

# Congress of the United States

Washington, DC 20515

Dr. Laurie E. Locasio  
Director of the National Institute of Standards and Technology  
100 Bureau Dr.  
Gaithersburg, MD 20899

March 6, 2024

Dear Director Locasio,

The U.S. bioeconomy has seen an increase in attention in the past year due to Executive Order (EO) 14081 on advancing the U.S. bioeconomy and the bipartisan CHIPS and Science Act of 2022 (P.L. 117-167). However, a [lack of standards for industrial biomanufacturing](#) limits this sector. Both the EO and the CHIPS and Science Act promote the establishment and advancement of biomanufacturing research to develop standards and establish metrics to grow and assess the state of the U.S. bioeconomy.

Division B, Title IV, Section 10402 of the CHIPS and Science Act establishes the National Engineering Biology Research and Development Initiative (the Initiative) and states that the Initiative focuses on “advancing areas of biomanufacturing research to optimize, standardize, scale, and deliver new products and solutions” and on “development of standards for databases, including for curation, interoperability, and protection of privacy and security.” Title IV also calls on the National Institute of Standards and Technology (NIST) to “advance the development of standard reference materials and measurements The Interagency Working Group on Data for the Bioeconomy, created in the EO, released its “[Visions, Needs, and Proposed Actions for Data for the Bioeconomy Initiative](#)” report in December 2023. The report calls for the development and adoption of new and existing standards and best practices to ensure data for the bioeconomy are findable, accessible, interoperable, and reusable and for a compendium of data standards to increase awareness and accessibility.

Relatedly, Congress created the National Security Commission on Emerging Biotechnology in Fiscal Year 2022’s National Defense Authorization Act (P.L. 117-81). The Commission is tasked with reviewing advancements in biotechnology as it relates to Department of Defense activities. The Commission released its [interim report](#) in December 2023 and, in line with the CHIPS and Science Act and Interagency Working Group, noted the importance of developing standards in this space, specifically working with our international allies to develop “international standards for the tools of biotechnology” that “align with U.S. values and ethics.” The report also states that “biomanufacturing faces barriers to innovation because of...lack of standardization,” among other hurdles.

The lack of standards has created numerous inconsistencies within even simple biomanufacturing phrasing that lead to confusion around basic parameters. A common language would go a long way in remedying undefined and interpretable terms.

Standardization within the U.S. bioeconomy will be pivotal to move industrial biomanufacturing forward, create a more resilient supply chain, and establish a durable, competitive U.S. bioeconomy. In

turn, strengthening the U.S. bioeconomy will improve Americans' well-being, promote well-paying jobs, and create a competitive and advantageous U.S. science and technology enterprise to achieve our national and societal goals.

To ensure the success of the Initiative and boost American economic competitiveness, as well as national security, it will be imperative to prioritize standardization within the U.S. bioeconomy. To achieve these goals, we support and recommend the following actions:

1) NIST should perform a landscape analysis and generate a report on existing standards that are relevant to or could be adapted for industrial biomanufacturing, gaps in standards, and lessons learned from previous standard-creating attempts. This analysis should include standards developed by U.S.-domiciled standards developers, standards developed in the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) and other international bodies, as well as relevant national or regional standards in current use globally.

2) NIST should work with the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIMBL), the Bioindustrial Manufacturing And Design Ecosystem (BioMADE), the Department of Energy's Bioenergy Technologies Office (DOE BETO), and the Department of Agriculture's Agricultural Research Service (USDA ARS) as it defines standards. Additionally, NIST should engage with industry, the American National Standards Institute (ANSI), and the Advanced Regenerative Manufacturing Institute (ARMI) on workability and usefulness of developed standards.

3) NIST should look to existing sector-specific communities and public-private partnerships within industrial biomanufacturing to establish needed standards within these sectors. This approach will facilitate consensus-building toward effective standards and will ensure that the standards are specific and fit-for-purpose.


4) NIST should prioritize standards for industrial biomanufacturing facility design that enable flexibility, retrofitting, and repurposing and thus maximize production and alleviate capacity constraints in the U.S. bioeconomy.

5) NIST should prioritize support for standards in industrial biomanufacturing that also address, contribute to, and support environmental sustainability in order to achieve a circular bioeconomy where the entire biomanufacturing process is sustainable.

6) NIST should facilitate community driven discussion around biomanufacturing data standards.

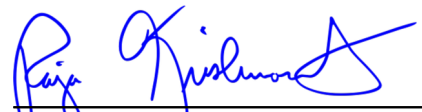
Prioritizing standardization within the U.S. bioeconomy will allow the U.S. to create a more dynamic supply chain and will alleviate industrial biomanufacturing capacity challenges that the U.S. is currently facing. Ultimately, these recommendations will enable a secure and sustainable U.S. bioeconomy that maintains the exponential economic growth we have seen this past year and allows for a competitive advantage that the U.S. has not yet realized.

Sincerely,



---

Jake Auchincloss  
Member of Congress



---

Raja Krishnamoorthi  
Member of Congress



---

Seth Moulton  
Member of Congress



---

Haley M. Stevens  
Member of Congress



---

Randy Feenstra  
Member of Congress



---

Darin LaHood  
Member of Congress