EBRC Engineering Biology Research Consortium

Standards and Metrics to Accelerate the Global Bioeconomy

A Policy Paper by the Engineering Biology Research Consortium

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The need for standards and metrics to advance the bioeconomy

The rapid emergence of biotechnologies has the potential to transform our current economy into a sustainable and secure bio-based economy. However, this emergence is happening largely in the absence of the standards and metrics needed to assess and sustain a successful bioeconomy through useful data, and to promote innovation. As an example, metrics are foundational for establishing useful benchmarks to assess performance within the bioeconomy. Such benchmarking would benefit startups and established companies alike by making it simpler to compare their new or alternative bio-based products to what already exists. Trusted standards and metrics also play a key role in securing investments in new technologies and commercialization in more established industries, but do not yet exist for bio-based processes. Common language, measurements, and widely adopted standards are critical for many activities within the bioeconomy, including:

- benchmarking to demonstrate the value-proposition of advancements in biotechnology developed in research laboratories to be translated to at-scale, industrial use;
- encouraging investment in commercialization;
- successful consumer and business-to-business transactions;
- and forming clear regulations to achieve a safe and secure bioeconomy, that spur rather than sacrifice innovation.

Establishing standards and metrics will not only accelerate U.S. bioeconomy development, it has important biosecurity implications. Standards and metrics will underpin the regulations and biosecurity assessments that will be critical to promote and protect the bioeconomy. The U.S. can demonstrate leadership in the global bioeconomy by recognizing and acting on the importance of clear, effective standards and metrics.

Challenges in developing standards and metrics

Though there have been previous attempts to establish standards within engineering biology – including the inactive NIST Synthetic Biology Standards Consortium, the NSF-funded Nuts and Bolts of Bioengineered Systems: A Workshop on Standards in Synthetic Biology, the EU-funded project BioRoboost, and an early British Standards Institute advisory paper, among others – with the exception of the International Gene Synthesis Consortium's standards of screening for DNA synthesis, none of these initiatives have had lasting impact on the industry. Many of those efforts were focused on research applications, rather than commercialization. While standards for research may have been more relevant for the nascent field, the low rate of adoption has led to a weakened value proposition for further development and use. Additionally, previous efforts in standardization were narrow in scope, and in many cases siloed, neither addressing the diversity and complexity of biological processes and data, nor being able to keep pace with the rapid advances in engineering biology development and translation. In addition, the overall breadth of standards needed to support various aspects of the evolving engineering biology field and the broader bioeconomy has led to a lack

of consensus amongst stakeholders on what standards are needed and when they should be developed. The lack of consensus extends to the definitions of the bioeconomy and how it should be measured. Spheres of biotechnology approach the development and use of standards with different incentives and priorities, necessitating consensus building to identify standards and metrics that would be useful across the industry. As the engineering biology industry matures, and its products have the potential to bolster the bioeconomy, there is an apparent and timely need for standards and metrics in the commercial space that are agreed upon and coordinated across the engineering biology community.

Next steps in establishing standards and metrics to promote a secure bioeconomy

While the standards landscape for the bioeconomy is as vast as the biotechnologies and biomanufacturing that it supports, a critical initial step is a common lexicon. Clear, generally agreed-upon, definitions for vocabulary related to the bioeconomy underpin all activities related to technology development, commercialization, and regulation. This makes the lexicon that NIST was directed to develop for the Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy a prerequisite for all other activities. Under the current Executive Order, NIST has 90 days to develop and release an initial list of terms and definitions. To support the growing bioeconomy, a more advanced, comprehensive, and maintained taxonomy would be needed. It is critical that the lexicon and taxonomy are developed by NIST in collaboration with a broader coalition of stakeholders from government agencies, academia, industry, and international partners.

Using the lexicon, stakeholders across the bioeconomy should be consulted and convened to determine what standards would be useful and relevant for advancing their industries continuously. The development of standards and metrics should then follow, guided by industry and community consensus, with the support of NIST resources and capabilities. NIST is thus poised to take a leadership role in facilitation, coordination, and promotion of these activities to ensure widespread adoption and use, thereby avoiding the pitfalls of previous standards setting attempts. Additionally, NIST laboratory programs should be expanded to support benchmark innovative engineering biology products and processes, while supporting the development and adoption of best practices.

The resulting standards and metrics will help enable risk assessment and more streamlined regulatory processes that lower barriers to commercialization and keep the bioeconomy and its consumers safe. These efforts will drive innovation by making it clear what startups and companies need to do to bring their products and services to market and to shift more of their manufacturing to bio-based processes.

Recommendations

1. Direct no less than 50% of the anticipated $14M increases in Biotechnology and Biomanufacturing in FY23 budget to support the development of standards related to engineering biology, including lexicon, technical standards, support and coordinate evolving engineering biology metrics and benchmarking development, and the underpinning laboratory program in microbial systems.
2. Implement a long-term public-private partnership program, helmed by NIST together with research and industry organizations (e.g., EBRC), to convene stakeholders and maintain ongoing dialogue for advancement of biometrology, engineering biology tools, capabilities and standards. Initial information gathering activities will need a budget of approximately $5M.

3. Appropriate $50M currently authorized for NIST in the CHIPS and Science Act to expand NIST engineering biology programs in support of the bioeconomy.
4. Provide funding to improve and/or expand laboratory infrastructure, including state-of-the-art laboratory spaces, to enable the development of engineering biology metrology and bioeconomy standards, and develop pre-competitive technologies.
5. Provide support for the Departments of Commerce, Energy, Defense, and other federal agencies involved in biomanufacturing, to further develop their respective infrastructures (including Manufacturing Innovation Institutes) to support and implement bioeconomy standards, and to coordinate their implementation of standards and metrics.
6. Coordinate the development of standards and metrics for engineering biology with updates and clarifications to biotechnology regulatory frameworks, ensuring that NIST is represented among agencies tasked with biotechnology regulations.