Engineering Biology Metrics and Technical Standards for the Global Bioeconomy

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Contents

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Executive summary

The global bioeconomy is growing rapidly, with more countries than ever now publishing national bioeconomy strategies in acknowledgement of the great benefits to be reaped, both economic and in terms of future sustainability. The World BioEconomy Forum estimates the global value of the bioeconomy to be around USD4tn,[1] with continued and accelerated growth expected. A new sense of urgency is 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. For example, in 2022 the US government pledged USD2bn[2] to launch a national biotechnology and biomanufacturing initiative, and in December 2023 the UK government announced GBP2bn[3] (USD2.5bn) of investment "to seize the potential of engineering biology". For many years there have been widespread and repeated calls for standardization within engineering biology, to enable more cost effective and faster innovation across the bioeconomy. The application of standards and metrics in this sector would help to ensure safety, improve efficiency in innovation pipelines, and support policies and legislation. Major issues could arise from continued global acceleration of the bioeconomy without standardization and metrics, from a lack of product quality assurances to interoperability of engineering biology technology.

There is currently no internationally agreed definition of the bioeconomy. In the context of this report, we refer to the bioeconomy as encompassing the production, utilization, and conservation of biological resources in the pursuit of developing new products, processes, and services that will contribute towards a more sustainable and circular economy. Across the world, at least 50 countries have published national bioeconomy strategies or are implementing policies that work towards a more sustainable bioeconomy.[4] In many countries, regional strategies are also implemented. The bioeconomy interlinks the natural ecosystems (terrestrial and aquatic) with all sectors that use the resources they provide, such as agriculture, forestry, energy, fisheries, and aquaculture.

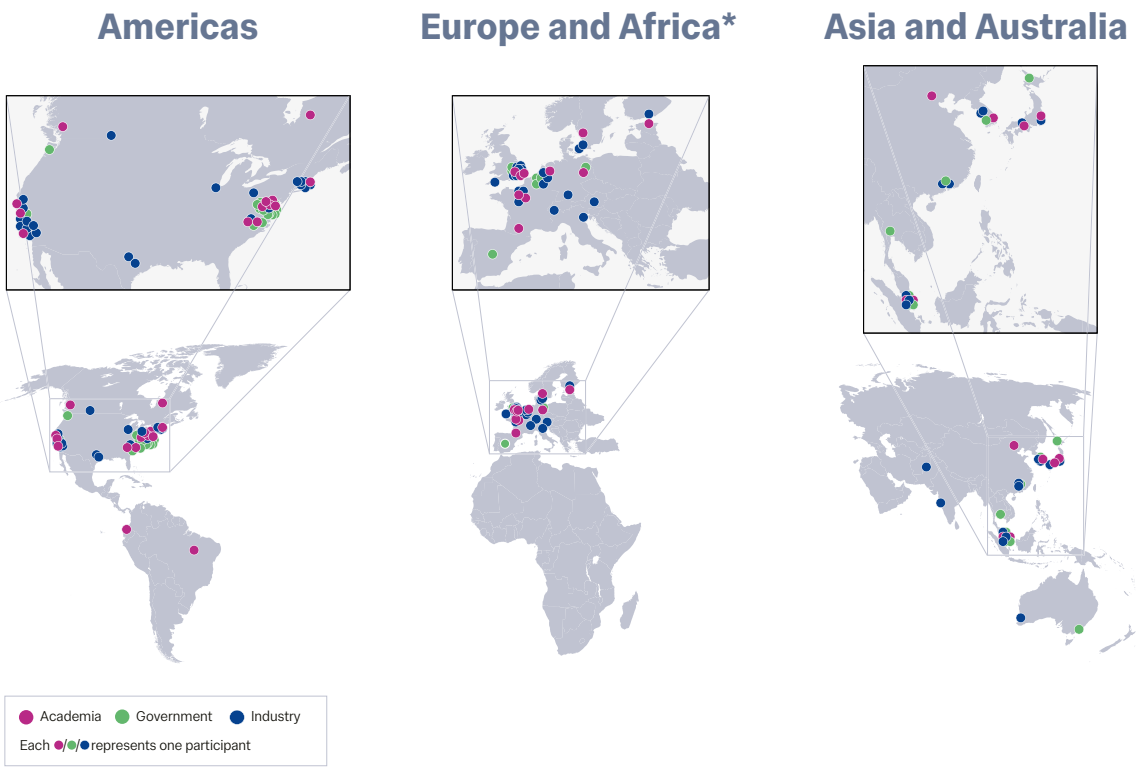
The Task Force on Engineering Biology Metrics and Technical Standards for the Global Bioeconomy was convened with experts from the US, Europe, and Asia, with the aim of identifying appropriate technical standards and metrics that will better enable continued scale-up and enhance performance across the bioeconomy. By assessing regional priorities, the program seeks to identify key areas where setting open, voluntary standards will directly address these issues and support scale-up and innovation.

This international collaboration was jointly coordinated by Imperial College London, the Engineering Biology Research Consortium (EBRC), the National Institute of Standards and Technology (NIST), and the National University of Singapore (NUS). A series of regional stakeholder discussions was convened to better understand the current state of the

global bioeconomy, and to learn about the potential for standards and metrics to promote innovation and commercialization within each region. Where possible, specific areas for development, both technical and non-technical, were identified and discussed, and recommendations were developed.

Three workshops took place: one in Washington DC suburbs for stakeholders from the Americas; one in Singapore for stakeholders across Asia and Australia; and finally in Brussels, for stakeholders from Europe and Africa. Figure 1 provides an illustration of participants present at each, representing industry, academia, and government agencies. 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 report was kept deliberately confidential until all three meetings had concluded, to avoid biasing any discussions with outcomes from another region. This 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.

Figure 1. Geographical spread of stakeholders attending the three regional workshops, representing academia, government and industry sectors.



* No African stakeholders were able to attend the workshop in person; views discussed were those of European stakeholders only. For consistency throughout the report, the workshop continues to be referred to as "Europe and Africa".

Areas of common understanding were developed into key recommendations. These are:

1. Data standards
2. Metrology and metrics to quantify biological processes
3. Scale-up and scale-out
4. Lexicon and terminology
5. Metrics and standardization for sustainability assessments
6. Standards to enable use of biomass feedstocks

Within these six key areas, opportunities are identified for focused activities to develop technical standards and metrics that will enable enhanced performance across the bioeconomy: improving reproducibility, supporting continued scale-up, and accelerating commercialization and industrial growth. Their ordering reflects the predominant priority order across stakeholders; however within each region different pictures of priority emerged (see Figure 2). This reflects the varying state of the bioeconomy, partly due to engineering biology technology readiness, and the different challenges and opportunities to be addressed globally.

A series of non-technical areas are also identified and explored, reflecting stakeholder discussions. In some instances, these areas are deemed essential to support the implementation of technical recommendations. Non-technical areas include:

1. Training and education on standards and metrics
2. Engagement with the public, and improvement of public perception and trust
3. Regulatory clarity
4. Biosafety and biosecurity

Discussions around both technical and non-technical areas for development are underscored by regional and cultural differences. Public perception of the engineering biology sector, for example, differs greatly across countries and regions, as does the level of risk deemed acceptable by consumers, organizations, and governments. There emerged a complex picture of the current landscape of key stakeholders and existing regulations around the world. As well as focusing on areas of common understanding, the report elaborates on some areas where distinct differences exist and global consensus might not be reached, highlighting these as potential focus areas for regional or national efforts going forward.

Key areas for standards and metrics development

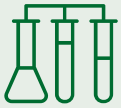
Ten consensus areas for standards and metrics development were identified across all the regional workshops. While the specific needs and context differed from place to place, these are the high-level areas where focused activities in developing standards and metrics can drive innovation and accelerate commercialization of engineering biology processes and products globally. The order of this list reflects the consolidated priorities of the regional workshop attendees.

Technical areas

1. Data standards

Data underpins process development, technology transfers, scale-up, and commercialization. Thus, standards that enable reproducibility and efficient data transfer would accelerate technology development within the bioeconomy. Standards for data formats, annotation, and metadata would make industry and academic data more interoperable, as well as make it easier to integrate datasets for machine learning (ML) and artificial intelligence (AI) applications. Standards tailored towards engineering biology data would accelerate technology and process development within the bioeconomy.

2. Metrology and metrics to quantify biological processes



Advancements in metrology and metrics to better assess and quantify engineering biology processes would enable reproducibility, reliability, and scale-up. Many current metrics serve as proxies for a desired measurable outcome, due to limitations of existing metrology. Furthermore, measurement technologies used at research laboratory scales are often not suitable for pilot or production scales, and vice versa. The measurement and metric needs for the bioeconomy span from simple, single-attribute quantifications – for example, of DNA concentration or cell density – to assessments for complex characteristics, such as sustainability and biocontainment.

3. Scale-up and scale-out

Realizing engineering biology processes at commercial scale is a major challenge across the industry. Measurement capabilities and metrics that perform consistently across scales, or can be translated between scales, are needed to support engineering biology process scale-up. Creating community-driven standard practices, reference materials, and other resources can help startups and other companies plan for and successfully navigate the scale-up and commercialization process. Another consideration for scaling up operations within the bioeconomy is the potential for distributed manufacturing, in response to the geographical distribution of unique feedstocks, markets, product specifications, and other factors. Guidelines for designing and metrics for evaluating the feasibility of various forms of distributed manufacturing schemes can help the bioeconomy respond to regional needs and opportunities.

4. Lexicon and terminology

Common definitions are needed for engineering biology to facilitate communication both within the technical community and with external stakeholders, including policymakers and the public. At the global level, translated definitions of key terms are needed. A shared lexicon will accelerate the commercialization process and promote commerce and trade, as well as facilitate global standards and metrics development activities.

5. Metrics and standardization for sustainability assessments

The sustainability advantages of engineering biology-based products and processes, both potential and realized, are a significant driver of the field. The ability to use renewable feedstocks, less energy-intensive processes, and more distributed manufacturing compared to traditional chemical and petrochemical processes have been foundational to the business and environmental justifications of many engineering biology technologies. However, there are no standardized approaches or universal metrics to quantify sustainability, limiting the ability to assess, compare, and develop market incentives for sustainable products and processes. The development of a standard life cycle analysis or similar assessments could address this need.

6. Standards to enable use of biomass feedstocks

There is desire across the global bioeconomy to utilize diverse biomass-based feedstocks that include heterogenous and waste streams. This is motivated by sustainability, resource circularity, and availability considerations. Though traditional biomass feedstocks, such as sugarcane and corn, are commonly used, other sources of biomass can be more complex and variable. Thus, standards for diverse biomass feedstocks can complement technological and policy advancements to enable their adoption and use in the bioeconomy. These may include standardized assessments and representations of biomass, supported by metrology and metrics, or standard preprocessing of biomass to more reliable feedstocks. Given that biomass availability and composition varies seasonally and geographically, globally aligned standards and metrics for characterization will be important in coordinating and developing biomass feedstock utilization. Such standards would be helpful for transferring existing fermentation processes to new locales that have their own unique biomass supply.

Non-technical areas

7. Training and education on standards and metrics

... are needed to promote the understanding and proper adoption of, and adherence to, the standards and metrics within the bioeconomy.

8. Public engagement, improvement of public perception, and building trust

... are critical factors for the growth of the bioeconomy and market success of the engineering biology-enabled products within it. Standards and metrics can aid in improving transparency and understanding of engineering biology technologies, which may improve public perception and trust.

9. Regulatory clarity

... is currently lacking for engineering biology products and presents a significant barrier to commercialization of new products. Regulatory clarity must be improved so that companies can efficiently acquire regulatory approvals on quality products that are safe and effective; standards and benchmarks can aid in these efforts.

10. Biosafety and biosecurity

... must be maintained for the successful function and growth of the bioeconomy. Considerations for biosafety and biosecurity are vast and complex, and would benefit from clear metrics and standards to substantiate ongoing conversations and policy development.

List of definitions

Bioeconomy: The production, utilization, conservation, and regeneration of biological resources, including related knowledge, science, technology, and innovation, to provide sustainable solutions (information, products, processes, and services) within and across all economic sectors and enable a transformation to a sustainable economy.[5]
Note: as there is currently no internationally agreed definition of the bioeconomy, the definition from the International Advisory Council on Global Bioeconomy is applied in this report. National definitions vary, for example, the US encompasses all economic activity derived from the life sciences, particularly in the areas of biotechnology and biomanufacturing, including industries, products, services, and the workforce.

Biotechnology: The development of new technologies and products through harnessing of cellular and biomolecular processes. Biotechnology is being applied to a range of sectors across the globe, including medicine, food, energy, and sustainability.

Downstream processing: The part of a process where the upstream product is recovered, purified, concentrated and formulated to meet quality requirements.

Engineering biology, or Synthetic biology:[6] The design, construction, and/or assembly of the components of living systems (including genetic circuits, enzymes, metabolic pathways, etc.) to achieve an intended function or outcome.
Note: both terms, Engineering biology and Synthetic biology, are often used interchangeably; to reflect this, the terms are assigned a single definition in this report.

Feedstock: Raw material to supply or fuel a machine or industrial process.

Global bioeconomy: The International Advisory Council on Global Bioeconomy defines global bioeconomy as one that "includes all levels of society and aims at improving the quality of life for all people, while respecting biophysical limits to economic growth". See also definition for *Bioeconomy*.

Life cycle analysis (LCA): A framework assessing the environmental impact of a product or process, from extraction of initial resources to final disposal. Also referred to as life cycle assessment.

Metrics: Quantitative measurements made to assess the (technical, economic, social, etc.) performance of a product or process to ensure that it is fit for purpose.

Metrology: The science of measurement and its application.

Process development: The exercise of creating a means to manufacture a given product in a given quantity.

Scale-up: The steps involved in progressing a manufacturing process, or section of a process, from laboratory scale to the level of commercial production.

Scale-out: A mode of increasing manufacturing capacity of a product or process by using multiple bioreactor vessels of smaller volume working in parallel. Scale-out has the potential to reduce operational risk, increase flexibility in manufacturing capacity, and increase paths to process validation.

Standard: (1) A document, reference data, reference material, or calibration service that enables measurement assurance to ensure that materials, products, processes, and services meet specifications and are fit for purpose. (2) Requirements that establish the fitness of a product for a particular use and may address product features, performance, quality, compatibility, or other product attributes.

Upstream processing: The first phase of the bioprocess, from cultivation to the cell expansion and/or fermentation process. The aim of upstream processing is generally to optimize production host growth to achieve a high enough yield of the target product to be used in subsequent downstream processing and scale-up.

Introduction

Across the globe, companies and technologies in the bioeconomy are seeing rapid growth and advancement, driven by the goal of achieving net zero and the commercial opportunities this presents for engineering biology and biotechnology. The global commercialization of technologies based on engineering biology is accelerating, resulting in an urgent need to address the current lack of related technical standards and metrics. The dearth of relevant standardization is already slowing or stopping advances across many aspects of the bioeconomy. With the objective of reaching consensus on the future role that standards and metrics can play in supporting the growth of the bioeconomy as enabled by engineering biology, this effort prioritizes seeking regional perspectives to inform a global overview of the current state of the sector.

What is the bioeconomy?

The Bioeconomy means different things to different people. In the United States, for example, the emphasis is on using living organisms to create new products. For the European Union, it means using biological resources from land and sea. In Scandinavia, traditional forestry is the main driver of the bioeconomy. But in every case, the bioeconomy is a shift in thinking, a move away from industries powered by fossil fuels to those that are based on renewable resources.

In one sense, the bioeconomy is ancient. People have always relied on biology for products, either for survival or for wealth generation. But biotechnology, aquaculture, and modern farming practices present vast new opportunities. By some estimates, the bioeconomy will produce products worth somewhere between USD4 trillion and USD30 trillion globally.

A note on nomenclature. Using the term, “the bioeconomy,” is unusual. We don’t talk about the petroeconomy, or the semiconductor economy. The name suggests people should know what it means, because they know what “bio” is, and they know what “economy” is. At least for now, “bioeconomy” is not a term that is immediately understood by most of the public.

The need for standardization

The application of standards has historically proven helpful to ensure safety and reliability, improve efficiency, and increase consumer confidence. From food safety management standards to cybersecurity and privacy protection, standardization is applied to everyday activities and processes across the globe.

Most countries around the world have their own standards-setting body, overseeing published national standards, for example, the American National Standards Institute (ANSI) in the US, the British Standards Institute (BSI) in the UK, the Singapore Standards Council (SSC) in Singapore, and the Japanese Industrial Standards Committee (JISC) in Japan. Internationally, bodies such as the International Organization for Standardization (ISO) and the International

Electrotechnical Commission (IEC) prepare and publish international standards. ISO has been publishing standards since 1951, with 170 national standards bodies currently engaged in developing and reviewing voluntary, consensus-based international standards. This standards-setting body has identified advancing environmental sustainability as one of its goals to meet global needs through its current strategy.

What are standards?

Standards often make use of measurements. For example, you can measure the number of parasitic cysts in freshwater herring, but that's just a number. It doesn't tell you whether there is a level of cyst contamination that will cause illness. A standard is often a decision about that level. But compliance with the standard is voluntary. It only becomes a legal requirement when it's made into a regulation.

The fishing industry needs standards to function. It's not at all uncommon for fish to be infected with parasites. If there were no allowable limit, entire catches would have to be discarded were a cyst found. The standard must balance the needs of the industry with the safety of the pescatarean public.

Safety is just one of the examples where standards are needed. Consider the game of soccer (football). FIFA is the body that regulates professional soccer around the world. FIFA's "Laws of the Game" describes the shape, size, weight, and pressure to which a ball must be inflated to be acceptable for competition.

A relevant effort to the bioeconomy is ISO/TC 276:[7] standardization in the field of biotechnology. Comprising only 35 published standards (at the time of writing), topics include bioprocessing, biobanking, analytical methods, and data processing. The very small number of published international standards relevant to engineering biology is a stark reminder of the issue being addressed by this particular project: the need for relevant standardization to support and drive acceleration of the global bioeconomy. Currently, internal standards are in place within many leading biotechnology manufacturing companies, for example relating to their use of reference materials, calibrants, or internal protocols. There is a resistance to sharing such standards, as companies protect their competitive edge. This creates a more challenging environment for small and medium-sized enterprises (SMEs) and new startup companies to enter the market and become competitively viable. A monopoly is therefore emerging within the engineering biology biomanufacturing sector, which may be affecting the development of new industry-specific standards.

ISO notes "the pace of development in this field and the breadth of its applications means that this is an area to watch for emerging-market needs".[8] This gap in specific standardization and metrics applicable to fast-paced,

advancing biotechnologies based on engineering biology is likely to cause significant challenges going forward. An additional challenge, though outside the scope of this report, is the need for incentivization to standardize, with some calls for governments to provide incentives.[9] The shortfall of standardization is slowing or stopping advances across many aspects of the bioeconomy innovation pipeline, such as data interoperability, regulatory clarity, product quality, and consumer transactions.

Who sets standards?

There are many ways standards can be created. A regulatory agency can set them based on a need for safety and quality. Like it or not, the Food and Drug Administration in the US has determined that it won't act to remove herring from the market so long as there are fewer than 60 parasitic cysts per 100 fish (fish averaging 1 pound or less) or 100 pounds (fish averaging over 1 pound). Governments can also set standards for economic reasons. The European Union has recently mandated that all mobile phones sold in Europe be equipped with a USB-C charging port. This was done in part to counteract a de facto standard that had been established by Apple. When iPhones started using a lightning port for charging, everyone who wanted the latest iPhone was obliged to buy a new charger, or at least a new charging cable. With the European Union making USB-C ports the standard, Apple modified the iPhone to comply with the new standard in order not to lose access to the enormous European market.

It's often the case that the industries jointly set standards. Starting with Thomas Edison and Alexander Graham Bell, industries related to electrical power, telephony, and the telegraph began adopting standards that would allow competing companies to know they would all share certain basic "rules of the road."

Newer industries have embraced this approach. Several communications companies have created the Mobile Satellite Services Association (MSSA), a nonprofit aiming to harmonize mobile satellite services for integrating with standardized devices.

Is now the time for standards?

Yes. The International Organization for Standardization (ISO) has created more than 25,000 standards for a variety of industries. Fewer than 40 of these directly relate to the bioeconomy. Why so few? There are many answers. It may be because the industries making up the bioeconomy are fairly new, and haven't matured to the point where standards would clearly be beneficial.

When an industry is small, it's understandable if a "wild west" mentality prevails. But as an industry or community grows, the need for standardization grows along with it.

There have been efforts to create a set of standards for applying engineering principles to biology. The effort described in this report was intended to add specificity to that goal.

Even if the way forwards is not completely clear, there was a broad consensus from attendees at the international workshops that led to this report that standards would be useful, if the right ones could be identified and an effective argument for their implementation could be articulated.

Engineering biology and the global bioeconomy

The global bioeconomy is currently estimated to be worth around USD4tn,[10] with accelerated future growth forecast as the sector is expected to contribute to mitigating and solving some of the biggest global challenges we face, such as climate change, food security, and healthcare.

A new sense of urgency is propelling the bioeconomy and its many potential benefits to the forefront of policy discussions, with new programs and funding streams being announced around the world. For example, in 2022 the US Biden Administration issued an Executive Order announcing USD2bn[11] in investment to launch a national biotechnology and biomanufacturing initiative, followed by the launch of the National Bioeconomy Board[12] in March 2024, to support the ongoing implementation of the bioeconomy executive order. In December 2023 the UK government announced GBP2bn[13] (USD2.5bn) of investment "to seize the potential of engineering biology".

Growth of the sector will see increased commercialization, scale-up, and distributed biomanufacturing, reflecting the expanding geographical distribution of markets, feedstocks, and production facilities, and promote manufacturing resilience by diversifying production streams beyond traditional chemical manufacturing. Realizing the full potential of this forecasted growth globally is not possible without a variety of standards and metrics to facilitate and enable this growth.

Despite repeated calls for standardization within engineering biology, past efforts have not succeeded in finding consensus on priority areas across the sector, highlighting the urgent need to engage with essential stakeholders, such as those from industry, academia, and different government agencies and regulatory bodies, to better understand the call for standardization and metrology. In some instances, past efforts have fallen short due to insufficient funding and resources. For example, the BioRoboost Biocontainment Finder,[14] an EU-funded open-source repository of existing and proposed biocontainment strategies, aimed to address the gap in relevant metrics and standards in biocontainment. However, this repository lacked continued funding, resulting in the last update recorded in 2021. Engagement and support from across industry and government are required to ensure such efforts are sustained and impactful.

With the aim of identifying standards and metrics to support the growth of the global bioeconomy, this effort has sought to convene regional perspectives and expertise to inform actionable steps toward standardization and metrology in engineering biology. As part of this effort, regional stakeholder discussions provided context on the varying priorities for the bioeconomy, with differing public perceptions and regulatory frameworks found to be among key contributing factors. To better understand the need for standardization and reasons for past efforts falling short, a focus on the lack of consensus around basic terminology is required. This was highlighted across regional discussions and emphasizes the need for a common understanding of key terms and definitions. For example, there is no current internationally agreed definition of the bioeconomy. Within this report, the International Advisory Council on Global Bioeconomy definition is applied, where bioeconomy is "the production, utilization, conservation, and regeneration of biological resources, including related knowledge, science, technology, and innovation, to provide sustainable solutions (information, products, processes, and services) within and across all economic sectors and enable a transformation to a sustainable economy". Public understanding of both engineering biology and the bioeconomy, and what these encompass, differs greatly across the globe. Reaching consensus on *what* is being discussed would better support the implementation of technical standards and metrics across the sector, as it allows global stakeholders to align on the same areas for standards development.

Project objectives and overview

The Task Force on Engineering Biology Metrics and Technical Standards for the Global Bioeconomy was convened by Schmidt Sciences, and jointly coordinated by Imperial College London, the Engineering Biology Research Consortium, the National Institute of Standards and Technology, and the National University of Singapore. This effort focuses on developing a strategic roadmap to lay the groundwork for establishing open, voluntary standards for engineering biology.

Three regional workshops were conducted to bring together key stakeholders to discuss the potential for scientific, technical, operational, and semantic standards in advancing commercialization of the bioeconomy. The first workshop took place

in Washington DC on 7–9 June 2023, with stakeholders from across the Americas. The second workshop with stakeholders from Asia and Australia convened in Singapore, 29–31 August 2023. And finally, the third workshop took place in Brussels, 25–27 September 2023, with stakeholders from across Europe. As the third workshop was intended to include stakeholders from Africa, for consistency throughout the report the workshop is referred to as "Europe and Africa". However, no stakeholders from Africa were able to attend in person, and as such the views represented during the workshop and reflected in this report are those from European stakeholders. The lack of African representation, and limited representation from the southern hemisphere as a whole, is a clear limitation of this project. Despite efforts to engage with bioeconomy stakeholders from across the regions, a greater representation of participants from the northern hemisphere is partly a reflection of the Task Force's own network of stakeholders. But this is also an indication of the more advanced bioeconomies in some regions compared to others, often paired with levels of technology readiness. The limited representation from Africa, for example, highlights the need to establish stronger engagement with nations across the southern hemisphere going forward, to raise awareness of the global bioeconomy movement, and efforts to develop standardization. But this is also an indication of the more advanced bioeconomies in some regions compared to others, often paired with levels of technology readiness. The limited representation from Africa, for example, highlights the need to establish stronger engagement with nations across the southern hemisphere going forward, to raise awareness of the global bioeconomy movement, and efforts to develop standardization.

During the three regional workshops participants were tasked with:

- Providing an overview of the current bioeconomy strategy within the relevant regional context.
- Discussing the current state of standards and metrics within the bioeconomy strategy.
- Attempting to reach consensus on the future role that standards and metrics could play in accelerating the global bioeconomy, enabled by engineering biology.

Discussions were facilitated by the Task Force and summarized in three workshop reports, developed through a collaborative drafting and peer-review process (see Appendix I for further information on the regional workshops). Differences in regional perspectives on the needs for standardization and metrology were identified and are widely discussed throughout this report.

The key technical areas for standards and metrics development were identified as:

1. Data standards
2. Metrology and metrics to quantify biological processes
3. Scale-up and scale-out

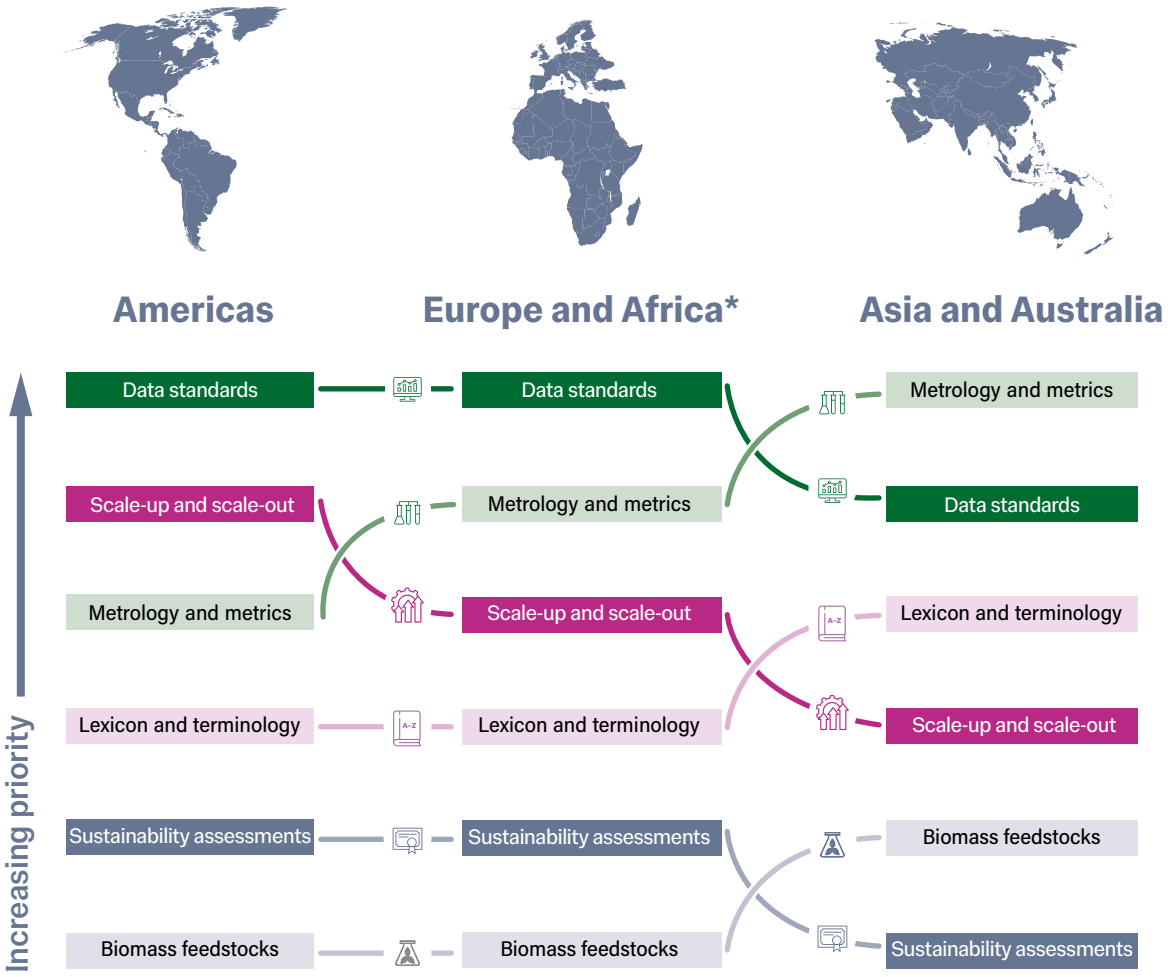
4. Lexicon and terminology

5. Metrics and standardization for sustainability assessments

6. Standards to enable use of biomass feedstocks

The ordering of these key areas reflects the predominant priority order across stakeholders, informed via a post-workshop survey inviting workshop participants to identify the priority order relevant to their region. The results of this survey highlight the variation in standardization priorities across the regions, as shown in Figure 2. Drivers behind these differing perspectives are discussed within each respective section of the report and feed into the overall findings and recommendations.

Figure 2. Priority order of key areas recommended for standards and metrics development.



Key technical areas are displayed as ranked by region, with highest priority areas at the top. This ranking is the result of responses to a survey inviting all workshop participants to identify the priority order as they see relevant to their region. Priority could be resultant from a combination of factors, such as the need for standardization coupled with technology readiness. Lower ranking may not therefore imply lesser importance.
* No African stakeholders were able to attend the workshop in person; views discussed were those of European stakeholders only. For consistency throughout the report, the workshop continues to be referred to as "Europe and Africa".

These are identified as key areas where standardization and metrology in engineering biology and biotechnology will better enable continued scale-up, improve reproducibility and safety, and enhance performance across the bioeconomy. Within this report, each of these six areas is explored in detail and specific recommendations for potential standards and metrics discussed. The key technical areas are interconnected, with the implementation of some necessary to the success of others. For example, data standardization is applicable across the sector, and a necessity in ensuring successful global scale-up and distribution of biomanufacturing. Reaching agreed understanding across regions on the lexicon and terminology to be used will also provide better foundations for international efforts, including, for example, shared understanding of terminology around sustainability assessments.

In parallel to these technical areas for consideration, four key non-technical areas are also identified:

1. Training and education on standards and metrics
2. Public engagement, improvement of public perception, and building trust
3. Regulatory clarity
4. Biosafety and biosecurity

The four areas identified are each a complex convergence of technical, social, and policy considerations. They are considered by stakeholders as necessary for the successful and sustainable implementation of the six technical areas identified above. However, the focus of this project is on technical standards, and as such the Task Force has considered non-technical areas in lesser detail. This by no means denotes a lesser importance to non-technical areas, but rather reflects the mandate of this particular project.

Engaging with the public to educate and improve perceptions of engineering biology processes and products is deemed vitally important, particularly in regions where consumer confidence and trust in products derived from engineering biology is low. Standardization is often acknowledged as a tool to enhance consumer confidence; however, it cannot be relied on to resolve this alone. Improved communication with the public is necessary in parallel to implementing standards. Similarly, training and education on existing and new standards and metrics are acknowledged as being essential to ensuring those in industry, as well as in academia and regulatory agencies, are aware of and able to successfully apply appropriate standards and metrics.

Regulatory processes and pathways to achieving approval for new products derived from engineering biology require improved clarity and guidance. This is especially important for SMEs to support efficient commercialization. Standards in documentation, assessments, and benchmarking, for example, can help to reduce complexity and ambiguity in existing regulation. Additionally, the need for more sector-specific regulation is discussed, supported by appropriate metrology.

Addressing concerns around biosafety and biosecurity is key to ensuring the continued growth of the bioeconomy, especially in light of rapidly advancing technologies including AI. Standardization can be applied to support the understanding and assessment of potential risks, with a focus on preventative measures to ensure the continued safe application of engineering biology technologies. Training and education in the workforce is intrinsically linked to safety management, and the appropriate adoption of existing or new standards in biosafety and biosecurity will help to build and maintain consumer confidence and public trust.

What happens without standards?

The simple answer is varying degrees of chaos. Imagine, for example, there was no standard for shoe sizes. Buying shoes would become a guessing game. Or imagine if there were no standard country codes for making international calls, no defined internet protocols for finding websites, or to get even more basic, no agreement for which side of the road to drive on.

A lack of standards can also be catastrophic. During the Great Baltimore Fire of 1904, some fire trucks arriving from neighboring cities could only watch as the city burned: their hoses would not fit on Baltimore's fire hydrants.

Even when standards are in place, there can be chaotic if sometimes humorous consequences. A product that may pass muster in Japan might be verboten in Germany. An example of the strange circumstances to which differing standards can lead came up at the Europe and Africa workshop. The Supplant Company takes agricultural side-streams such as husks, cobs, and stalks, and uses a biotechnology-based process to make replacements for the world's most common ingredients. A company representative wanted to share some chocolate containing a sugar replacement made this way that's for sale in the United States, but has not yet been approved for sale in Belgium, nor the rest of the European Union. So the chocolates handed out had to be purchased in the United States and carried to Europe as gifts.

Next steps

The rapid pace of fundamental understanding and technology development sets engineering biology apart from other industries. The inherent complexity has been a further barrier to global standardization across the sector. This effort has sought to understand the specific areas where standards and metrology might support commercialization, taking account of regional differences in needs and priorities. This report lays the groundwork for establishing voluntary standards and metrics to support the accelerating growth of the global bioeconomy. The key areas outlined in the report should inform further discussions of the development and implementation of necessary standards and metrics for engineering biology.

Establishing best practices offers a natural starting point, ahead of setting standards. Often seen as a prerequisite to more formal standards, best practices can provide an appropriate step towards identifying and developing specific standardization. They also provide the opportunity to leverage existing informal practices already embedded in industrial, research or academic settings. Enhanced sharing

of best practices already tested and applied within industry and academia is key, although some form of incentive or protection for competitive advantage may be necessary to encourage large industries to share these more widely. Specific areas where best practices should be established, or where existing ones should be more widely shared toward sector-wide consensus, include: scale-up; pilot facility and Contract Manufacturing Organization (CMO) selection; metrics development; data security and protection of intellectual property; software customization and interoperability; regulatory processes; and systemic and impact analyses of products and processes.

Establishing best practices and developing technical standards and metrics specific to engineering biology will only realize its impact when implemented successfully by those working in the sector. New standardization and metrology must be accessible and shared widely, with a process available to allow for continuous feedback and development. Standards must be continuously updated to reflect rapid advances in bio-based technologies, including applications of AI. An open forum, such as a shared portal, should be established to compile and share details of common best practices, as well as new and existing standardization and metrology relevant to the field of engineering biology. An open platform would encourage collaboration across the global community, allow feedback from users, and ensure everyone is able to access the most up-to-date recommendations. The Standards Coordinating Body for Regenerative Medicine[15] offers an excellent example of a collaborative sharing platform for standards. Engagement with regional organizations, such as the Association of Southeast Asian Nations (ASEAN), to help facilitate standards setting and implementation would support this goal. Existing frameworks in parallel sectors, such as the food industry, should be utilized; coordination between established networks and the bioeconomy should be enhanced to avoid conflicts and duplication.

Continued collaboration and communication are necessary, not only across the sector with industry partners, academics and policymakers, but also internationally; ongoing discussions are needed to further explore the key areas recommended for development, and their relevance both nationally and internationally. Improved engagement with the southern hemisphere will be an important factor moving forward, especially with countries that already have established biomanufacturing industries (*e.g.*, South Africa) and those with published bioeconomy strategies (*e.g.*, Colombia). The development of standards should be done in consultation with stakeholders from across the sector. This effort brought together stakeholders from industry, both large and small, academia, government and regulatory agencies, nonprofits, and research institutes. The connections and conversations initiated through this effort should be built on and strengthened, embedding a collaborative foundation for the ongoing discussions around standardization and metrology for the global bioeconomy.

How to use this report

This report provides a snapshot of the priority pain points across engineering biology, in particular those most relevant to startups and SMEs, and aspirations for standards and metrics development that might avail these, as informed by participants of the three regional workshops. Regional differences in viewpoints and approaches are noted across discussions of each of the key areas for standards development. An understanding of the regional context and perspective should be considered when addressing priority pain points.

The technical and non-technical key areas identified, or a subset thereof, can motivate further projects for standards and metrics development in engineering biology. The content of these focus areas hold relevance to a range of stakeholder groups, including researchers, standards-setting bodies, and government organizations. To further build on the content of this report, and to develop recommendations with more specificity, additional comprehensive stakeholder consultation is needed on those topics identified.

Regional differences in viewpoints and approaches

Why the bioeconomy?

For some, working in the bioeconomy is just another way of making money. But at the workshops that led to this report, there was another motivation that kept appearing: a desire to do something that will help stave off the global climate catastrophe looming because of an over-reliance on fossil fuels. "We're all motivated to save people's lives," is the way one of the participants in the Americas workshop put it.

The bioeconomy presents opportunities for more sustainable use of resources. The idea is not just to recycle "waste," but to design a system where it can be reused. Although transitioning to a bioeconomy won't solve all the challenges of global climate change, it can be an important part of the solution.

Acknowledging global differences in the current state of the bioeconomy, applications of engineering biology and biotechnology, and public perceptions of bioengineered products and processes is necessary when considering standards and metrics that might be applied internationally. The three stakeholder workshops uncovered regional differences in perspectives, approaches, barriers, innovation landscapes, bioeconomy development, and more. Observed differences across the regions are detailed below. Despite these differences, national or regional standards and development efforts can be undertaken. Outstanding strengths of each region can also position local stakeholders to lead in standards development efforts within the global bioeconomy.

Americas

In the Americas, the conceptualization of the bioeconomy is built upon recent technologies and advances in engineering biology, alternative foods and proteins, pharmaceuticals, and more. Thus, enabling innovation is a high priority for stakeholders. This is achieved by a bottom-up approach, in which startup companies and SMEs drive innovation and bring novel products to market. There was a prevalent view that standards can hinder innovation, coupled with some wariness around standards for that reason. Stakeholders from the US want standards and metrics that make technical progress and innovation more efficient. Stakeholders from countries in South America shared concerns that strict or burdensome standards would deplete their comparatively fewer resources compared to the US, making it even more difficult to commercialize products and compete in a global bioeconomy. In this region, it is likely that innovation will push forward, and standards development activities will occur in response to private sector advancements.

Asia and Australia

The Asia and Australia region, including New Zealand and the Pacific Nations, has a diverse set of national bioeconomies with no consensus on the direction or scope of the bioeconomy. However, all the major economies in the region are looking into advancing and integrating engineering biology into their economies. The countries in the region have fragmented interactions pertaining to the

bioeconomy, and generally, interactions are not deep. There are some existing regional collaborations, for example, the Association of Southeast Asian Nations (ASEAN), which seeks standards harmonization across Southeast Asia, and the Asian Synthetic Biology Association (ASBA), which promotes collaborations across Asia. Though there are examples of collaboration, they are not comprehensive; for example ASEAN does not currently include some of the larger economies in the region, such as China, South Korea, or Japan.

The participants of the Asia and Australia workshop skewed towards research and early process development. There was high representation from biofoundries, which comprise highly automated and experimental infrastructure to accelerate the design-build-test-learn (DBTL) cycle. The biofoundry infrastructure in Asia is a unique feature of the region, where biofoundries play a large role in engineering biology innovation and standards development. Academic collaborations that share best practices for biofoundries support their operations. The biofoundries serve as settings for trialing and developing metrics and reference or calibrant materials, as well as standardized methods and protocols. For example, there was discussion about future designs of biofoundries, and whether they should have identical, standardized equipment and unit operations, or be customized and apply standards in operations, rather than facilities. There are also vertically integrated process data standards being developed, in part to enable data-sharing and reproducibility through a network of global biofoundries. Sharing the advancements developed in biofoundries will require effort. In addition to the lack of widespread engineering biology collaborations mentioned above, some national biofoundries are restricted in the public release of standards developed. Thus, solidifying regional and global collaborations is necessary to capitalize on developments from biofoundries across the global bioeconomy.

Standards are tightly tied to regulations in this region and are essential for product commercialization. Thus, standards and regulatory development are pursued in concert with technical advancements.

Europe

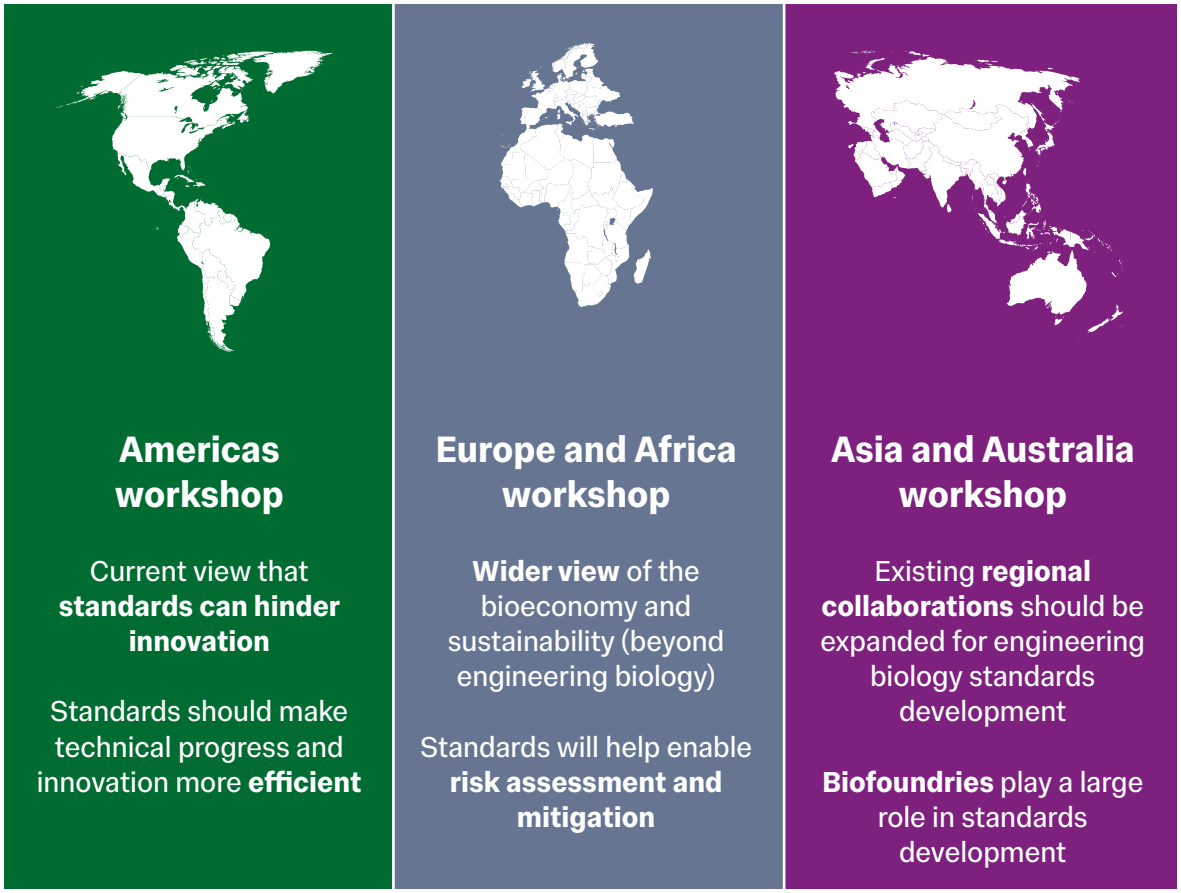
Europe takes a broad view of what comprises the bioeconomy, with engineering biology being a small and recent addition. In this region, the bioeconomy includes more traditional, bio-based industries, such as forestry, agriculture, and food production. In addition, Europe takes a more holistic approach to sustainability, considering a variety of factors, such as the impact of land use and biodiversity implications, in their assessments of biotechnologies. Stakeholders from Europe focused on the need to improve public perceptions of engineering biology to support the advancement of the sector and create market drive. This was seen as a crucial step in developing the engineering biology-based portion of the bioeconomy.

Europe maintains a substantial network of pilot fermentation and demonstration facilities.[16] Because of this, US companies commonly carry out pilot-scale testing in Europe. However, industry often looks elsewhere for full industrial-scale biomanufacturing and the regulatory frameworks to support bringing products

to market. For example, the new alternative-proteins and alternative-foods regulatory systems in Singapore are drawing companies as they are able to have their products approved more efficiently than in Europe.

Standards in this region are seen as a tool to help enable risk assessment and mitigation; thus, standards organizations can drive the success of engineering biology products by demonstrating safety and quality. The technical community anticipates top-down standards development through governmental activity.

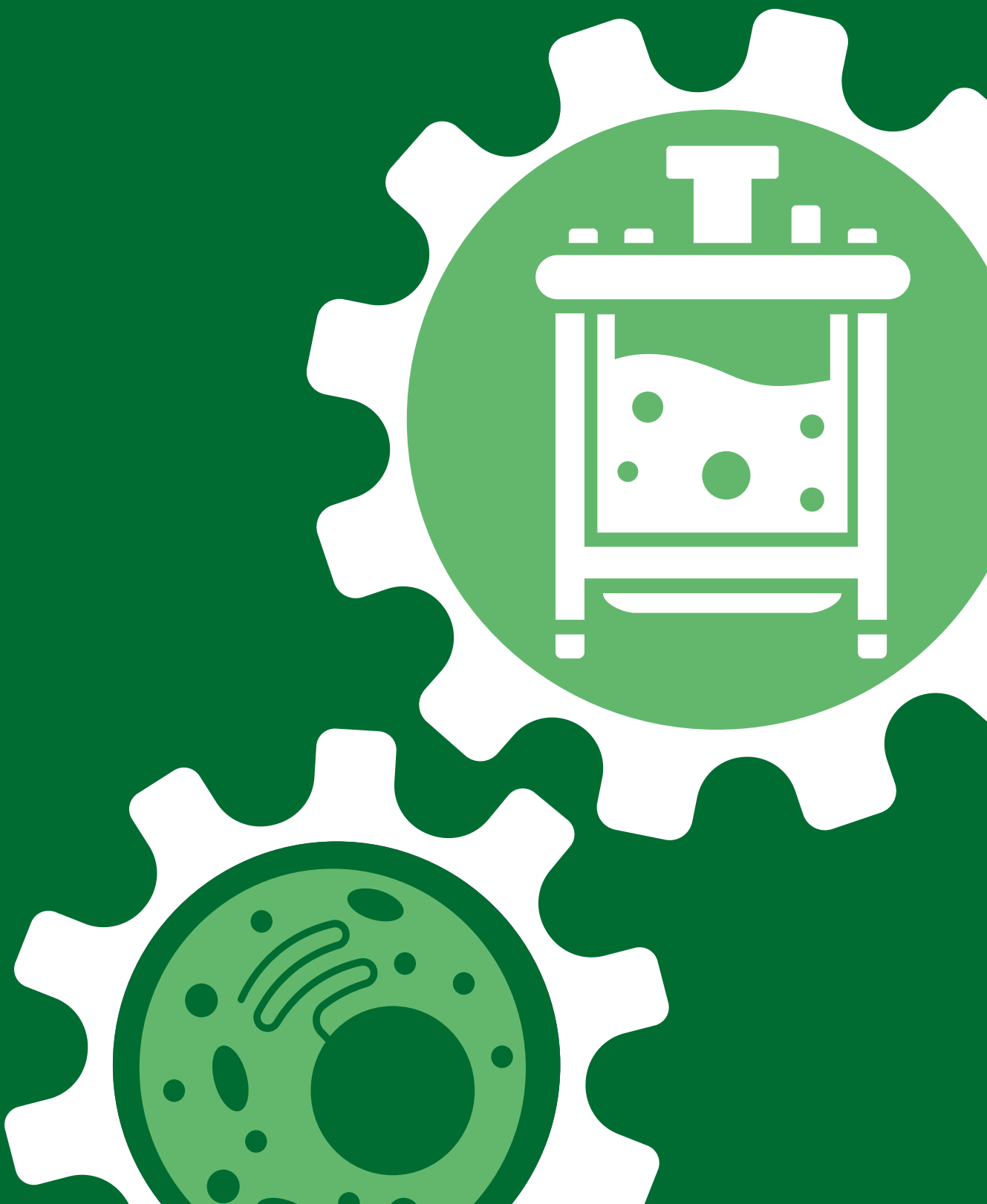
Figure 3. Distinct regional perspectives that emerged from the regional workshops.



Leveraging regional strengths in standards development

Regional strengths could be leveraged to determine specific areas where each region could lead on engineering biology standards development for the global bioeconomy. For example, Europe's holistic approach to sustainability and environmental impact should inform sustainability assessments and life cycle assessments (LCAs). Southeast Asia's organized and consensus-driven standards development can guide harmonizing standards development globally. Across the Americas, standards development can be initiated quickly in response to emerging technologies. This global-level coordination could expedite development of needed standards for engineering biology and allow regions to learn from the strengths of others.

Details and regional distinctions within the key areas



Technical

Data

There is currently no standardized way to annotate and share data across the engineering biology community. Though some data standards, frameworks, and resources – such as ISO 20691:2022[17] for data formatting and description in the life sciences; the findable, accessible, interoperable, and reusable (FAIR) principles;[18] and FAIRsharing.org[19] – exist, they are not widely adopted and impactful across the bioeconomy due to lack of specificity to engineering biology, cost and time required to implement, and lack of clear value added. Engineering biology-specific data standards and supporting resources should be developed to mitigate industry-wide pain points, such as improving reproducibility of experiments; ease of (inter)operability of instruments and equipment, especially from different manufacturers; pooling knowledge to solve community-wide challenges, and more. Establishing, refining, and incentivizing straightforward data standards and tools related to engineering biology would enable data sharing within and beyond individual regions, as well as accelerate process development within the bioeconomy. The more widely data standards are adopted, the more impactful and worthwhile they would be for new companies to use. This report focuses on the needs for technical data standards, though incentives for data standards will be important to encourage adoption.

Much of the existing data-related standardization and infrastructure efforts focus on general biological data. Framing data guidelines and standards around the DBTL cycle would bring these activities into greater relevance for engineering biology. The data produced through DBTL cycles encompass a wide range of data types, including sequences, metabolite concentrations, images,

and more. Entities that work in bioinformatics, such as the National Center for Biotechnology Information (NCBI) and European Bioinformatics Institute (EBI) are at the forefront of the discussions regarding standardization, sharing, and intellectual property (IP) of such data. Their outputs and policies should be integrated into data standards development.

Data usability and interoperability is often a barrier to efficient technology transfer and scale-up. Data format standards would help laboratories and companies involved in instrumentation, software, and biotech, as well as vendors, interoperate to share and develop engineering biology technologies. For example, standards regarding the description and cataloging of strains of organisms would help to make strain selection and transfers more accurate and predictable. In another example, standardizing data formats for common instruments and software would provide greater usability and flexibility for process developers. Instrument and software companies are disincentivized to make their products interoperable in order to be the sole provider of instrumentation for a process. Thus, movement towards data standardization and interoperability will need to be incentivized or externally enforced.

Community-level problem solving could be supported by data sharing guidelines, tools, and structures, including IP protection and security measures. Many companies troubleshoot similar obstacles during process design and scale-up, such as those encountered when designing product purification steps. Sharing of data around common pain points – and failures and successes in addressing them – could help companies avoid siloed, redundant efforts across the bioeconomy, which would save time and money on the path to commercialization. Initiatives aiming towards this community-level problem solving must balance and protect each company's competitiveness; risk to competitiveness is a primary deterrent against this type of data sharing. A community-driven data sharing platform could provide a place for knowledge exchange, including sharing of pain points and failures, in the interest of sharing or developing public solutions. Funding opportunities that include requirements for data sharing is one example of a mechanism that could incentivize companies to participate in community data sharing activities.

Public databases are also a crucial resource to elevate the field as a whole, both for in-depth understanding of complex biological processes and to provide sufficient data for ML and AI applications. Data formatting, annotation, and metadata standards would make datasets and databases more easily interoperable, so that data from various sources could be combined for greater understanding. For example, different omics studies could be consolidated for a more comprehensive understanding of an organism's function. Large datasets of high quality (*i.e.*, having attributes including accurate, precise, complete, accessible, and reliable), well-annotated biological data are required for ML and AI model training and testing, so the ability to combine data from multiple generators would help the field leverage the powerful modeling and predictive capabilities of ML and AI.

In Asia, the prominence of biofoundries provides opportunities for vertically integrated research and development (R&D) processes and associated data processing and standardization. For example, participants at the Asia and Australia workshop discussed how the Shenzhen Institute of Synthetic Biology in Shenzhen, China is researching data standardization that the biofoundry could apply to their R&D processes. These biofoundries could serve as a test bed for data standards development.

Standards that support data quality, and ease of sharing, usability, and interoperability of data from engineering biology activities within the bioeconomy are needed. Technical considerations for data standards include the following:

Data sharing. An important first step would be to determine what data is crucial to share in order to achieve specific goals within the bioeconomy. As described above, there are many agreed-upon benefits for data sharing, but also significant barriers. It is unrealistic that all data can or will be shared, nor should this be the goal of data sharing efforts. Furthermore, strategies to ensure the quality and traceability of shared data will be important for data sharing endeavors. Work must be done to identify what types of data are commonly shared, and what types of data need to be shared to address common pain points. For example, standard guidelines could be created for data sharing from a company to a scale-up facility or CMO; determining what data is needed to create community knowledge of purification process development; and identifying what datasets could be pooled to train protein expression prediction models. In many cases, companies do not want to participate in these types of valuable data sharing initiatives in order to maintain their competitive advantage. Thus, guidelines, standards, and incentives will likely need to be developed by public and nonprofit sectors, with considerations of how to get private company participation.

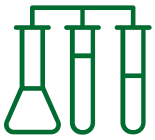
Data format. Standardizing data formats will support the data sharing efforts described above. One existing example is the STRENDA Guidelines[20] for enzyme kinetics data, which include metadata requirements (discussed below). There is a large variety of software available that output uniquely formatted data; utilizing formats that are standard across the global engineering biology sector will improve the usability and interoperability of shared data. Standards for data format will need to specify the structure to be followed, for example, by including: data labeling, data units, mandatory and optional data types, and indication of technical or biological replicates. Inclusion of associated metadata is also necessary (see Metadata section below).

Metadata. Data, especially from processes that involve biological components, need metadata to be meaningful and reproducible. Biological performance is highly sensitive to environmental and measurement conditions. Thus, standards for metadata collection, format, and sharing, alongside primary data, should be developed. Some electronic laboratory notebooks and information management software collect metadata automatically; standardization around what metadata is collected could help to guide these functions across different softwares.

These efforts will ensure better reproducibility and understanding of processes, improved data quality, and aid in troubleshooting efforts along the process development pipeline.

IP and data security. Concerns over loss of IP and other risks to data security are significant barriers to public data sharing. Companies in the US and elsewhere want to maintain their competitiveness through IP protection and/or trade secrets, though IP concerns exist company-to-company, regionally, and internationally. These concerns must be addressed, through tools, guidelines, and standards for IP and data protection, to achieve full participation of data sharing across the industry. One way to address this could be to begin by sharing data models, rather than actual data. Thus, best practices and standards can be developed for data models as a way to keep companies' data private. Another approach could be to share failed data so that the company can reap the benefits of their successful bioprocess IP while allowing the community to learn from the pitfalls encountered along the way. Standards to control the quality of shared failed data would need to be developed for this strategy to be useful.

Metrology and metrics



Advancing metrology and metrics for engineering biology technologies is needed to help improve understanding, predictability for design and control, and decision-making during development, operations, and scale-up. Simple, robust, and accessible measurements are desirable to track key process parameters across scales and to aid reproducibility.

This topic area featured prominently throughout the discussion at all three regional workshops. Of particular interest were metrology and metrics needs to support and speed efforts to scale-up processes and products. The Americas workshop highlighted a regional need for specific metrics and measurements for biomass or cell density of the product, characterization of the fermentation

What are metrics?

Metrics and measurements have some overlaps. Metrics can be abstract or subjective: the hardness of a material or the robustness of a computer program. Measurements are concrete: a material will have a particular score on the Mohs Hardness Scale, a computer program will have a precise number of lines. How you measure, what you measure and why you measure can be variable, but the results of those measurements are what they are.

Sometimes metrics are straightforward: elemental composition, weight, pH, etc. But not always. For example, it's not necessarily obvious what are the correct metrics for determining whether a product generated by biotechnology is halal or not. It may be necessary to do genetic sequencing to guarantee the product has not been tainted by material from a non-halal source.

Failure to establish the proper metrics would restrict access to a USD1 trillion market, according to a participant in the Asia and Australia workshop.

broth – including amount and concentration of the product, impurity, inhibitor, and feedstock – and environmental sensing of the conditions within a bioreactor. In Europe, there was a general consensus on the need for metrics to ensure product provenance, safety, functionality, and sustainability. Additional discussion explored the feasibility and potential of equipment standardization (*e.g.*, for fermentation) and validation of predefined operational range, without reaching any consensus on specific measurement requirements. Biomass and its relationship to product yield, were highlighted as a potential metric to track across scales, through the discovery, pilot, and commercialization of products. The Asia and Australia region called for measuring uncertainty in biological systems and processes to improve prediction and control when engineering biological systems toward specific functions or phenotypes. Of note were: the needs for measurements and metrics to ensure product safety and biosecurity; standardization of phenotypic datasets to enable informatics leveraging ML and AI approaches; assays for accelerating the DBTL cycle, including characterization of starting raw feedstocks; and, metrics and best practices for sharing and reporting data, including ensuring data quality and longevity.

Existing measurement technologies and approaches have been generally developed at a specific scale, (*e.g.*, discovery versus commercial), with few efforts to successfully transition these across scales or to establish new methods applicable across many scales. Many metrology tools are developed and optimized at the laboratory scale during the discovery phase of product development. With regards to accelerating upstream research and discovery, the use of biofoundries and laboratory automation has become commonplace, for example through the establishment of the Global Biofoundry Alliance[21] and regional cloud laboratories. While industry has yet to widely share the metrology it has developed specific to these systems, academic and government laboratories allow access to their protocols through publication in peer-reviewed journals (*e.g.*, Springer Methods in Molecular Biology and Cell Press STAR Protocols), online data repositories (*e.g.*, GitHub and GitLab), and

collaborative platforms for organizing and sharing protocols (*e.g.*, Protocols.io). At commercial scale, engineered biological processes can look to existing metrics and standards for commercial scale production used in other sectors, such as the chemical and petrochemical industries, as a potential starting place to then modify best practices to suit the bioeconomy. There are bright prospects for leveraging AI-driven automation to control the scale-up process, but further research and development of appropriate metrology and metrics is needed to make this a reality.

Measurements do not always scale successfully or favorably. Measurement technologies used at laboratory scales may be different from those in pilot and production bioreactors, with measurements of cell density a notable example. Similarly, the measurements used to characterize engineering biology processes have varying suitability across scales. In research settings, product titers are a primary metric used to describe a process. However, in production settings, productivity and other metrics that account for the duration of fermentation become relevant. Standards are needed to specify useful, informative metrics for engineering biology processes across scales. Furthermore, methods and metrics to compare performance at different scales should be developed, particularly when suitable metrology differ at each scale. Challenges and barriers continue to prevent the adaptation of existing measurement methodologies across scales. Efforts to overcome this will require significant investment of resources.

A significant barrier is developing ways to quantitatively compare manual and automated measurements and workflows to facilitate technology transfers between regions with differing investment in and use of automation. The cost of labor (for manual measurements) versus instrumentation (for automated measurements) varies globally, and in some regions, the lower cost of labor results in preference for manual measurements.

A further challenge is the need for clear understanding of the measurand(s), measurement technique(s), calibrant(s), validation(s), and acceptable tolerance(s) that are appropriate for each scale. For example, the engineering biology community has yet to identify which measures give the most information relevant at each scale (*e.g.* discovery, pilot, and commercial) for various biological processes. Additionally, it is unclear which specific calibrants, best practices, and metrology tools should be prioritized in each region. Participants at each workshop discussed how to quantify biomass and whether this quantity is a significant process parameter, with no actionable conclusions. Traceable reference materials for calibration and validation to ensure measurements are comparable across scales are still lacking. Because there is generally greater variability in biological systems than non-biological ones, having standard reference materials and calibrants for critical metrology can anchor metrics and increase comparability between different measurements, sites, users, and scales. One example of an existing effort to facilitate comparability of measurements across biological systems is the NIST Flow Cytometry Standards Consortium,[22] which seeks to develop and facilitate broad adoption of standards for quantitative flow cytometry, primarily for the biomanufacturing of cell and gene therapies.

Finally, there remains a lack of fundamental understanding of the acceptable variability at each scale for a specific biological process that ensures that products and processes remain fit-for-purpose.

A robust standards portfolio underpinned by sound metrology and clear metrics would be beneficial to advancing the global bioeconomy, but each regional workshop highlighted the challenge of reaching consensus on what measurements to standardize and what priority various measurements should be given in efforts to support the global bioeconomy. Defining and developing a core set of generally applicable engineering biology metrics could expedite technology transfer and commercialization around the world.

Scale-up and scale-out

There were regional differences in challenges faced at each scale (*e.g.*, discovery, pilot, commercial) and in how standards and metrics could be used to reduce the burden of scale-up. For example, scaling up as part of the discovery phase may be tied closely to laboratory automation, which uses liquid handlers for pipetting into multi-well plates. Although this topic was most emphasized at the Americas workshop, it is relevant globally. Scale-up from benchtop to pilot scale may focus on optimizing biological processes for use with fermentors of various sizes. This is a challenge faced in every region but may be less burdensome in regions with increased access to pilot fermentation facilities and expertise. Scale-up from pilot to commercial scale may focus on partnering with the appropriate CMO. This topic was heavily discussed in the Europe and Africa workshop but is a common need across the globe.

Scale-out is an adjacent and newer concept to the bioeconomy, focusing on increasing manufacturing capacity by using multiple bioreactors of smaller volume in parallel. Scale-out has the potential to reduce operational risk (for example, from a bad batch of reagents), increase flexibility in manufacturing capacity (for example, by leveraging manufacturing sites across several geographic regions), increase paths to process validation (for example,

What is scale-up and scale-out?

For the chemical industry, scale-up can simply mean taking processes perfected in small beakers and using the same process in giant tanks. But when it comes to biological organisms, that's not always possible. The yeast strain that is perfectly at home fermenting the sugars in a 5-gallon plastic bucket full of beer may not do the same job in a 20,000-liter stainless steel tank. Modified processes may be needed in biological scale-up, as well as new testing methods for the final product.

What's more, scaling up chemical processes usually means building large, centralized facilities, since the final product is most economically produced in tanker-car quantities. But for biological processes, where the final product might be measured in grams or milliliters, production at larger quantities may involve multiple smaller facilities all producing the same product.

Such distributed manufacturing can be an important quality of the bioeconomy, since startup costs are far smaller than what would be needed for a large, centralized facility.

by comparing data from multiple batches across different sites and operators), and increase supply chain resilience.

For scale-up during the discovery phase, the Americas region focused on identifying measurement capabilities that would reduce the burden of optimizing protocols and processes to scales beyond benchtop. For example, quantitative measurements of automated methods that are informative of process performance at the discovery phase would help identify which processes should be scaled-up to the pilot phase. Specifically, guidelines for standardizing automation protocols for improved quality and readability could facilitate adaptation of benchtop protocols to automated workflows.

For scaling up to pilot and commercial scales, the Americas region also called for a toolkit to accelerate scale-up especially for startups. This should include modeling tools for techno economic analyses (TEA) and other risk assessments, resource utilization and recovery, and process control monitoring. In addition to the toolkit, a sector-specific scale-up checklist could accelerate efforts to identify process constraints, feedstocks that limit potential scale-up, and steps to navigating IP and licensing. Furthermore, standardized digital representations of the capabilities offered by pilot facilities and CMOs could streamline communication and facilitate partnerships between SMEs and production facilities. This checklist and toolkit would likely need to be tailored to specific applications and sectors of the bioeconomy. This guidance through the scale-up processes could lead to higher success rates of commercialization, on a faster timeline, and reduce resources spent by individual companies to achieve similar outcomes.

All three regions called for greater understanding of how biological systems themselves behave at larger scales (*e.g.*, mL to L and beyond) to support scale-up of manufacturing processes that use biological systems. Operational best practices for scaling processes through pilot to commercial scales would smooth interactions with regulatory authorities for startups, SMEs, and established industries. Standardized fermentation parameters, including consensus on

construction materials for fermenters,[23] at the pilot and commercial scales would support the transition of biological systems and processes between scales. Metrics to assess quantitatively the feasibility of transitioning a process to larger scales in terms of performance (*e.g.,* yield) and efficiency could further reduce the burden of scaling up and scaling out by identifying the optimal scale for a specific biological process or biomanufactured product.

Additionally, all three regions highlighted the potential of data sharing and predictive modeling to reduce the challenge of scaling biological systems and processes. Standards for data collection and sharing would reduce the cost of troubleshooting common challenges in scale-up and drive technology transfer and adoption. Commonly available datasets would enable advances in predictive modeling of biological systems to predict how these systems are likely to change at different scales, due to differences in hardware availability, and with varying process conditions. Important parameters at each scale (discovery, pilot, and commercial) could be identified, for example, through the use of digital twins, to ensure a rational transition of processes between scales.

It is costly and labor intensive to scale-up biotechnology processes to production scale, particularly for small companies. Across the globe, the path to scale-up remains generally unclear for startups and SMEs looking to enter the market. New companies often face obstacles as they navigate the path to commercialization, including: securing regulatory approvals, often in an opaque regulatory landscape; assessing the feasibility of their process or product through TEAs or by other means; and finding a path to scale-up either through capital expenditure or through partnership with suitable pilot and CMO facilities. Public resources to support engineering biology startups and SMEs through the scale-up process would accelerate many products to market in the bioeconomy. Any standards and metrics development in scale-up will have to directly address these challenges, to enable small companies to accelerate their commercialization pathway and ultimately lead to a diverse and vibrant industrial ecosystem to enable the global bioeconomy.

Both the Americas and Europe regions emphasized the need for improving the economics of scale-up for startups and SMEs, as well as the use of public resources to support scale-up. This includes understanding the cost and feasibility of scaling up from discovery to pilot to commercial scales. One example of an existing metric that startups and SMEs can use to assess the economic burden for scaling up at the discovery phase is called the Experimental Price Index (EPI).[24] The EPI quantifies the operational expenditure of using laboratory automation in terms of processing time and number of samples. Furthermore, investments in automation through the use of modular systems can facilitate flexible workflows that vary in complexity and support biomanufacturing with different engineered biological systems.

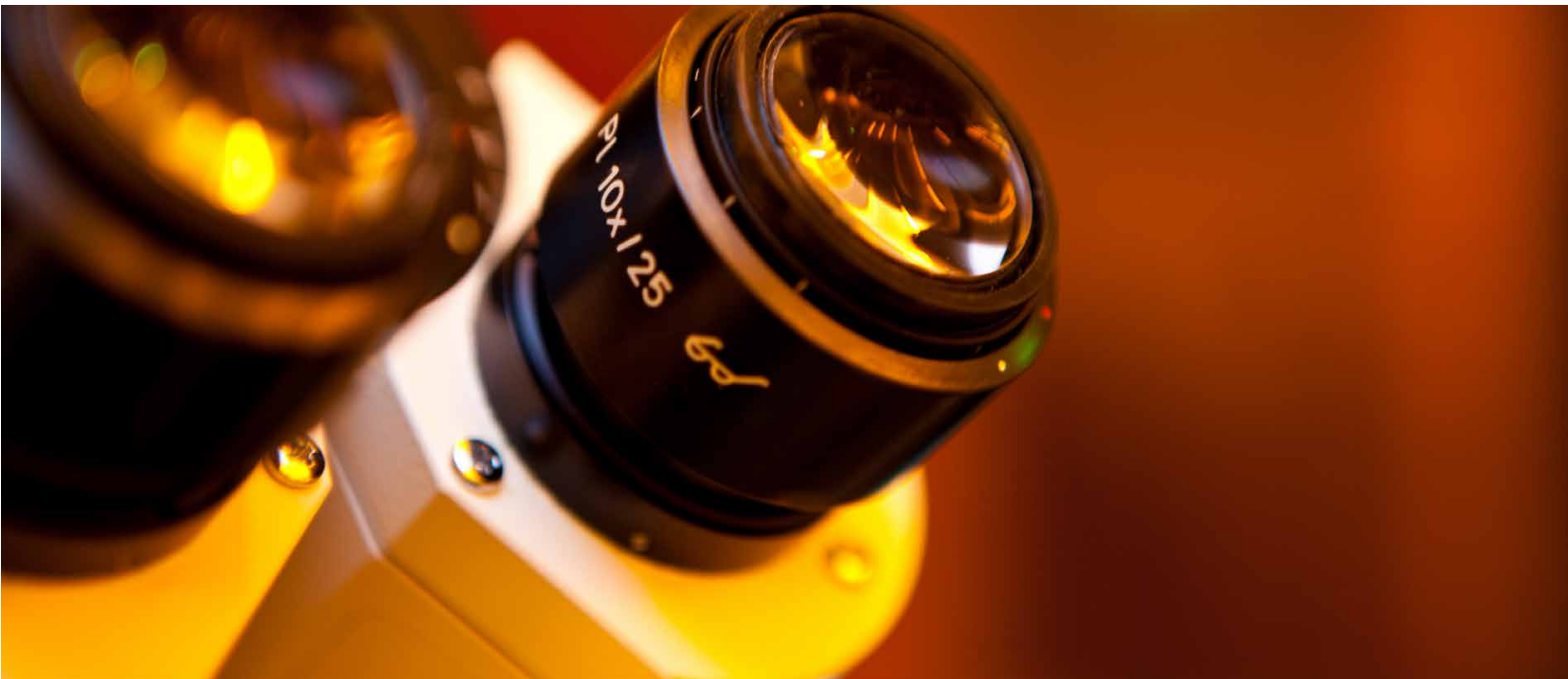
Because startups and SMEs often do not have resources to scale-up themselves, they partner with CMOs to outsource the manufacturing of bioproducts at commercial scales. In part due to government funding, Europe and Asia have more established networks of CMO facilities than elsewhere, including

the Pilots4U database of all existing open access pilot facilities in Europe.[25] While this may offer significant advantages to companies in certain regions of the globe, CMO selection remains challenging, for example, due to availability in technical expertise, equipment, and raw materials, history of successful regulatory filings, and implementation of relevant quality control such as LCA and TEA. Cross-regional support and infrastructure for identifying existing CMOs and their capabilities would expand regional markets, strengthen the potential from cross-regional business partnerships, and support diversification and resilience of global supply chains. Without guidance and technical and economic resources for scale-up, startups and SMEs are vulnerable to failure from costly, ill-informed attempts to scale and commercialize their products.

Lexicon and terminology

A standard lexicon and format for communicating biological information can serve to expedite engineering biology-related communications, while preserving accuracy and understanding. Both technical and non-technical terminology is needed, to communicate within the engineering biology community and to communicate outside of it, with external stakeholders, policymakers and regulators, and the public. Even definitions and conceptions of the "bioeconomy" differ across regions. For example, Europe's bioeconomy includes traditional biomass-related sectors, such as agriculture and forestry, while the US focuses its bioeconomy on new biotechnologies. For the technical lexicon, standards for terminology to describe strain modifications, growth conditions, and downstream processing needs, and so on, could ensure that protocols, documentation, and technology transfers are unambiguous, easily understood, and readily reproduced by any party.

For the public, having clear non-technical terminology for engineering biology can help to improve transparency within the field and aid with public perception. The controversy around genetically modified organisms (GMOs) was in part due to misunderstandings of how organisms are modified and for what purpose. The National Institute of Standards and Technology (NIST) is developing a Bioeconomy Lexicon,[26] which defines common bioeconomy-related terms.



Translations and addition of terms that may be prevalent in other regions, as well as expansions of the lexicon, will help to bridge communications across languages and regions, to support the development of a global bioeconomy.

Sustainability assessments

There is widespread agreement that sustainability assessments are wanted and needed as part of a comprehensive understanding of engineering products and processes. Results from sustainability assessments, such as the life cycle assessment (LCA), can serve as a way to compare products within and outside the bioeconomy, as evidence of meeting sustainability criteria, and to inform regulations and economic incentives that can further bolster the bioeconomy. LCAs attempt to quantify the environmental loads and impact, including material and energy usage, of a product over the course of its lifetime, from production to disposal. Results of different LCA frameworks for the same product can vary, as they are dependent on the boundaries selected and the data used. For example, if an analysis chooses to incorporate feedstock processing steps and has data around the energy requirements of those steps, the result could indicate more energy consumption to produce a product than an analysis that does not include those considerations. The relative cost in time and labor to perform LCAs is especially high for startups and SMEs. The resources discussed in this section could help to lower the burden of performing LCAs.

LCAs are already commonly used across the bioeconomy and standards relating to LCA exist. Most notable is ISO 14044:2006,[27] which specifies requirements for LCAs including defining the scope, reporting requirements, and limitations. However, there are widespread concerns across academia and industry over

the variations in methods and data used in these assessments. The interpretation and application of LCA standards may also differ from user to user across engineering biology-enabled sectors. Therefore, there is a need for more specified criteria, *e.g.*, through sector-specific considerations that can augment existing LCA standards and frameworks. A standard framework or guidance should be developed that outlines how LCAs must be performed, including boundary selection, reference datasets, collecting data to support the assessment, calculating and accounting for relevant criteria, and sector-specific considerations.

A standard LCA for engineering biology products could include:

- origin and renewability of feedstocks;
- impacts of feedstock transportation;
- land use;
- biodiversity impacts;
- carbon intensity (including for infrastructure use, *e.g.*, biocontainment facility);
- process waste and by-product impacts; and
- recyclability of the final product.

There is a suite of activities that can support standard LCAs for engineering biology products. Public reference datasets of quality data are needed for the field to support standardization around common calculations, *e.g.*, cost of transportation, or land use effects. Regions should have their own tailored datasets to improve accuracy. Measurements and metrics will need to be developed and refined to suitably quantify assessment considerations. Independent verification and certifications could help to establish trust in the assessment methods and results. Labeling could be established to easily identify products that meet a benchmark for environmental impact. There are many examples of existing labeling schemes used to demonstrate adherence to performance standards, such as the FAIRTRADE Mark.[28]

In Asia, biomass feedstock utilization (further discussed below) is a key pillar of sustainability in the bioeconomy and sustainability initiatives are being developed in national efforts. For example, Japan is standardizing LCAs nationally and will make them mandatory for new engineering biology research and development projects. Sustainability was highlighted as one of the key drivers for the bioeconomy in the European Union (EU). There, evaluations of factors such as land use are commonly integrated into sustainability considerations when assessing various technologies. Stakeholders from the Americas focused on the importance of determining appropriate metrics and best practices to measure the environmental impact of engineering biology products and processes. Expanding standards for engineering biology LCAs globally would enable trusted comparisons of biomanufactured products between countries, increase international competitiveness, and accelerate trade within the global bioeconomy. Developing a harmonized, global LCA will be a lofty technical, social, economic,

and policy challenge; there must be a balance between assessing and elevating sustainable products and avoiding protectionism for products made in different international markets.

Biomass feedstocks

Interest in the utilization of non-traditional process feedstocks (*e.g.*, agricultural residues, municipal waste, and gas emissions) is growing rapidly around the world amongst researchers, industry, and government. This report focuses on complex, heterogeneous biomass feedstocks, including waste biomass, because those were explored most deeply during workshop discussions. The availability, viability, and sustainability of biomass feedstocks need to be properly characterized to enable development and use going forward. Given the high variability of biomass, globally aligned standards and metrics for characterization and processing will be important for an interconnected bioeconomy that comprises products made from regionally specific biomass feedstocks. Standards and metrics can be a significant complement to technological advancements to support the utilization of biomass feedstocks in precision fermentation and other biomanufacturing processes. Standards and metrics can help to specify the types and compositions of feedstocks that are available, accelerate the characterization and use of new feedstocks that were previously unexplored, enable the transfer of existing processes to new locations with their own unique biomass supply, and identify new technologies that are needed to incorporate these feedstocks into the bioeconomy.

Developing measurement technologies and tools to support biomass feedstock standards will be crucial, since characterization – including of availability and composition – will likely comprise numerous measurements of various aspects of the biomass. The availability of the diverse biomass in Asia is already being

Feedstocks

Spinning straw into gold is the stuff of fairy tales. But making valuable products from what's considered agricultural "waste" is very much a reality. Fuel, nutritional supplements, and laundry detergents are just some of the products that today are made from what are known as biomass feedstocks.

The variety of these feedstocks is enormous. They can come from agriculture "side streams," such as corn husks and almond shells, purpose-grown crops such as switchgrass, or leftover material from logging and forest thinning. But they also can come from waste food, solid waste, or organic waste from livestock.

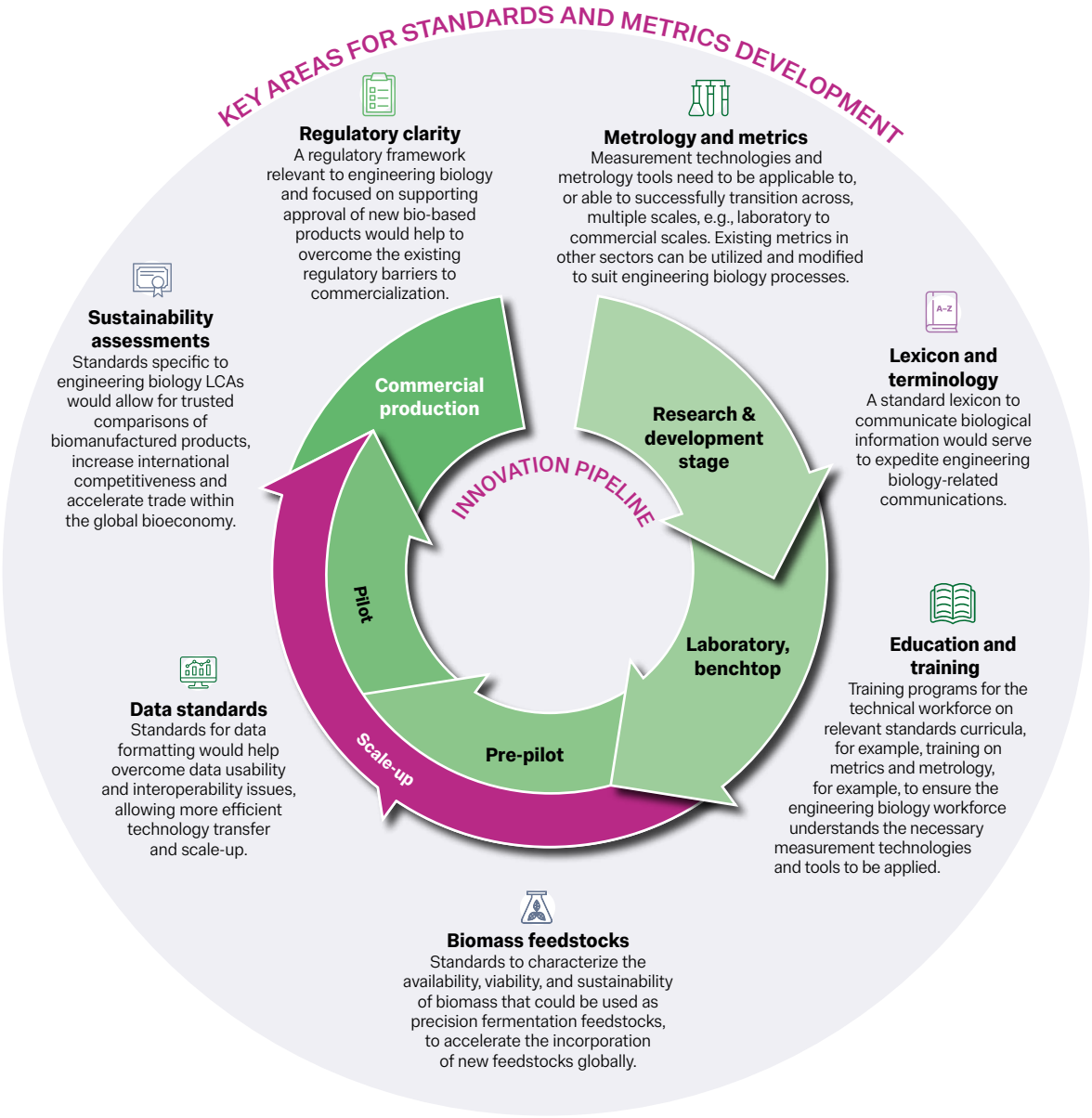
Even though such feedstocks may be widely available, manufacturers like well-characterized starting material. To that end, participants in all three workshops said the development of new products from biomass feedstocks would be accelerated by more information about the make-up of the feedstock.

assessed; reports on the biomass available for bioenergy production in various Southeast Asian countries have been issued by authors such as the International Renewable Energy Agency,[29] ASEAN,[30] academic researchers,[31] and more. The US Department of Energy (DOE) published its calculations of the potential supply of US biomass in the 2016 and 2023 Billion-Ton Reports.[32] While these types of reports are a valuable resource, advancements are needed to provide more technical and regional granularity on the available biomass. An example of a more granular biomass resource is a specification sheet for potential feedstocks. The specifications would build on associated measurement technologies and metrics. This resource would allow researchers and industry to select appropriate and interesting feedstocks based on a set of pre-defined characteristics, including availability, location, and viability. This could also provide a framework for cataloging biomass.

A specification sheet on feedstocks could include the following attributes:

- identity and source;
- quantity, such as total volume, mass, etc.;
- composition (including carbon content, lignin content, types of components (such as hydrocarbons, sugars, sulfur compounds), components ratios);
- inhibitors and non-fermentable parts;
- energy density;
- seasonality and/or long-term availability;
- storage conditions;
- preprocessing conditions, if applicable;
- a measure of sustainability or circularity, *e.g.,* carbon index; and
- including a report-back function, whereby users could report on unexpected impurities, for example, would further enhance this tool.

Figure 4. Recommended standards applied across the engineering biology process, to support accelerated commercialization of the global bioeconomy.



Another useful tool would be a map detailing potential feedstocks suitable for biomanufacturing processes, including the characteristics listed above. Such a map would assist companies with engineering biology process development and biomanufacturing site selection. Assessments to match available biomass with production of engineering biology-based products would allow for better tracking of supply and demand. This is a key area of activity identified by the US Department of Agriculture,[33] as part of an overall plan to enable the bioeconomy through building a resilient biomass supply. Biomass utilization, standards, and measurements will also be linked to sustainability; feedstock assessments will need to be incorporated into LCAs and sustainability considerations.

The favored approach for developing biomass feedstock standards differed by region. In the Americas, the primary focus was on standards and metrics advancements in the characterization of feedstocks for easier utilization in

process development. Similarly, stakeholders in Europe called for standardized feedstock analysis to complement technical advancements for the development of new biomass feedstocks. Stakeholders from Asia and Australia discussed the merits of standardizing the feedstocks themselves, through consolidation and preprocessing, so that biomass can become more like homogeneous petrochemical feedstocks.

Non-technical

Training and education on standards and metrics

To ensure all the above recommendations are appropriately understood and adopted by those working in the sector, training and education will be required. Standards and metrology education could be introduced into existing course curricula, followed by ongoing, job-specific training throughout careers in the bioeconomy. Technical workforce training programs could also introduce relevant standards curricula, such as those around data and metrology. Training will serve to improve understanding and implementation of existing and new standards across the bioeconomy.

Standards and training have a two-way relationship, in which training would be greatly beneficial for the workforce to thoroughly understand standards, and curriculum and certification standards for training programs can help to ensure a properly trained workforce for the bioeconomy.

Additionally, education on the importance and role of metrics and metrology is key to ensuring engineering biology trainees understand measurement technologies, what is being measured, and how metrics support engineering biology technology development.

Public engagement, improvement of public perception, and building trust

Positive public perception was discussed across all three workshops as a priority goal and critical factor to market success of engineering biology products in the bioeconomy. Notably, the lingering negative connotations of genetic modification (GM) from the 1990s, especially in the context of food, has had a lasting impact on public acceptance of bio-based products in different regions. In Europe GM crops are still not permitted, whilst in the US they have been grown for many years,[34] and in Asia there is increasing adoption of GM crops. Negative consumer perceptions can act as a deterrent for companies to commercialize engineering biology products and technologies to their full potential. Although specific concerns and perceptions may differ globally, stakeholders agreed that improved information sharing with the public is needed around the benefits and uses of engineering biology, as well as transparency around the processes and risk assessments employed.

Improving public perception and trust can be achieved, in part, through clear metrics and standards for language, documentation, certifications, and training. A standard lexicon, as recommended in this report, could help to build better understanding of the sector. Engagement from industry, academia, and government bodies with the public is necessary to reshape negative perceptions and communicate the positive impacts of engineering biology. Communication strategies should consider the need to disprove or challenge unevidenced negative claims, which can lead to mistrust and reputational damage that affects the whole sector. Standard documentation, certifications, and training for engineering biology can lead to improved public perception by increasing the transparency and traceability of products and processes. For example, standardized labeling can help the public easily identify sustainable or safe engineering biology products. It would be helpful to connect this type of labeling to existing labels and standards for various products, including food, cosmetics, and medicines. Finally, clear metrics for areas of public concern are important to support public engagement. If a product is labeled as "safe," it is important to understand how that is quantified, and communicate that information to the public.

Public perception should be considered in the context of the specific country or region, as perceptions can differ globally depending on cultural and societal contexts. This is especially important in the EU, where stakeholders cited public acceptance and positive perception as necessary forces to drive regulations, incentives, and market development. Additionally, public perception was said to be a substantial determinant of a country's biotechnology competitiveness in Asia.

Regulatory clarity

Regulations exist to ensure that safe and effective products are brought to market. While many engineering biology-enabled products and processes have gained approvals and are on the market today, navigating the regulatory landscape is a major challenge for companies in the bioeconomy. Improved regulatory clarity and transparency are needed for engineering biology startups and SMEs to efficiently commercialize new products. Standards in documentation, assessments, and benchmarking, supported by metrology and metrics, can facilitate regulatory clarity by laying out what is needed for, and providing structure to, achieving regulatory approvals. Current regulation is often unnecessarily complex and ambiguous, presenting prohibitive hurdles towards successfully bringing new products to market. In the Americas and Europe and Africa workshops, similar anecdotes were shared that certain engineered organisms or engineering biology products were denied regulatory approval even though they were comparable to approved, non-engineered organisms or products. This illustrates the need for appropriate metrics to inform quality and safety assessments within regulatory frameworks, without biases towards engineering biology technologies if they are not relevant to the end product.

Conversely, there are instances in which regulations specific to engineering biology products, with considerations towards the sector, are needed. Existing regulatory frameworks are often applied to engineering biology products, though they are not always suitable, and this can result in assessments that are irrelevant to the intended use of the product, to the industry, or to the purpose of the regulations. One example from Europe is the lack of appropriate regulatory considerations for enzyme-based pesticide field testing; the regulatory pathway used for chemical pesticides is applied. This makes regulatory approval very difficult to achieve, as biological materials such as enzymes have vastly different characteristics compared to chemical-based products, including half-life and persistent impact on the environment. A more appropriate regulatory pathway is needed to account for the characteristics of biological elements used as pesticides and other products.

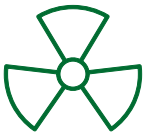
There are regional differences in whether regulations focus on the products or processes of engineering biology. For example, Europe has a narrow regulatory scope that focuses on processes. Innovators, including stakeholders from Europe, prefer regulations for the product, not the process. Implementing performance standards and subsequent regulations for engineering biology products would allow flexibility and agility within the bioeconomy to respond to technological advancements around processes, while maintaining desired attributes of the product, such as function, quality, safety, and sustainability. Where products are replacing non-biologically produced ones, existing product performance standards and regulations should be adapted, if necessary, and applied to reduce redundancies. The above sections highlight the challenges and the necessary balance of establishing appropriate performance standards and regulations for engineering biology products. Metrology will be required to ensure that measurement tools to assess existing performance standards are functional and fit for purpose for biological systems and products. In the Americas, discussions noted that outcome-based product performance standards are desirable, *e.g.*, compared to requirements for infrastructure, as these would be more accessible and easily achieved by companies with less resources.

Mapping out the regulatory landscape for engineering biology products, and highlighting where standards, metrics, or entirely new regulatory pathways are needed, would help companies understand and navigate what is currently a substantial barrier to commercialization. Even with the relatively consolidated governance structures in the US and the EU, there is a lack of clarity around what is required to approach agencies for regulatory approval. In the US, different federal agencies have different purviews and requirements, especially regarding engineered organisms or biological components. The U.S. Coordinated Framework for Biotechnology Products attempts to provide a transparent and coordinated regulatory framework across all the US regulatory bodies and aims to provide public confidence and improve efficiency in regulating biotechnology products. However, American companies are often still unclear on where their product fits into the regulatory landscape. Concerns in the EU center around long delays awaiting decisions, since there is no formal limitation on how long approvals may take, and the binary nature of the decision-making means that products can be refused regulatory approval after an indeterminate time frame.

Regulatory complexity is identified by the European Commission as one of the key challenges the EU biomanufacturing sector currently faces, with approval for some products notably taking up to three times longer to achieve than in the US.[35]

Startups are particularly vulnerable to current regulatory hurdles, noting the high costs associated with acquiring approval, and the risk of resources being depleted while awaiting decisions by regulatory agencies. One American startup CEO in the alternative food sector shared that if a startup is unsuccessful in acquiring regulatory approval on the first attempt, the cost could lead to bankruptcy. Within the Asia and Australia region, there is a more diverse set of national regulations, with discussions focusing on the need to establish consensus, harmonization, and shared values. Global standards will be imperative to this since the development of standards and regulations are more closely tied in Asian countries, where standards are often used as the basis for regulatory assessments. Beyond Asia and Australia, community-driven technical standards for engineering biology products could aid in regulatory harmonization across the global bioeconomy.

Biosafety and biosecurity



Ensuring biosafety and biosecurity for consumers, workers, the public, and the environment is critical to the successful function and growth of the bioeconomy. There have been persistent concerns regarding the safety of engineering biology technologies since the field's inception; new advancements, in areas such as oligo synthesis and AI, are garnering added concerns around biosecurity. While it is critical to assess and mitigate risks emerging from the field, one school of thought argues that preventative measures should be proportionate to risk so that safe research and innovations can progress within the bioeconomy. Open, technical frameworks for risk assessments would enable appropriate understanding and response to risks, complement regulations around biosafety and biosecurity, allow companies to efficiently assess their products and processes, and help to communicate these efforts to the public. Risk assessments for biosecurity must evolve to accommodate technological advances, including AI.

To assess risk, and determine levels of biosafety and biosecurity, it is necessary to determine what to measure, and how – *i.e.*, metrics and metrology. These should be tailored to the intended use of the product. An example of considerations for biosafety metrics is: what needs to be quantified to determine if field tests of engineered biological products are safe for the environment, or that engineered alternative proteins are safe for human consumption? Documentation standards for biosafety and biosecurity can improve traceability of engineered organisms; risk assessments and reference materials will also support these determinations. For example, modified organisms that are already approved for environmental deployment can serve as benchmarks for performance when assessing if a new engineered organism is ready for field testing.

Biocontainment considerations represent a unique subset within the broader topic of biosafety and biosecurity. Under the umbrella term of "biocontainment" there are two main cases: physically containing biological material within

bioreactors and facilities, and containment in the context of deliberate release of genetically engineered organisms into open settings, such as agricultural fields. Containment within bioreactors is well understood, long practiced, and supported by existing standards. Technologies to support the deliberate release of engineered organisms are still in nascent stages, with research actively being conducted on genetically engineered biocontainment strategies. For deliberate release cases, there is disagreement across the field on whether engineered genetic biocontainment is the best solution, and whether the level of containment should be proportionate to the associated risk or uniform across every application. Some argue that it is better to ensure traceability of engineered organisms rather than intrinsic biocontainment, for example through genetic barcoding. Barcoding of organisms can also ensure traceability for unintended release incidents from bioreactors. Common metrics and benchmarks for biocontainment and barcoding could help to quantify these discussions on best practices for deliberate release of organisms. They would also facilitate technology development targets and regulations. Biocontainment standards and benchmarks could aid regional and international coordination, especially for legislative regions that share borders. Definitions and standards for biosecurity are also needed to enable tracking and regulating possible breaches.

Training around biosafety and biosecurity metrics and standards will enable researchers and the workforce to assess and respond to risks properly. Biosafety and biosecurity can be codified by incorporating these metrics and standards into regulations. Finally, these efforts can support improving public perception by providing evidence of safety for engineering biology technologies and commercial products.

Levels of acceptable risk vary across institutions, organizations, and governments, for example regarding biocontainment in the environment. These must be considered when harmonizing standards for biosafety and biosecurity around the world. While there will likely never be consensus on what is and is not acceptable regarding risk, the standards and metrics detailed above can help parties have precise conversations and comparisons across their differences.

Figure 5. Panel a. An illustration of the engineering biology process, from R&D through to product commercialization, highlighting areas where standards and metrics could be implemented to accelerate the process. Panel a details specific stages of the process, with examples taken from two case studies; panel b provides examples of standardization that could be implemented to help accelerate the process.

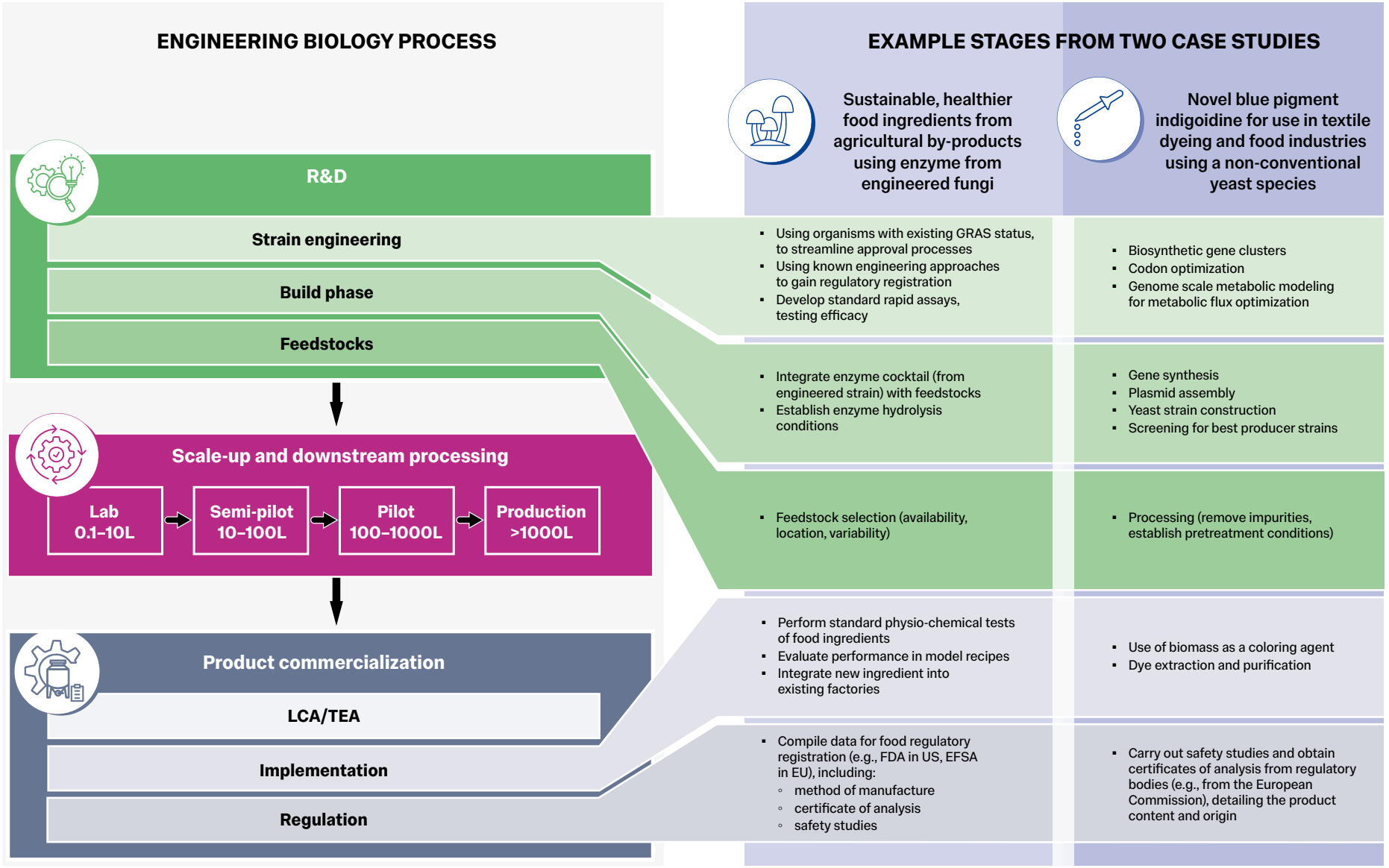
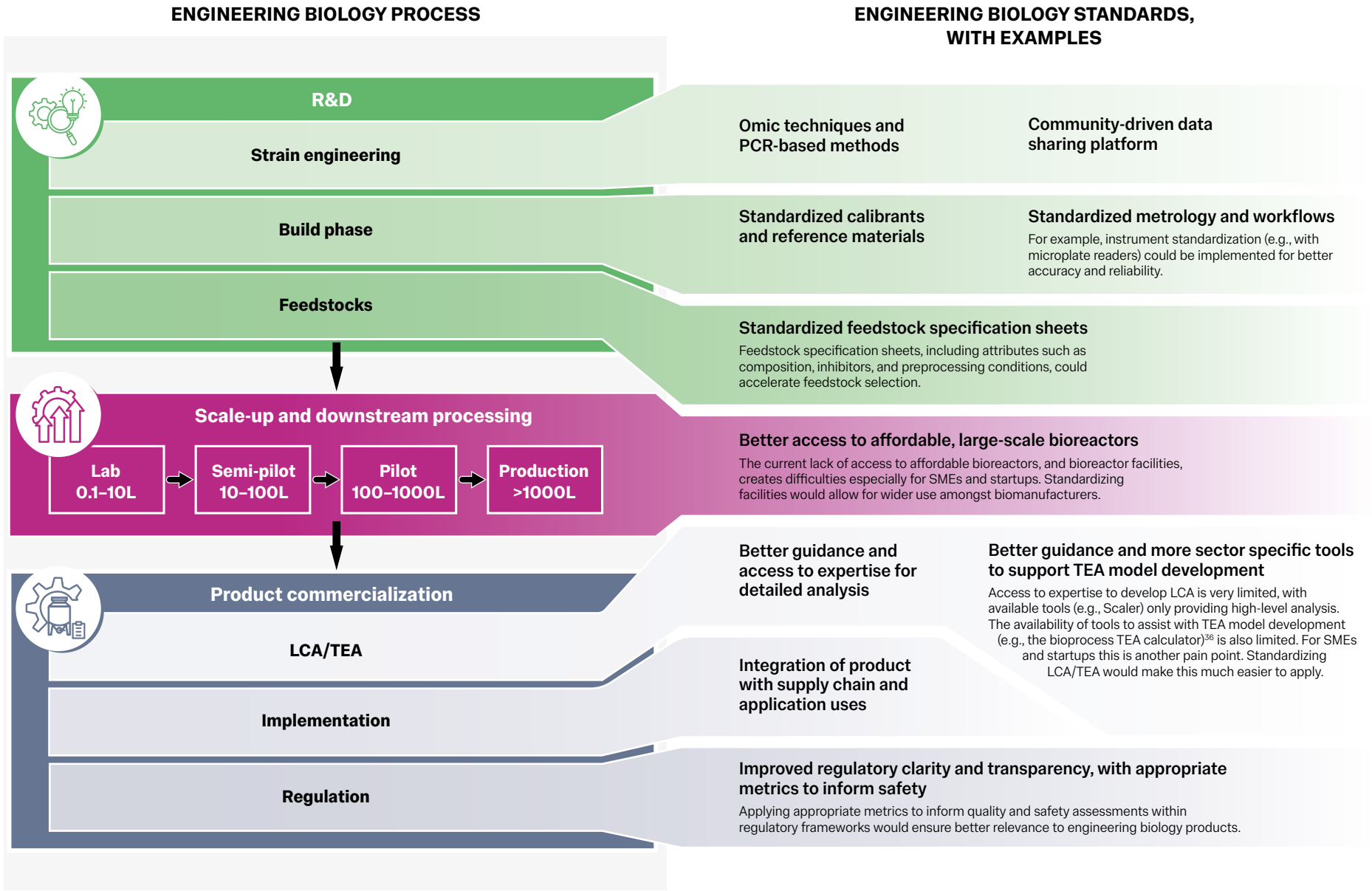
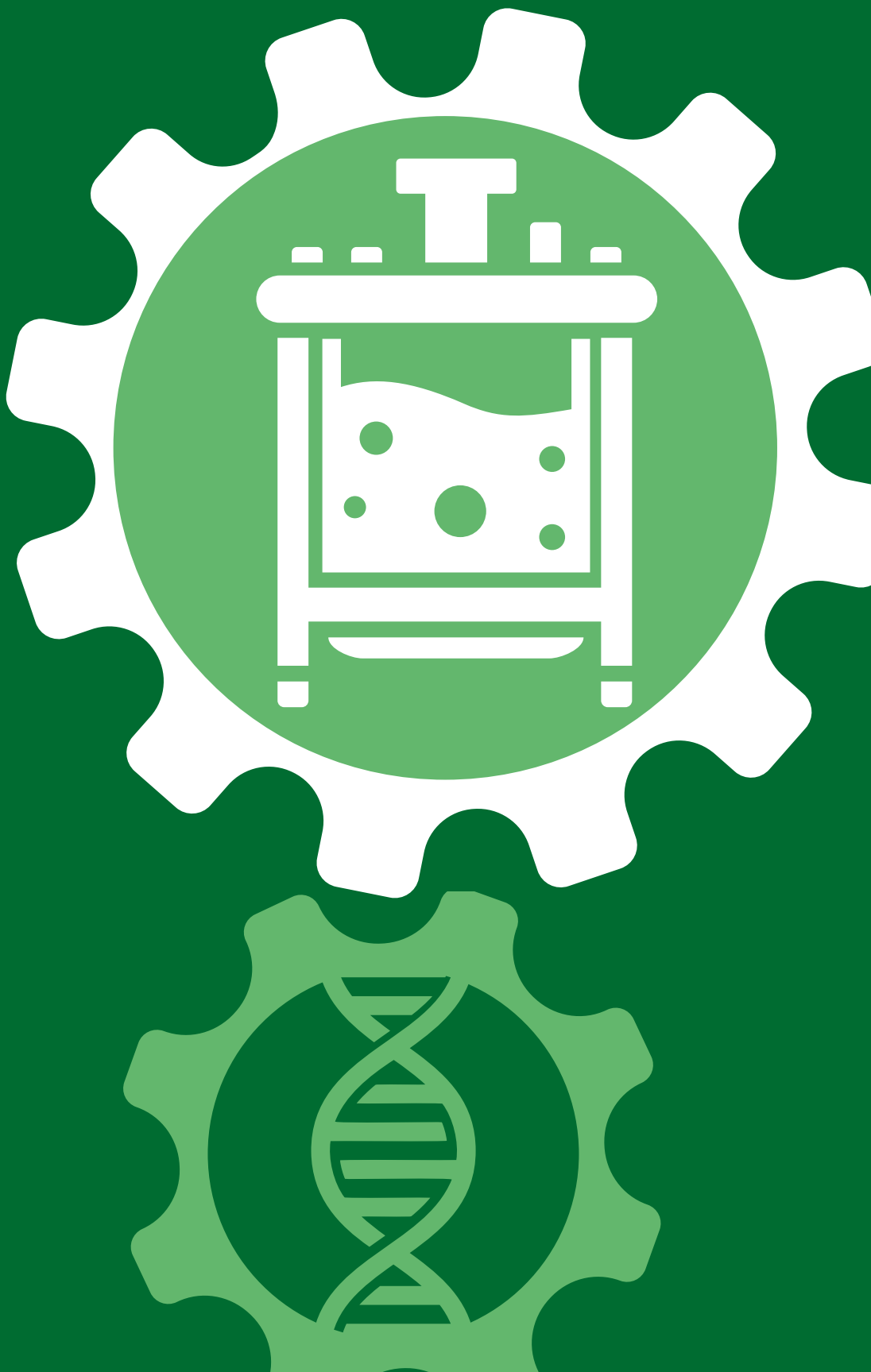


Figure 5. Panel b.



Concluding remarks



Overview

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. Open voluntary standards relevant to engineering biology and the bioeconomy need to be identified by the community. To better understand and address the need for standardization across the globe, regional convenings were conducted, bringing together key technical stakeholders to discuss regional needs and identify specific aspects of the innovation pipeline that should be prioritized for standardization. In addition to identifying regional priorities, the Task Force sought areas of consensus across the regions, should any exist.

The dialogue differed across the regions, reflecting the varying state of the bioeconomy, and differing priorities. As part of these discussions, national priorities and needs were also raised, highlighting further the varying state of play across the bioeconomy. Regional variations were underscored by differences in levels of public support, regulatory clarity, innovation landscape, and technology readiness. These factors combine to play significant roles in determining the priority needs of a nation or region. National or regional standards and development efforts should be pursued to build on individual strengths and priorities.

The workshops provided a sound understanding of the current state of the bioeconomy within each region, though discussions were naturally limited by the perspectives and experiences of participants. In convening each workshop, the Task Force made efforts to engage with a range of stakeholders representing a variety of small and large industry, nonprofit organizations, academic institutions, and government agencies. However, the limitations of each cohort should be noted. For example, within the Americas workshop participation was dominated by participants from the US, with only a few representatives in attendance from Canada and South American countries. Similarly, the Europe and Africa workshop unfortunately lacked African representation, and although stakeholders from Africa were engaged during the drafting of this report, the discussions held during the workshop were representative of European views. Within the Asia and Australia workshop, there was a general emphasis on early-stage research as opposed to scale-up and biomanufacturing, a reflection of the expertise of those attending. Going forward, stronger engagement across the breadth of the bioeconomy, and with an expanded network including stakeholders from the southern hemisphere, will be essential to ensure discussions are globally relevant. This report can be used as a starting point for such continued discussions, both regionally and globally.

The ten **key areas for standards and metrics development** are the outcome of workshop discussions that were observed and summarized by the Task Force. 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

7. **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.
8. **Public engagement, improvement of public perception, and building trust**, addressing negative consumer perceptions by improving communication and transparency.
9. **Regulatory clarity** to efficiently commercialize new products and processes, through standards in documentation, assessments, and benchmarking.
10. **Biosafety and biosecurity** for consumers, workers, the public, and the environment, for future successful functioning and growth of the bioeconomy.

Next steps

The key areas noted and discussed in this report represent the priority pain points within engineering biology, as identified in regional workshop discussions. The workshops provided an opportunity for stakeholders across the sector to share thoughts and aspirations pertaining to the opportunities for standards and metrics to help overcome some of these pain points. Those discussions were limited, in terms of the number of stakeholders present, the time to discuss such a broad topic area, and the specific experiences and expertise of those attending. Further investigation and stakeholder discussions are needed to delve deeper into the topics identified, and to add more specificity to recommendations for how standards and metrics can best enable the advancement of the global bioeconomy.

Regional contexts and perspectives are included throughout the report, to reflect the differing needs and priorities for the bioeconomy. Where differences exist, whether as a result of varying technology readiness, or public perceptions and needs, there are opportunities to develop standards that apply to smaller regions. Leveraging regional strengths could allow for certain regions to lead on specific areas of engineering biology standards development, whilst ensuring they are appropriate for the context. In parallel, global coordination and harmonization could help to guide standards development in engineering biology, especially from the knowledge of those that are farther ahead or have more established practices.

To support continued efforts to further investigate and develop recommendations for standards and metrics for the bioeconomy, input is required from across the sector, including from stakeholders in government, academia, and industry, as well as coordination with standards-setting bodies. Funding programs are required to support such ongoing efforts. As the global bioeconomy continues to grow, international collaboration on standardization efforts will be key to ensuring sector-wide buy-in and application. For example, the Global Centers initiative – which has a funding stream focusing on addressing global challenges through the bioeconomy – may provide a suitable platform for ongoing work in this area. It is a joint partnership with funding from the US, Canada, Japan, Republic of Korea, Finland, and the UK.[37]

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Appendix I
Regional workshop

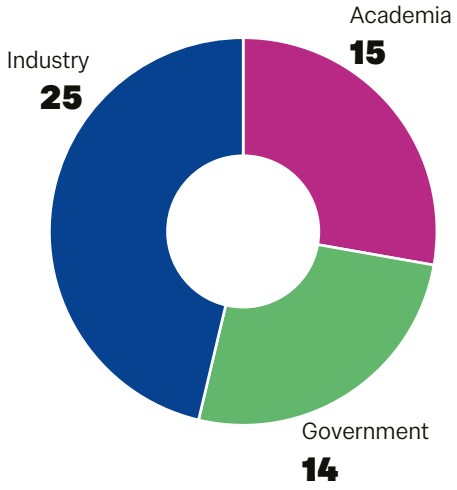
The Americas

Americas workshop

The Americas workshop included an evening reception at the Cosmos Club in Washington DC on 7 June 2023, followed by two days of technical programming at the Institute for Bioscience and Biotechnology Research in Rockville, Maryland, 8–9 June 2023. The workshop welcomed participants from four countries in North and South America, though participants were predominantly US-based. 38 organizations were represented, including 33 with technical representatives in attendance and six US federal agencies. In total, some 60 attendees from industry, academia, and the US federal government engaged in passionate and thoughtful dialogue about what standards and metrics are needed in their industries and fields.

For many workshop participants, it was the first chance they had to describe how the right standards could speed innovation and lower barriers to technology transfer, whether they were running a startup, working for a more mature biotech company, or in a regulatory agency. No one questioned the value of standards and metrics; the challenge was to identify broadly useful ones. The technical content consisted of a day of brief presentations interspersed with panel and audience discussions on topics including upstream processing, downstream processing, scale-up, data sharing, process development, and more; and a day of breakout sessions that enabled more in-depth discussions on those topics, and beyond.

Americas workshop attendees by sector (not including members of the Task Force).



An abridged agenda from the workshop is provided below. Full details of the workshop discussions are available in the Interim Workshop Report: Americas, available for download from the project website: imperial.ac.uk/engbiosgb

Abridged agenda

Day 1: 8 June 2023

8:30 **Welcome to Day 1**

India Hook-Barnard (EBRC) and Andrea Hodgson (Schmidt Sciences)

Dr. Hook-Barnard and Dr. Hodgson will provide an overview and objectives of the workshop.

9:00 **Developing Metrics and Setting Standards**

Paul Freemont (Imperial College London) and Plenary Discussion

Prof. Freemont will present key definitions for the workshop, describe current, past and failed efforts, and the purpose for the current effort.

9:30 **The Current State of Standards and Metrics**

Sheng Lin-Gibson (NIST) and Plenary Discussion

Dr. Lin-Gibson will present the current state of engineering biology metrology, metrics, and standards and NIST efforts.

10:00 Break

10:30 **Informal Standards are Barriers to Using Non-Model Organisms** – Sarah Richardson (MicroByre)

10:50 **Panel 1: Upstream Processing and Feedstocks**

Moderator: Eugenia Romantseva (NIST)

Panelists: Aaron Schaller (MeliBio), Jonathan Jacobs (ATCC), Marilene Pavan (LanzaTech), Sarah Richardson (MicroByre), Swami Srinivas (Ginkgo)

12:00 Lunch

13:00 **Downstream Process Development for Precision Fermentation** – Stan Herrmann (Amyris)

13:20 **Panel 2: Downstream Processing and Scale Up**

Moderator: Emily Aurand (EBRC)

Panelists: Elizabeth Onderko (Capra Biosciences), Sean Hunt (Solugen), Stan Herrmann (Amyris), Steve Evans (BioMADE), Vikramaditya Yadav (UBC)

14:30 Break

15:00 **Standards and Benchmarks for Automated Experimentation** – Pete Kelly (Align to Innovate)

15:20 **Panel 3: Process Development and Data**

Moderator: Cynthia Ni (EBRC)

Panelists: Dave Vance (BU DAMP Lab), Emiley Eloe-Fadrosh (LBL), Nathan Hillson (LBL), Pete Kelly (Align to Innovate)

17:00 Adjourn

Day 2: 9 June 2023

9:00 **Welcome to Day 2: Overview and Objectives**

9:30 **Breakout Session 1**

Standards and metrics for **engineer*ed* biology as the product** (*e.g.*, T-cells, crops)

Feedstocks: components, consistency, and sustainability

Standards and metrics for **engineer*ing* biology as the process** (*e.g.*, organism, enzyme, strain platforms for biomanufacturing)

10:45 Break

11:15 **Breakout Session 2**

Standards that support regulations and biosecurity

Translating and coordinating with existing standards and benchmarks

Metrology: tools, platforms, and equipment

12:30 Lunch

13:45 **Breakout Session 3**

Best practices for data sharing and platform interoperability

Safety, sourcing, traceability, public perception

Connecting capabilities and competencies of CMOs for scale-up and DSP

15:00 Plenary Discussion and Workshop Summary

16:00 Adjourn

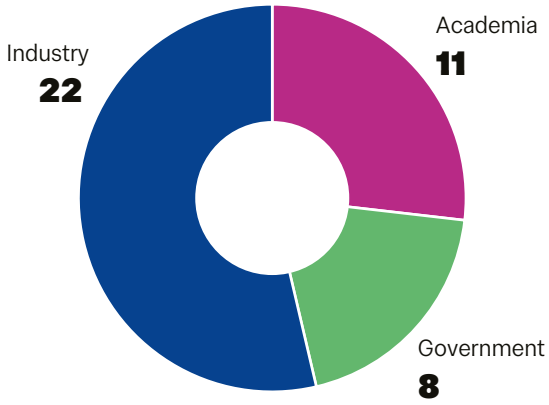
Regional workshop

Europe and Africa

The Europe and Africa workshop took place in Brussels, 25–27 September 2023. The event opened with an evening welcome reception held in the Grand Place, where over 50 participants from industry, academia and government came together, alongside representatives from the European Commission, to discuss the potential for standards and metrics in engineering biology to support the growth and success of the bioeconomy. The two-day workshop comprised participants from 14 countries, though representatives from Africa were unable to attend due to unforeseen circumstances. The workshop discussions, and resulting report, therefore largely pertain to the European context. This imbalance is believed to partly reflect the level of activity in engineering biology within Europe as compared to Africa, where technology readiness may be a significant factor.

On day one of the workshop a series of scene-setting presentations and panel discussions took place. On day two, deeper-dive breakout sessions covered key topics, including: data standards and access; coordinating with existing standards; safety, sourcing, and traceability; and biomass and sustainability. There was an overriding consensus that Europe needs to move forward more quickly; to harness the growing momentum arising out of academia and industry, as part of a rapidly advancing global bioeconomy. In particular, support needs to be garnered from policymakers and, most importantly, citizens, without whom a bioindustry in this region would simply not compete globally. Participants discussed the potential for standards and metrics to help simplify current regulatory processes, which many deemed more complex than in other geographical regions. A need was also identified for improved communication and stakeholder engagement with potential investors, customers, and the general public, to better convey the needs and opportunities for engineering biology to address pressing global issues, such as climate change and sustainability. No one disagreed that standards and metrics would assist with reproducibility and global interoperability.

Europe and Africa workshop attendees by sector (not including members of the Task Force).



An abridged agenda from the workshop is provided below. Full details of the workshop discussions are available in the Interim Workshop Report: Europe and Africa, available for download from the project website: imperial.ac.uk/engbiosgb

Abridged agenda

Day 1: 26 September 2023

09: 00 **Welcome to Day 1**

Overview and objectives of the workshop

Andrea Hodgson (Schmidt Sciences)

Developing Metrics and Setting Standards: Presenting key definitions for the workshop, describing past and failed efforts, and the purpose for the current effort.

Paul Freemont (Imperial College London)

Introduction to the International Organization for Standardization (ISO)

Elena Ordozgoiti (UNE, Spain)

09:30 **Strategy for the bioeconomy: setting the scene for the European context**

Peter Wehrheim (European Commission)

10:00 **Panel 1: The European strategy: how can Europe advance its position in the global bioeconomy?**

Moderator: Roel Bovenberg (DSM)

Panelists: Deimena Drąsutytė (HERLab), Martin Langer (BRAIN Biotech), Vítor Martins dos Santos (Wageningen University), Peter Wehrheim (European Commission)

11:00 Break

11:30 **The current state of standards and metrics within biotechnology**

Jens Erik Nielsen (Novozymes)

12:00 **Panel 2: The importance of standards and metrics within the European biotechnology industry: Why and where are they needed?**

Moderator: Gilles Truan (CNRS)

Panelists: François Bertaux (Lesaffre), Patrick Rose (SPRIND), Alexandra Whale (LGC Group)

13:00 Lunch

14:00 **The need for regulation and standardization for the bioeconomy 2.0**

Virginia Claudio (SpinGaia)

14:30 **Panel 3: Biosafety standards and metrics**

Moderator: Steffi Friedrichs (AcumenIST)

Panelists: Virginia Claudio (SpinGaia), Michele Garfinkel, Natalio Krasnogor (GitLife Biotech Ltd.), Markus Schmidt (Biofaction)

15:30 Break

16:00 **Risks and challenges in the alternative food industry: Experiences from Supplant**

Jeremy Bartosiak-Jentys (The Supplant Company)

16:30 **Panel 4: The need for standards and metrics for alternative food systems and industry**

Moderator: Fayza Daboussi (INRAE)

Panelists: Jeremy Bartosiak-Jentys (The Supplant Company), Lars Højlund Christensen (Chr Hansen AS), Adrian Leip (European Commission)

17:30 Recap of Day 1: *Paul Freemont (Imperial College London) and India Hook-Barnard (EBRC)*

Plans for Day 2: *Juliette Malley (Imperial College London)*

18:00 Adjourn

Day 2: 27 September 2023

09:00 **Welcome to Day 2**

Overview and Objectives

Paul Freemont (Imperial College London) and India Hook-Barnard (EBRC)

Instructions for Breakout Sessions

Juliette Malley (Imperial College London)

09:30 **Breakout Session 1**

1.1 Biomass and sustainability. *Leads: Payam Ghiaci (RISE) and Merja Penttilä (VTT)*

1.2 Data standards and access: best practices for data sharing.
Leads: Misha Delmans (Colorifix) and Laura Sherlock (bit.bio)

1.3 Translating and coordinating with existing standards and benchmarks.
Leads: Davide De Lucrezia (Officinae Bio) and Eugenia Romantseva (NIST)

11:00 Break

11:30 **Breakout Session 2**

2.1 Standards and metrics for engineered biology as the process.
Leads: Mart Loog (University of Tartu) and Emily Aurand (EBRC)

2.2 Standards and metrics for engineered biology as the product.
Leads: Cai Linton (Multus Bio) and Kate Royle (Better Dairy)

2.3 Safety, sourcing, traceability, public perception. *Lead: India Hook-Barnard (EBRC)*

13:00 Lunch

14:00 **Report back from all breakout sessions**

15:00 Plenary Discussion and Next Steps

Paul Freemont (Imperial College London)

16:30 Adjourn

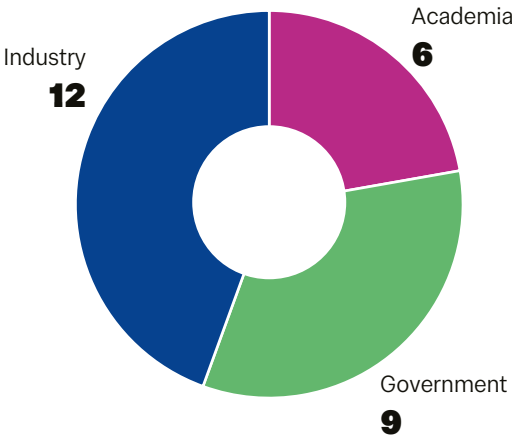
Regional workshop

Asia and Australia

The Asia and Australia workshop brought together key stakeholders in the region at the Shangri-La Rasa in Sentosa, Singapore, 29–31 August 2023. Nearly 40 attendees from 13 countries engaged in dynamic discussions to harmonize metrics and standards in this rapidly evolving field. The workshop shed light on the challenges and opportunities posed by standards and metrics in engineering biology in the region. Participants overwhelmingly acknowledged the importance of establishing standards in engineering biology, despite the complexity of defining the problem space. There was a shared belief that standards are a lynchpin for innovation, although the exact path toward achieving this goal is still being developed.

A key focus was the collaborative dialogue among stakeholders about existing standards, vital for establishing a foundational framework. There was a clear consensus on the need to standardize the increasing volume of biological data generated worldwide. The success of standard-setting efforts in medical imaging, genomics, and genome editing, served as a powerful example, illustrating the potential of community-driven standardization initiatives. Productive discussions led to several action items and collaborative initiatives, including harmonizing data formats under the Global Biofoundry Alliance's potential leadership, promoting data sharing and collaboration between academia and industry, and emphasizing the roles of regional organizations like ASEAN in shaping the vision for engineering biology standards.

Asia and Australia workshop attendees by sector (not including members of the Task Force).



An abridged agenda from the workshop is provided below. Full details of the workshop discussions are available in the Interim Workshop Report: Asia and Australia, available for download from the project website: imperial.ac.uk/engbiosgb

Abridged agenda

Day 1: 30 August 2023

08:30 **Welcome to the Workshop**
Matthew Chang (National University of Singapore, NUS and Singapore Consortium for Synthetic Biology, SINERGY)

08:35 **Overview and Objectives of the Workshop**
Genevieve Croft (Schmidt Sciences)

08:45 **Session 1: Engineering Biology Standards and Metrology: Opportunities and Challenges**
Chairs: Juliette Malley (Imperial College London) and Kostas Vavitsas (SINERGY)
Paul Freemont (Imperial College London)
Developing metrics and standards for Engineering Biology
Sheng Lin-Gibson (National Institute of Standards and Technology, U.S.A.)
Engineering Biology metrology and standards and current US efforts
Ran Wang (BGI Group, China)
Opportunities and challenges in advancing Engineering Biology metrology and standards
Kanchana Wanichkorn (ASEAN, Indonesia)
Metrology and standards for bioeconomy policy
Makiko Matsuo (University of Tokyo, Japan)
Policy and regulation for metrology and standards
Ajay Perumal (Economic Development Board, Singapore)
Metrology and standards for bioeconomy
Discussion

10:00 Break

10:30 **Session 2: Engineering Biology Metrology and Standards: Current State and Development**
Chairs: India Hook-Barnard (Engineering Biology Research Consortium, U.S.A.) and *Wen Shan Yew (NUS)*
Celine Tan (Enterprise Singapore)
Engineering Biology metrology and standards in Singapore
Fan Jin (Shenzhen Infrastructure for Synthetic Biology, China)
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Haseong Kim (Korea Research Institute of Bioscience and Biotechnology)
Engineering Biology metrology and standards in Korea
Sivinee Sawatdiaree (Office of National Higher Education Science Research and Innovation Policy Council and National Institute of Metrology, Thailand)
Engineering Biology metrology and standards in Thailand
Robert Speight (CSIRO, Australia)
Engineering Biology metrology and standards in Australia
Wataru Mizunashi (New Energy and Industrial Technology Development Organization, Japan)
Engineering Biology metrology and standards in Japan
Discussion

12:00 Lunch

13:30 **Session 3: Metrology and Standards in Industry: Engineered Biology as the Product**
Chairs: Emily Aurand (EBRC) and *Wataru Mizunashi (New Energy and Industrial Technology Development Organization, Japan)*
Santanu Dasgupta (Reliance Industries, India)
Metrology and standards in the biotechnology industry
Laura Navone (EdenBrew, Australia)
Metrology and standards in the agri-food industry
Lei Dai (SynBiome, China)
Metrology and standards in the microbiome industry
Soichiro Tsuda (bitBiome, Japan)
Metrology and standards in the microbiome industry
Chionh Yok Hian (GenScript, Singapore)
Metrology and standards in the gene synthesis industry
Jungjoon Lee (ToolGen, Korea)
Metrology and standards in the genome-editing industry
Ramon Gonzalez (Mojia Bio, Singapore)
Metrology and standards in the biomanufacturing industry
Discussion

15:00 Break

15:30 **Session 4: Metrology and Standards in Industry: Engineering Biology as the Process**

Chairs: Cynthia Ni (EBRC) and *Ran Wang (BGI Group, China)*

Seokmyung Lee (CJ CheilJedang, Korea)
Metrology and standards in biomanufacturing processes

Tomohisa Hasunuma (Kobe University, Japan)
High-throughput analytics and automation for Engineering Biology metrology and standards

Jianzhi Zhang (Chinese Academy of Sciences)
Biofoundry for Engineering Biology metrology and standards

Koichi Yoshioka (Bacchus Bio, Japan)
Metrology and standards in the biofoundry industry

Chueh Loo Poh (NUS, Singapore)
Metrology and standards in the bioimaging industry

Donghyuk Kim (UNIST, Korea)
Biological data management and sharing

Erhan Simsek (Agilent, Singapore)
Metrology and standards in the bioanalytics industry

Discussion

17:00 **Discussion and Summary**

Kostas Vavitsas (SINERGY)
Engineering Biology metrology and standards: Current state, opportunities, and challenges

17:30 Adjourn

Day 2: 31 August 2023

08:30 **Welcome to Day 2**

Matthew Chang (NUS and SINERGY)
Overview and Objectives; Instructions for Breakout Sessions; Introduction of Discussion Leads

08:35 **Breakout Session 1**

Standards and metrics for engineered biology as the product
Leads: Santanu Dasgupta (Reliance Industries) and Laura Navone (EdenBrew)

Best practices for data sharing and platform interoperability
Leads: Chionh Yok Hian (GenScript) and Jungjoon Lee (ToolGen)

Metrology and Standards that support regulations and biosecurity
Leads: Kanchana Wanichkorn (ASEAN) and Makiko Matsuo (University of Tokyo)

09:45 Break

10:00 **Breakout Session 2**

Standards and metrics for Engineering Biology as the process
Leads: Seokmyung Lee (CJ CheilJedang) and Ramon Gonzalez (Mojia Bio)

Translating and coordinating with existing standards and benchmarks
Leads: Ran Wang (BGI) and Erhan Simsek (Agilent)

International partnership and engagement
Leads: Kostas Vavitsas (SINERGY) and Robert Speight (CSIRO)

11:00 **Discussion and Workshop Summary**

Matthew Chang (NUS and SINERGY)
Engineering Biology metrology and standards: Collaborative initiatives and action items for Asian and Australian communities

12:00 Lunch

13:30 Adjourn

Appendix II
List of contributors

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Bovenberg, Roel

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Chionh, Yok Hian

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SpinGaia

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