Remains an important early adopter and demand catalyst for advanced fuels, especially drop-in fuels for aviation, maritime, and logistics uses. DoD procurement and testing programs can de-risk commercialization, validate performance, and strengthen domestic supply chains for strategic materials and fuels.
Infrastructure Investment and Jobs Act (IIJA)	Continues to support transportation, grid, ports, rail, and logistics infrastructure that can improve movement of biomass feedstocks, renewable fuels, and bioproducts. Also funds energy, resilience, waste-to-energy, hydrogen, and carbon management projects that indirectly benefit bioeconomy deployment.
Inflation Reduction Act (IRA)	Provides 45Z Clean Fuel Production Credit, SAF-related incentives, 45Q carbon capture, and manufacturing credits that improve economics for biofuel, biogas, and biobased production projects.
CHIPS and Science Act	While focused on semiconductors and domestic manufacturing, it established a modern federal model for using investment tax credits, industrial policy, supply-chain resilience, workforce development, and place-based manufacturing incentives. Increasingly viewed as a template for future bioindustrial and biomanufacturing policy.
Biobased Materials Investment and Production Act (2026, proposed)	First explicit attempt to apply CHIPS/IRA-style tax credits directly to renewable materials and chemicals. Would allow producers to choose either a 30% investment tax credit for facility construction/retrofits or a $0.10/lb production credit (up to $10 million annually). Could significantly accelerate domestic renewable chemicals, bioplastics, and broader bioindustrial manufacturing if enacted.

Industry Leadership and Public–Private Partnerships

The private sector drives domestic biotechnology investment and helps shape policy. Notable initiatives include:

BIO's Bioeconomy Task Force

The Task Force comes from *Schmidt Futures* and related partners, and its work is laid out in a strategy document titled *"The U.S. Bioeconomy: Charting a Course for a Resilient and Competitive Future"* (often called the BioFutures report), which emphasizes a systems-of-systems approach: not just R&D, but providing a strategy /roadmap for workforce, feedstocks, scale-up/infrastructure, regulatory/regulatory alignment, supply chain, and equitable economic opportunities. Specific outputs include case studies, quantified scenarios of scaling bioproduction, discussions of policy gaps (e.g. regulatory, measurement, workforce) and suggested investment levels (e.g., for infrastructure and R&D).

The report has played an important role in broadening the visibility of the U.S. bioeconomy, highlighting its significance well beyond traditional health and pharmaceutical applications. By underscoring opportunities in bioindustrial manufacturing, chemicals, materials, fuels, and supply chain security, it has helped elevate the conversation around biotechnology as a pillar of economic and national resilience. In doing so, the report has shaped discussion on the urgent requirement for scale-up capacity, pilot and demonstration facilities, regulatory modernization, and a skilled workforce. Several of these priorities are now beginning to surface in federal funding streams and legislative proposals. In addition, the report's findings and recommendations have served as direct input into government initiatives, including the White House's *Data for the Bioeconomy Initiative*, which advances guidance on data sharing, measurement, and valuation of the bioeconomy across sectors.

BioMADE (Bioindustrial Manufacturing and Design Ecosystem)

BioMADE (Bioindustrial Manufacturing & Design Ecosystem) is a U.S. Department of Defense–backed Manufacturing Innovation Institute under the Manufacturing USA network, launched in April 2021. The institute began with an initial award of roughly $87 million over seven years from the DoD, supported by more than $180 million in non-federal cost shares from universities, industry, states, and other partners. Since then, its budget ceiling was increased in 2023 by the DoD to exceed $500 million**,** enabling more ambitious programs and facility investments.

BioMADE has grown to include more than 300 member organizations spanning academia, private firms, state economic development agencies, and nonprofits across 38 states. In its project portfolio, it has funded dozens of initiatives: projects aimed at supply chain resiliency,

sustainability, defense-relevant materials, novel bio-based chemicals and fibers, workforce training, and regulatory or process scale-up challenges. For example:

- Recent deliverables include a demonstration-scale facility in Maple Grove, Minnesota, announced in April 2025. This 122,000 square foot facility features two 25,000-liter fermenters and is intended to help move bioindustrial technologies from pilot toward commercial scale, especially in materials, lightweight composites, and other defense-relevant products. The investment (roughly $132 million from DoD and the Minnesota Department of Employment and Economic Development) underscores the growing scale of BioMADE's infrastructure ambitions.

- Another recent project is a new bioindustrial manufacturing facility near Ames, Iowa: a multi-user, pilot-scale plant with large fermenters and downstream processing, set to open in 2028, with cost-shares from the DoD, Iowa State University, and the Iowa Economic Development Authority.

- Also, BioMADE recently announced a set of three projects (totaling $6.4 million) through its "Sustainable Logistics for Advanced Manufacturing" call, producing defense-relevant lubricants from food waste, bio-based carbon fiber, and enhanced textile fibers.

BioMADE is working to close the "scale-up gap" by providing infrastructure and demonstration facilities that allow R&D innovations to move more quickly toward commercial production without having to shift expensive scale-up work overseas. It is also contributing to supply chain resilience and national security by focusing on defense-relevant materials and processes (e.g., bio-based carbon fiber, lubricants, specialty fabrics). Furthermore, BioMADE's regional facility projects are expected to generate economic development and jobs in feedstock-rich and rural areas, expanding the distribution of bioindustrial capacity across the country.

Other Private-Sector Influencers

At the industry and advocacy level, the Biotechnology Innovation Organization (BIO) serves as the principal national trade association, playing a central role in shaping federal biotechnology policy across regulatory modernization, tax incentives, and supply chain security. Alongside BIO, a broader ecosystem of sector coalitions — including the National Corn Refiners Association, the Plant Based Products Council, Growth Energy, the Renewable Fuels Association, the American Coalition for Ethanol, and Clean Fuels Alliance America, etc.

Complementing these advocacy networks is a growing layer of venture capital, platform biotechnology firms, and commercialization accelerators that underpin the scale-up economy. Firms such as Flagship Pioneering, Ginkgo Bioworks, and IndieBio (SOSV) have helped define new models of platform-based biotechnology development, while climate-focused investors such as Breakthrough Energy Ventures are increasingly channeling capital into industrial

biomanufacturing, carbon utilization, and next-generation materials. These private-sector actors operate alongside federal Manufacturing USA institutes beyond BioMADE — such as NIIMBL and ARMI — creating a distributed but increasingly coordinated infrastructure for advancing biomanufacturing, accelerating commercialization, and reducing scale-up risk.

Federal Regulation and Standards of the Bioeconomy

Regulatory modernization is a central enabling condition for scaling the U.S. bioeconomy. The current oversight system is grounded in the Coordinated Framework for Regulation of Biotechnology, first established in 1986 and updated in 1992 and 2017. The framework was designed to ensure product safety while avoiding the creation of a single, centralized biotechnology regulator.

Responsibility instead is distributed across existing statutory authorities within three primary agencies:

1. The Environmental Protection Agency (EPA)
2. The Food and Drug Administration (FDA), and
3. The U.S. Department of Agriculture (USDA)

EPA regulates biotechnology products that function as pesticides or environmental inputs under authorities such as TSCA and FIFRA; FDA oversees foods, drugs, biologics, and selected synthetic biology applications; USDA regulates plant health and agricultural biotechnology products, including genetically engineered crops.

The framework rests on a “product-based” regulatory philosophy that focuses on the characteristics and intended use of the final product rather than the engineering process used to create it. This approach aligned well with early biotechnology applications, particularly genetically modified crops and first-generation genetic engineering. However, the structure now strains under the pace and complexity of modern innovation, including synthetic biology, precision fermentation, platform-based microbial engineering, and rapidly iterative design cycles enabled by artificial intelligence, automation, and advanced biomanufacturing.

Several structural challenges define the current regulatory environment:

- **Fragmented and overlapping jurisdiction**. Developers often navigate unclear boundaries across agencies. Products can trigger multiple, sequential, or duplicative review processes. Differing statutory interpretations of risk frequently produce inconsistent regulatory outcomes.

- **Process inefficiency and extended timelines**. No unified entry point exists for biotechnology products, requiring companies to move agency by agency. Unpredictable review timelines increase capital risk and delay commercialization.
- **Regulatory uncertainty for novel technologies.** Emerging products that do not fit legacy categories face the greatest ambiguity. Startups and investors encounter unclear approval pathways, which dampens investment and slows scale-up.
- **Global competitiveness pressures.** Peer economies — including the United Kingdom, Singapore, parts of the European Union, and China in select domains — are advancing more streamlined or centralized regulatory models. Without modernization, U.S. leadership in industrial biotechnology and biomanufacturing faces erosion.

Parallel efforts are emerging to address these gaps through updated standards and technical infrastructure. Priority areas include harmonized frameworks for synthetic biology, AI–biotechnology convergence, and sustainable aviation fuel certification. The National Institute of Standards and Technology (NIST) is advancing foundational work on bio-based materials standards and secure bio-data infrastructure, helping lay the groundwork for a more modern, interoperable regulatory system.