EBRC Engineering Biology Research Consortium

US Leadership in a Global Bioeconomy

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The emergence and growth of bioeconomies around the world is marking the beginning of a global transition to a sustainable, bio-based future built on engineering biology. In this early stage, there is an opportunity to establish international norms, standards, and regulations in the bioeconomy, as countries will look at precedents set by each other when making their own policies. The US should seize this leadership opportunity. It should develop and promote standards and regulations to simultaneously i) ensure the future of a secure domestic bioeconomy and ii) lead and steer the development of an equitable, healthy, and sustainable global bioeconomy through international coordination and cooperation. Herein, we describe four key focus areas where international best practices, norms, and/or standards are nascent or underdeveloped, and thus where there is real need and opportunity for US leadership: 1) Standards, Metrics, and Norms, 2) Regulations, 3) Biosecurity and Biosafety, and 4) Horizon Scanning. Development of these four areas have significant benefits to creating a robust bioeconomy both domestically and internationally. Leveraging action in these focus areas, the US can also demonstrate its international leadership by supporting the advancement of engineering biology in countries with less developed bioeconomic plans and infrastructure, thereby accelerating the formation of a well-integrated global bioeconomy. If the US does not provide such support, other nations likely will, and the US will cede leadership to them.

1) Ensure that US standards, metrics, and norms become de facto global standards for industry

Widely adopted standards and metrics are the foundation for commercialization, transactions, and regulations that spur innovation in a secure bioeconomy. As examples, bioindustrial products may need to meet certain purity standards. Reference genomes and naturally-occurring variants may need to be established to ensure safety and security of products (see Genome in a bottle—a human DNA standard). Globally-recognized standards and metrics are needed to enable products that are exempt from regulation in the US but not in other countries to be assessed and traded. The absence of such standards and metrics needs to be addressed the world over. If the US is able to fulfill the policy of the Biden Administration to "promote standards, establish metrics, and develop systems to grow and assess the state of the bioeconomy," it will be well-positioned to lead efforts to establish universal standards for the global bioeconomy. Operating from shared standards would enable easier trans-national trade, thus adding value to and enhancing connections in the global bioeconomy.

In addition to technical standards, there is an opportunity to develop standards and guidelines on ethical and behavioral norms within the bioeconomy. As advancements in engineering biology blur the line between natural and synthetic biological systems, global norms could ensure ethical development and deployment of biotechnology. The US can coordinate these efforts by building off existing domestic examples, such as the EBRC Statement of Ethics in Engineering Biology Research. This approach, in tandem with horizon scanning,

would strengthen the security of the bioeconomy by preempting misuses of engineering biology, rather than relying on ad hoc responses to incidents that arise.

2) Enable a global bioeconomy despite varied regulatory approaches

The US has demonstrated regulatory coordination across agencies through the Coordinated Framework for Regulation of Biotechnology. These efforts are commendable and must be continued for the success of the domestic bioeconomy. In a global landscape, challenges arise due to the product-based regulatory approach of the US compared to the process-based approach used by most other nations. As a result, biotechnology products that are exempt from regulation in the US might be regulated in other countries. The US then needs to understand which types of products are regulated differently between countries, work to develop mutual recognition agreements and/or coordinate the sharing of regulatory approvals and/or dossiers, and provide information to US companies on how to approach an international stage with widely variable regulatory approaches. Any such understandings or arrangements will necessarily be informed by commonly defined and accepted standards and metrics. The USDA Foreign Agricultural Service plays an important role in linking the US agricultural system to the rest of the world. An interagency working group with counterparts at EPA and FDA may be useful as the more and different engineered products become ready to potentially enter global markets, and global coordination with regulatory bodies outside the US a necessity. This approach will strengthen the US bioeconomy and better enable bio-based products to be used for a more sustainable future.

3) Maintain global leadership for biosecurity and biosafety standards

As the bioeconomy advances on a global scale, it would be prudent to coordinate efforts to address biosecurity and biosafety. New research breakthroughs can not only be used to develop exciting new bio-based products, but also to inadvertently or deliberately create products or tools that could be used in ways that harm people, animals, plants, or the planet. The US can work with international partners to establish and share frameworks for risk assessment at all stages of the research, development, and commercialization lifecycle. In so doing, the US should recognize the importance of considering both the biosafety risks and the biosecurity risks associated with developing technologies, and seek to provide international leadership for each.

To demonstrate global biosafety leadership, the US could foster international recognition and agreements around safety standards for high-containment laboratories; partner to develop shared standards for recognizing the safety of engineered enzymes or products in food, cosmetics, or other consumer products; and pursue and share advanced approaches to biocontainment to preserve environmental integrity. Such activities would ensure that the deployment and consumption of technologies within the bioeconomy are safe for users and the environment.

To demonstrate global biosecurity leadership, the US should promulgate currently-developed best practices and guidance, such as the existing guidance for providers of synthetic DNA. The US government should fund innovative, collaborative international research to develop tools that reduce biosecurity risk. The US should also continue to identify the vulnerabilities of our domestic bioeconomy and, as appropriate, exchange information about these vulnerabilities with allies, working together to reduce risk and promote stability across the global bioeconomy. Crucially, in the face of real security concerns, the US must maintain focus on the benefits of an interconnected, collaborative global bioeconomy and avoid measures that lock down information or technologies.

4) Ensure that horizon scanning activities under the EO are global and widely shared

The US should undertake horizon scanning activities both internally and with international partners to better position itself to anticipate both the positive outcomes and negative consequences that could stem from biotechnology developments. The importance of horizon scanning for new developments in biotechnology has been recognized by countries such as Australia and by Parties to the Convention on Biological Diversity. Global issues, such as the impact of the bioeconomy on climate and the environment, require the perspectives inherent in multilateral collaboration. Global horizon scanning for engineering biology capabilities and for the applications of those capabilities would enable the US to identify areas for technical and/or regulatory partnership and break down international silos. Horizon scanning also enables biosafety and biosecurity preparedness, enabling preparation for coming dual use technologies and informing US funding decisions for research that minimizes or mitigates potential negative consequences (e.g., research on biocontainment).

Currently, the US has a few mechanisms for horizon scanning. EBRC produces technical research roadmaps that identify technical innovations and their applications that may be attainable over the short-, medium-, and long-term. The roadmaps have a US focus but are intended for global use. Products on the horizon, but drawing closer as companies actively work on them, are tracked by Future Bioengineered Products. The existence of these roadmaps and resources demonstrates horizon-scanning capabilities amongst US biotechnology stakeholders that could be leveraged on a global stage; international horizon scanning activities would enable people and the planet to reap the benefits of biological advancements while mitigating associated negative outcomes.