

# U.S.-EU Synergy to Bolster Transatlantic Biotechnology and Biomanufacturing

Continued transatlantic partnership between the United States and the European Union is critical for mutual security, prosperity, and innovation, and the European Commission's commitment to building the future with biotechnology aligns with ongoing efforts and strategies in the U.S. In the EC's March 2024 communication, Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU, the EC identifies challenges within the EU's biotechnology and biomanufacturing sector and proposes actions to strengthen the EU's framework. Key challenges outlined by the EC include transferring technologies, navigating a complex regulatory environment, and safeguarding economic security. As the EU and U.S. share similar constraints and concerns when it comes to scaling biomanufacturing and the biotechnology industry, there are opportunities to identify joint solutions and address challenges through partnerships.

## U.S.-EU partnership for global leadership in biotechnology

Together, the U.S. and the EU's 27 Member States represent nearly half of the world's gross domestic product<sup>2</sup> as well as half of all global research funding.<sup>3</sup> Data from 2021 also show that the U.S. and the EU are the two largest contributors to the global biotechnology market, contributing 60% and 12%, respectively.<sup>4</sup> By strengthening ties and aligning approaches as strategic allies, the U.S. and the EU have the opportunity to advance biotechnology research and innovation at a transformative scale, strengthen critical global supply chains with biomanufacturing, and lead the world in safe and responsible governance of biotechnology.

### Opportunities for continued U.S.-EU engagement

Outlined below are areas of alignment between the U.S. and EU and opportunities for continued and new collaboration.

**Expand global market access for biotechnology products:** New biotechnology products are entering the market at a faster pace, accelerated by low-cost sequencing and accessibility of genome editing tools. In response to regulatory obstacles within the EU, the EC proposes a study to analyze the EU regulatory framework, to establish regula-

tory sandboxes where developers can test novel products, and to establish an EU Biotech Hub to help biotechnology companies navigate the regulatory framework. Similarly, the NSCEB recognizes regulatory hurdles for biotechnology products both within the U.S. and by trading partners. The NSCEB is considering policy options to improve U.S. oversight of biotechnology products and to encourage regulatory convergence for biotechnology products across international borders.

**Develop international standards for biotechnology** and biomanufacturing: As biotechnology is an increasingly important global economic driver, developing standards and metrics from which an international community can operate is critical. The EC recognizes the importance of standards to facilitate market access and innovation and will encourage updating European standards for biotechnology and biomanufacturing. As standards are intrinsically tied to global economies, the U.S. must continue to work with allies and like-minded countries, including the EU, to develop standards that are broadly useful as biotechnology evolves to ensure interoperability and enable technology transfer.

#### Secure global supply chains with biomanufacturing:

The U.S. and the EU are working towards similar aims in securing and growing their respective emerging biotechnology industries. The EC notes obstacles in identifying sufficient feedstock to support bio-based value chains. Securing supply chains requires the U.S. to examine opportunities for both onshoring and friendshoring. Strengthening ties with the EU will be critical to ensuring that U.S. supply chains are secure and resilient for both sides of the Atlantic through biomanufacturing. There are opportunities to work in tandem to grow the emerging biotechnology industry by increasing market access, providing infrastructure for the industry to scale, or lowering trade barriers for bioproducts. Furthermore, the U.S. and the EU can also work towards similar understandings of risk and transparency in their modelling of biotechnology-related supply chains.

Protect biotechnology and other critical technologies: The EC identified biotechnology as one of ten critical technologies for which they are conducting a risk assessment. Strengthening international collaborations on biotechnology and other critical technologies to counter

policies and practices of competitor countries that may pose risks to national and economic security will be important to protecting shared interests between the U.S. and the EU. This involves assessing ways to protect intellectual property, and to cooperate on research security, export controls, and investment screening. Importantly, a mutual understanding of potential risks and vulnerabilities that biotechnology poses must underlie the U.S.'s and EU's commitment to promote safe and responsible use of biotechnology.

Enable biotechnology innovation with Al and data: High-quality and high-quantity data are vital to enable Al-biotechnology convergence to improve human health and accelerate industrial innovation. The EC outlined actions in their initiative to foster data application and accelerate uptake of generative AI in EU biotechnology companies. As the NSCEB looks to improve data generation, collection, and integration for Al we are exploring ways to share best practices, promote AI and bioliteracy, and collaborate on related efforts with the EU. For instance, connecting high-performance computing between the U.S.'s National Laboratories and the European High Performance Computing Joint Undertaking (EuroHPC) supercomputers is a potential avenue to enable AI across the Atlantic. Importantly, the NSCEB will look for opportunities to collaborate with the EU to ensure that as AI and biotechnology convergence is catalyzed across industries that it is done so responsibly and safely.

Foster continued U.S.-EU collaboration: Continued engagement with international partners to foster research collaboration and exchange of talent and knowledge is critical to remain at the leading edge of biotechnology innovation. The Joint Consultative Group on Science and Technology Cooperation convened in March 2024 and reaffirmed their commitment to advancing transatlantic scientific cooperation through shared priorities in research, development, and innovation. Additionally, the U.S.-EU Trade and Technology Council (TTC), established in 2021, enables shared objectives in trade and investment, including enhanced cooperation on biotechnology to safeguard economic and national security and to address global challenges. The TTC's sixth ministerial meeting in April 2024 underscored the importance of U.S.-EU coordination and joint leadership to create rules for emerging technologies.5 Proposed actions for transatlantic advancement of biotechnology include diversifying strategic supply chains to reduce vulnerabilities, promoting innovation while fostering interoperability of technologies, supporting international standardization of critical and emerging technologies, cooperating on export controls and investment screening, and equipping workforces with necessary skills. The NSCEB supports the goals of the Joint Consultative Group and the TTC and looks forward to continued activity to foster U.S.-EU collaboration on biotechnology and advancing solutions to address global challenges.

In December 2023, NSCEB Commissioners conducted official visits to Belgium, Denmark, and Germany. Commissioners met in Brussels with officials from the EC Directorates-General for Internal Market, Industry, Entrepreneurship and SMEs (GROW) and for Research and Innovation (RTD). These discussions illuminated the EC's efforts to develop economic opportunities aligned with biotechnology and to conduct risk assessments of critical technologies.<sup>6</sup> Commissioners also met with government officials, academic institutions, businesses, and non-profit organizations across the three aforementioned EU Member States. These stakeholder discussions helped Commissioners better understand the biotechnology and biomanufacturing landscapes in these countries and examine where strengthened partnership between the U.S. and the EU could add potential value.

As biotechnology evolves at a rapid pace, continued U.S.-EU dialogue and collaboration are critical to assess new opportunities and risks, forecast trends, and capture critical capabilities to secure transatlantic economic and national security. The NSCEB looks forward to continued engagement with EU partners and international allies to continue collective momentum for building a global future with biotechnology.

### **Sources**

- 1 European Commission. "Building the Future With Nature"
- 2 IMF. "GDP, Current Prices"
- 3 National Center for Science and Engineering Statistics. "Academic R&D"
- 4 Statista. "Value Share of the Biotech Sector Worldwide as of 2021"
- 5 The White House. "U.S-EU Joint Statement of the Trade and Technology Council"
- 6 European Commission. "Commission Recommends Carry Out Risk Assessments on Four Critical Technology Areas"

For any questions about this white paper, or related work at the National Security Commission on Emerging Biotechnology, please contact us at <a href="mailto:ideas@biotech.senate.gov">ideas@biotech.senate.gov</a>.

Staff at the National Security Commission on Emerging Biotechnology authored this paper with input from the expert Commissioners. The content and recommendations of this white paper do not necessarily represent positions officially adopted by the Commission.

