ENGINEERING BIOLOGY METRICS AND TECHNICAL STANDARDS FOR THE GLOBAL BIOECONOMY

ORGANIZATIONAL SPECIFICS

Standards Organizations:	n/a
Technical Committees:	n/a
Other Partnering Organizations:	Imperial College London, National University of Singapore (NUS), Engineering Biology Research Consortium (EBRC)
Government Organizations:	NIST
Industry Sector(s) / Technology:	Bioeconomy
Program / Activity Website URL(s):	https://ebrc.org/engineering-biology-metrics-and-technical-standards-for-the- global-bioeconomy/

STANDARDS DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

The Engineering Biology Research Consortium (EBRC) is a non-profit, public-private partnership dedicated to bringing together an inclusive community committed to advancing engineering biology to address national and global needs. A Task Force composed of EBRC and partners at Imperial College London, the National University of Singapore, and the U.S. National Institute for Standards and Technology led an initiative resulting in the report: "Engineering Biology Metrics and Technical Standards for the Global Bioeconomy."

This report was specifically created as there is a new sense of urgency pushing the bioeconomy and its many potential benefits to the forefront of discussions by policymakers, with new programs and funding streams being announced around the world. The driver for this effort was to identify appropriate standards and metrics that will better enable continued scale-up and enhance economic activity across the bioeconomy. A lack of shared and interoperable vocabulary, methodology, and metrology across the engineering biology pipeline is envisaged to create major challenges as the global bioeconomy grows.

PPP Goals:

EBRC promotes research in engineering biology, identifies pressing challenges and opportunities in research and application, and articulates compelling research roadmaps and programs to address challenges and opportunities in advanced engineering biology. The four focus areas, driven by member-led working groups, are Research Roadmapping, Education, Security, and Policy & International Engagement.

To support the above mission, EBRC and the Task Force members sought to identify community and stakeholder driven scientific, technical, operational, and semantics standards to enable and drive scale up capabilities, improve reproducibility across batches and geographies, and enhance the performance of microbial factories and bio-products.

The report, "<u>Engineering Biology Metrics and Technical Standards for the Global Bioeconomy</u>," identifies ten key areas as recommended for standards and metrics development. The report lays the groundwork to establishing open, voluntary standards for engineering biology to enable the rapid growth and success of the global bioeconomy.

Public Sector Role & Participation:

EBRC, with partners at the U.S. <u>National Institute of Standards and Technology</u> (NIST), <u>Imperial College London</u>, and the <u>National University of Singapore</u> (NUS), and supported by <u>Schmidt Futures</u>, made up the Task Force which led the development of the report.

In the U.S., the development of engineering biology/biotechnology standards is being driven primarily by industry, though bottlenecks around data and information sharing (in particular) are increasingly making this difficult, and much of this work is in its nascency. USG, primarily through NIST, is trying to drive many efforts to loosen the bottlenecks and encourage more engagement on establishing public metrics and standards, including through participating in and sponsoring PPP efforts around standards development.

While the Task Force for this initiative was led by academia, government, and non-profit entities, industry from the U.S. and Europe were participants and significant contributors to the development of strategies and recommendations. (In Asia, contributions came mostly from government and academic institutions; government plays a larger role in Asia in standards development, though the degree to which varies by country.)

Implementation Methods:

EBRC's efforts are accomplished through convening stakeholders, most often experts in engineering biology and related fields from academia, the biotechnology industry and nonprofits, and the federal government. For example, the report above reflects contributions from three stakeholder workshops which took place around the world: one in the Washington DC area for stakeholders from the Americas; one in Singapore for stakeholders across Asia and Australia; and finally, one in Brussels, for stakeholders from Europe and Africa.

Discussions that took place within each region, including during group plenaries and deeper-dive breakout sessions, were captured by the Task Force and summarized within workshop reports. The content of each workshop report was kept deliberately confidential until all three meetings had concluded, to avoid biasing any discussions with outcomes from another region.

This final report summarizes the key areas that emerged from those stakeholder discussions, pulling together common themes and identified needs that arose across the regions. The content was drafted in collaboration with stakeholders and peer-reviewed by workshop participants.

Measurement of Success:

The ten key areas for standards and metrics development are the outcome of workshop discussions that were observed and summarized by the Task Force and published in the final report. Stakeholders are encouraged to take these technical and non-technical topics, or a subset thereof, to motivate future projects for standards and metrics development in engineering biology.

Technical

- 1. Data standards to enable interoperability, integration, and efficient data transfer, accelerating technology development within the bioeconomy.
- 2. Metrology and metrics to quantify biological processes to better assess and quantify engineering biology phenomena to enable reproducibility, reliability, and scale-up.
- 3. Scale-up and scale-out supported by metrics that perform consistently across scales and across equipment and process conditions, and community driven standard practices to support startups in navigating the scale-up and commercialization process.
- 4. Lexicon and terminology to facilitate communication within the technical community, and with external stakeholders, at national and international levels.
- 5. Metrics and standardization for sustainability assessments to support comparability and develop market incentives for sustainable products and processes.
- 6. Standards to enable use of biomass feedstocks to complement technological and policy advancements to enable their adoption and use in the bioeconomy.

Non-technical

1. Training and education on standards and metrics to ensure understanding and adoption by those working in the sector, and to improve implementation of existing and new standards across the bioeconomy.

- 2. Public engagement, improvement of public perception, and building trust, addressing negative consumer perceptions by improving communication and transparency.
- 3. Regulatory clarity to efficiently commercialize new products and processes, through standards in documentation, assessments, and benchmarking.
- 4. Biosafety and biosecurity for consumers, workers, the public, and the environment, for future successful functioning and growth of the bioeconomy.

The published report has been referenced by participants in existing SDOs and informally during USG activities. Many of the workshop participants and report contributors continue to participate in technical standards development, including new and follow-on initiatives.

Key Takeaways:

- 1. The different role taken by public vs. private vs. government entities in the development of standards for the bioeconomy in different parts of the world: depending on where you are, the different entities take more responsibility and onus for standards development (e.g., in the US, industry leads the way; in Asia, it is more government led).
- 2. USG can play a significant role in easing bottlenecks and promoting communication and sharing between private and public entities in standards development for the bioeconomy.

Advice for Others:

EBRC notes it is valuable to have the audience and the stakeholders involved in the process, not just the experts.

Last updated September 2024. This use case was developed as part of an ANSI <u>project</u> performed under the following financial assistance award 70NANB24H075 from U.S. Department of Commerce, National Institute of Standards and Technology.