

Implementation of the United States Government National Standards Strategy for Critical and Emerging Technology (USG NSSCET)

An EBRC Response to NIST RFI 88 FR 61527 Docket No.: 230818-0199 6 November 2023

The Engineering Biology Research Consortium (EBRC) appreciates this opportunity to provide comments on the implementation of the USG NSSCET. EBRC is a non-profit, public-private partnership that brings together an inclusive community committed to advancing engineering biology to address national and global needs. *Our comments primarily consider CET related to engineering biology and biotechnology, as that is the area of expertise of our organization and the members we represent; while many ideas herein are applicable across CET, our focus is intended to be on biotechnologies specifically.* EBRC is part of the Task Force on Engineering Biology Metrics and Technical Standards for the Global Bioeconomy (https://www.engbiosgb.org/) that has held three workshops around the world to identify standards and metrics needed to accelerate commercialization in the bioeconomy; we are working to synthesize the workshop findings into a strategic roadmap for global engineering biology standards and metrics development that will be published in Spring 2024. Thus, while only EBRC members directly contributed to the development of this response, our comments are informed by the perspectives of a broader community of engineering biology experts from around the globe.

General Questions

1. Are there potential benefits, opportunities, or risks associated with increased U.S. participation in standards development activities for CET?

Given that CET encompasses novel, emerging technologies, there is an opportunity for early U.S. leadership to make a lasting impact in what standards are established, in how CET is deployed domestically and internationally, and in ensuring our technical and non-technical values are reflected in these activities on the global stage. Not only are there benefits to producing technically appropriate guidance and considerations for CET, norms and best practices can also be codified through standards. For example, as biotechnology-related CET advances, the number of applications involving the intended release of engineered biological components or organisms will likely increase. For such applications, technical measures of biocontainment are critical, as are considerations of biosafety and acceptable risk to ecosystems, among others; these topics are discussed further in the answer to Question 2.

On the other hand, broad-stroke approaches to standards development for CET could put at risk compliance and adoption of U.S.-led efforts. CET development may be application specific, and disagreement can arise between application sectors when the standards developed for one application are not suitable for another, thus drastically limiting compliance. For example, the needs addressed by standards for bio-based fermentation products used as chemical precursors would be different from those for products used as food or drug additives. This highlights the importance of

broad stakeholder engagement to ensure that the standards developed accelerate, rather than hinder, CET development and use. One way to approach this is to specify applications in CET standards development. Additionally, the USG, in consultation with stakeholders, should define assessment criteria for how well standards function across application sectors. In the international landscape, different countries use biotechnology standards to different extents, e.g., as voluntary guidelines or as part of regulations; increased U.S. participation may lead to friction with other countries due to different approaches to standards development and degree of requirement, or even due to differences in biotechnology adoption and utilization itself. Once again, this risk can be ameliorated through collaboration with international standards developers and regulators.

2. What are the potential risks or implications of decreased U.S. participation in standards development activities for CET?

The U.S. risks losing its leadership position in global technology development with decreased participation in CET standards development; decreased participation could also be seen as the U.S. deprioritizing CET. This would give other countries an opportunity to take over our leadership position in standards development, which could result in CET standards that are difficult for U.S. companies to adopt, or incongruous with how they utilize CET. In many other countries, there is a strong or direct link between biotechnology standards and regulations. Thus, if the U.S. decreases engagement and participation in standards development, we could also be ceding our leadership in developing regulations for biotechnology as well.

The link between standards and regulations in other countries has ramifications for the biotechnology investment and development landscape, which is heavily influenced by transgovernmental companies and industries. Thus, technological isolationism at the level of standards development is ultimately counterproductive to U.S. interests. The more the U.S. can foster transparency and trust, the more likely fair, equitable, and balanced biotechnology standards that benefit U.S. researchers and industry will be promoted and accepted by external and transnational stakeholders.

For biotechnology specifically, issues of environmental release, traceability, and safety of engineered bioproducts are likely to become more prevalent as technologies develop. These topics have repercussions for health, safety, and security for people and the planet. However, overly conservative standards and regulations can impede human benefits from new technologies. For example, concerns over, and opposition to, genetically engineered, vitamin A-rich Golden Rice limited its global adoption and its potential to abate vitamin-A deficiencies and related diseases for decades after its creation. In recent years, these concerns have been proven to be unwarranted and Golden Rice has been approved for consumption by many countries, including the U.S. Of course, there are instances of biotechnology research and development in which biosafety and biosecurity risks are high and a more conservative approach is appropriate, such as with research that uses virulent organisms. Thus, a robust risk assessment framework for biotechnologies and other CET should be established that can evolve as the technologies and practitioners evolve. These matters are complex and require thoughtful and nuanced approaches for standards and governance. Decreased involvement with standards development for such technologies can risk lost benefits or unaddressed hazards that stem from CET. Aligning on standards early can help to ensure that the global approach to risk includes measures that the U.S. deems important and necessary, not only technologically but also with respect to health, safety, and other social considerations.

3. What are the most important challenges faced by the private sector (*i.e.,* industry, including start-ups and small- and medium-sized enterprises (SMEs), academic community, and civil society organizations) when participating in standards development activities for CET, and how can these challenges be addressed?

Standards may impede innovation and agility in the private sector; this view leads to reluctance by some to support or engage in standards development activities. Standards development needs to take into account, and be responsive to, novel technology and processes. Additionally, developers should consider how the standards will enhance efficiency, safety, and quality, and not pose a barrier to innovation, and ensure these attributes are communicated to those who may adopt them. Unclear and cumbersome standards are expensive for SMEs to navigate; these are front-end expenses that serve as large barriers to new SME investment and launch.

Lack of equity also poses a challenge to participating in standards development. Smaller organizations do not have the time, money, and personnel to dedicate to standards development. To engage such organizations equitably requires incentives and supportive systems in order to ensure their perspectives are captured with reduced cost, especially compared to larger companies or those with more resources. There should be measures taken to ensure equity between established industry – with the resources to dedicate to standards development and to advocate for standards and metrics that benefit them – and nascent industry, academia, and civil organizations. Additionally, some standards, such as those for facilities and infrastructure, can present significant barriers for the private sector from regions and countries with less biotechnology development and fewer resources to support bio-related CET. Representatives from diverse geographies, both domestically and internationally, should be consulted to ensure that the developed standards are accessible, appropriate, and can achieve their intended goal around the world.

Finally, there are opposing viewpoints on whether or not the intrinsic variability of biology makes standardization in biotechnology too challenging or impractical. This highlights the importance of getting private-sector agreement on what appropriate biotechnology standards are and what metrics and measurements are the most suitable to support them. One way to remedy these challenges is to create a system for, and incentivize, the sharing of biological information and data, such as genetic parts sequences, plasmids, strains, genome sequences, and mutation characteristics, in order to benchmark exactly what is being characterized. The difficult balance of competition, including protection of IP, and collaboration across the private sector to solve the challenges of controlling highly variable biological systems is one that will be critical in developing standards for emerging biotechnologies.

USG NSSCET Objective 1: Investment

4. How can the U.S. Government establish policies that promote standards development for CET as a critical component of U.S. innovation culture?

Excitement, attention, and resources are markers of the U.S. innovation culture, especially around valued CET. Policies that promote standards development as part of this culture need to ensure that sufficient engagement and support is given to them, as they are to the technologies themselves; these policies should also treat standards development as a companion activity to technology development, rather than as a separate endeavor. Standards development policies should be

inclusive of and responsive to the diversity across CET, including various application spaces, companies across the size spectrum (e.g., startups vs. large, established companies), and evolving and novel technologies. Thus, policies should incentivize standards to be open and adaptive, and mandate standards to undergo regular review and revision in response to stakeholder feedback and new technological developments. Given the numerous facets of CET innovation, policies that promote related standards development should focus on inclusivity and making standards accessible, as these attributes will help make the resultant standards suitable to the technologies they govern.

An example of how policies can integrate standards development into innovation culture is by requiring participation in development activities as part of Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR), and other federal grants and contracts. Additionally, training, compliance, and reporting on standards could be incorporated into the System for Award Management (SAM) registration. Such policies would promote participation in, and knowledge of, standards and standards development as part of the innovation ecosystem.

5. How can the U.S. Government utilize Federal spending on research and development to drive technical contributions for CET standards development activities?

The U.S. Government can establish grants to fund research projects to develop technical contributions for CET standards. For biological applications, open datasets for omics and sequencing data would greatly benefit bio-based CET development and serve as reference materials and test cases for biotechnology standards development. Additionally, leveraging artificial intelligence (AI) and machine learning (ML) technologies for biotechnology advances requires large, high-quality datasets. These datasets are needed to train and test AI/ML models, and could also be used to set standards for traceability and biosecurity in the use of AI and ML on biological data. There is a lack of funding, incentives, and coordination on who will generate these open datasets – this is an area that the USG should support with federal spending. Federal research grants could also promote the establishment of standards research "sandboxes" for experimentation on the format of biotechnology standards, as well as on education and dissemination strategies for stakeholders.

The USG could also fund NIST to coordinate CET standards research and development with academia, industry, and CET-oriented organizations. These funds should enable NIST to conduct and facilitate surveys and other assessments of what standards and metrics are needed for biotechnology and other CET, to perform their own research on these topics, and to provide resources for public and private sectors about current and developing standards.

6. How can the U.S. Government facilitate the adoption of standards-based CET by industry stakeholders, including start-ups and small- and medium-sized enterprises (SMEs)?

The USG can make regulatory pathways clear, simple, and underpinned by standards. If adopting standards-based CET will accelerate the regulatory process for industry, they will do so from the onset of their technology development.

Additionally, adoption of standards-based CET by industry can be incentivized with grants and other funding sources. Standards adoption and compliance requirements could be part of federal contracts, as discussed in the answer to Question 4. The USG can also hold workshops and events for two-way feedback to ensure the existing and developing standards are suitable for industry stakeholders.

Finally, USG can encourage industry stakeholder adoption by being responsive to and inclusive of their nascent technologies and by recognizing their competing challenges, including for time and resources to commit to standards development and adoption.

7. How can the U.S. Government better support publicly funded and private research in standards development activities for CET?

The USG can facilitate research efforts by providing government employee and affiliate staff hours and resources to coordinate these activities, as well as to publicize their status and outputs. This can avoid redundancies in research and allow for quick utilization of research outputs, whether as the basis of standards development or further research projects. The USG can also provide and oversee a third-party resource to secure data and other IP that comes from these research activities, e.g., through anonymization of data contributions.

USG NSSCET Objective 2: Participation

8. How can the U.S. Government increase the amount and consistency of private sector (i.e., industry, including start-ups and small- and medium-sized enterprises (SMEs), academic community, and civil society organizations) engagement in standards development activities for CET?

To increase private sector engagement in CET standards development, there must be a value proposition. This could include financial incentives for continuous participation, a competitive advantage based on participation (e.g., better understanding of the standards that must be adopted, especially if they are tied into regulatory approvals), or positive publicity in the industry and public for participation. Contributing individual experiences and expertise to open standards development can risk the loss of competitive advantage or exposing intellectual property (IP); even without these risks, consistent participation in activities outside of direct business comes at a cost to the organization. In addition to mitigating the cost of engagement, security measures surrounding engagement must be put in place to manage these risks. For example, protection and anonymization of data or other operational details can encourage the sharing of specific, technical expertise.

9. How can the U.S. Government improve communications among the public and private sector (*i.e.,* industry, including start-ups and small- and medium-sized enterprises (SMEs), academic community, and civil society organizations) to address potential participation gaps in standards development activities for CET?

The USG can provide one central place for consolidated communications, that includes the ability to receive feedback from stakeholders across sectors to address gaps in CET standards development, e.g., a website with a posting board. This website could have multiple uses by serving as the place to publish updates, ongoing activities, and other related CET standards information. Generally, the USG can bolster engagement in standards development and adoption by providing platforms to host standards, standards related data, and resources for assessing standards compliance. This would be much more effective than relying on the private sector to share or report on standards and development activities on their own, using their own resources.

10. How can the U.S. Government foster early collaboration with private sector (i.e., industry, including start-ups and small- and medium-sized enterprises (SMEs), academic community, and civil society organizations) stakeholders to identify standards for CET that would encourage market and regulatory acceptance as needed? At what stage is early collaboration most effective?

Forums, workshops, and other opportunities for engagement on biotechnology and other CET standards identification should be held to foster early collaboration with private sector stakeholders. The objectives, opportunities, and incentives for private sector engagement should be clearly communicated. Biotechnology startups are generally aware that the regulatory process can be unclear and cumbersome, but do not know how to avoid or mitigate this. Making early collaboration common practice towards identifying and developing standards as one way to facilitate market and regulatory acceptance would be a welcome option to make those processes clearer and for stakeholders to give input on what and how standards could be useful. USG should engage now with existing and established industry to learn where biotechnology and other CET standards could be adopted that are not duplicative or incompatible with existing processes, products, and regulatory frameworks. Regulations may need to be updated to better suit biotechnologies and their associated standards.

USG should engage with the academic community, civil society, start-ups, and SMEs to learn about new biotechnologies in development, before they are realized commercially, so that they can be prepared to revise or adapt existing standards to meet new technologies, or develop new standards, when the time is right. Identifying and developing standards before biotechnologies are commercialized is likely too early, as the details of how that technology is realized may be different than expected. However, responding to biotechnologies that are already on the market misses an opportunity to guide standards development from the outset. Thus, USG should be prepared for new technologies and work in collaboration with private sector stakeholders early so that the timing of standards development can align with market development and entry. This can be incentivized and fostered through regular, consolidated communications (see response to Question 9) that are welldisseminated. Stakeholders need to know what exists and where, and explicitly what role the USG plays in developing and setting standards; they also need to know how those standards lead to regulations and rules about biotechnology adoption and commercialization.

11. What roles do the academic community and civil society organizations play in standards development activities for CET, and how can they increase their contributions to a private sector-led system?

Academics should be engaged and consulted so that awareness of future technologies can inform preparation and development of related standards. There is movement between academia and the private sector – of information, technologies, and people; this movement can translate into more agile and frequent development and revision of CET standards. Engaging the academic community in biotechnology standards development means that the novel innovations coming from laboratories can be developed for industry with standards in mind. Trainees interested in moving to the private sector can get an early education on how standards influence biotechnology deployment in industry. Academia also serves the critical role of workforce training, not only for future technology leaders, but technicians, compliance officers, industry workers, and more. Thus, academia can serve future society

by being engaged in standards development at the earliest stage to shape, promote, and acculturate standards.

Civil society contributions are important because they will use – and be directly impacted by – the products and capabilities that emerge from CETs. Given that standards will ensure the safety, security, viability, sustainability, etc. of current and future biotechnology-based products, the involvement of civil society in standards development will serve two important purposes: i) providing information and transparency will promote informed understanding of biotechnology and standards that govern their safety and efficacy, and ii) the understanding of biotechnology and standards will hopefully lead to improved public perception and willingness to accept and purchase biotechnology-based products. As an example, the controversy and distrust of genetically modified crops and food may be mitigated by open discussion with civil society on how standards are ensuring that they are safe for consumption. Standards and public perception can inform each other: the academic community and civil society organizations should be consulted on issues arising from CET development and informed on how standards address these issues.

12. How can the U.S. Government better support state, local, and tribal governments in participating in standards development activities for CET?

The USG can provide opportunities and compensation for state, local, and tribal governments to participate in CET standards development. At a minimum, these governments will need the money to take on new activities around standards development.

USG NSSCET Objective 3: Workforce

13. How can the U.S. Government leverage existing or develop new digital tools and resources that facilitate access to standards development processes, and increase engagement by private sector (i.e., industry, including start-ups and small- and medium-sized enterprises (SMEs), academic community, and civil society organizations) CET stakeholders?

The U.S. Government can ensure that any relevant digital tools and resources are open access, as well as easy to use, secure, and publicized so that users are aware of them. These digital tools can be the basis for two-way exchange of data and standards. For biotechnology, open omics and sequence databases can adhere to data formatting, sharing, and security standards, thus demonstrating the utility of those standards while encouraging users to share their data because they will be easily incorporated into the databases. Then, with well-utilized digital resources such as databases with robust datasets, standards developers can adapt relevant biotechnology standards to be suitable to the most up-to-date data (data is discussed further in the response to Question 5). Responsiveness of standards development to private sector contributions to digital tools and resources can serve as an incentive for engagement, as the resultant standards will be relevant to the entities that participated. Existing or new government websites, repositories, reference materials, and other resources can serve as a demonstration of the value of private sector engagement.

14. How can the U.S. Government incentivize the modification of existing curricula and/or the creation of new curricula, to include faculty professional development, by educational institutions for pedagogy to support standards development activities for CET?

Currently, to our knowledge, there is no U.S.-based education on standards in biotechnology- or biomanufacturing-related training programs. Education on CET standards and development processes can be disseminated through early-, mid-, or late-career training. Stand-alone teaching material could be developed around CET standards. Alternatively, and likely more effectively, education on standards could be integrated into relevant existing curricula. For example, biotechnology data standards could be integrated into college lab courses and the scientific discovery process; data security standards would be apt for technical workforce training programs. The USG could incentivize this type of curriculum development by including biotechnology standards education as part of federal accreditation for various training programs. The USG could also support this type of curriculum adoption by providing teaching resources on standards. Additionally, the USG should survey the knowledge of standards before and after these training programs and link the results to funding support of standards curricula.

An important consideration for education and training on standards is that there is a direct link between standards, metrics, and metrology. Current technology curricula rely heavily on metrics and metrology; this can be leveraged to inculcate metrics and measurements *towards* standards development and compliance as part of technological pedagogy.

Finally, standards could become a more widespread recommendation or requirement for publication and reporting. For synthetic biology and bioengineering fields, standards and protocols for measurements are poorly represented. If this becomes a requirement for federal research awards, then curricula – including for faculty professional development – would likely be amended to include standards education. There is disagreement amongst academics on whether standards requirements in academic research are useful and necessary, or a hindrance to quick innovation. More investigation must be done on whether, and what types of, standards in publishing and reporting would be appropriate.

15. What standards development activities for CET can U.S. government and private sector (*i.e.,* industry, including start-ups and small- and medium-sized enterprises (SMEs), academic community, and civil society organizations) stakeholders promote or develop to encourage increased participation by students and trainees?

The USG and private sector stakeholders can establish and incentivize direct engagement opportunities, such as internships, related to CET standards development for students and trainees. Examples of internship opportunities include working at NIST, or other standards organizations, on standards development activities, and working at private sector companies to assess the standards development landscape for their sector and how it affects the company directly. The USG and private sector could also establish training criteria or certification in CET standards for the incoming workforce. There should also be explicit inclusion of trainee voices in USG meetings or feedback sessions guiding the development or assessment of standards.

16. How can the U.S. Government support both private sector and public sector recognition for standards development expertise and how can this recognition be utilized to increase standards development activities for CET?

The USG can support recognition of standards development expertise through the establishment of government-validated certifications and of an advisory oversight board, with limited-service terms, on the topic. Support is also needed for biotechnology standards development and implementation recognition at the level of publications and journals. Positive support will likely be met more favorably than additional standards-related requirements to the publishing process, given the reluctance in the discourse around the need for rigorous, government-defined standards in scientific research.

USG NSSCET Objective 4: Integrity and Inclusivity

17. How can the U.S. Government work with private sector (i.e., industry, including start-ups and small- and medium-sized enterprises (SMEs), academic community, and civil society organizations) stakeholders to more effectively coordinate with international partners and reinforce private sector-led standards development activities for CET?

Standards are not private sector-led in every country; therefore, working with the private sector is not always the right leverage point to coordinate with international partners. Identification of the correct parties that drive standards development for each country is an important initial assessment that must be done before meaningful coordination can occur.

The USG must demonstrate to international partners the value of private sector contribution to, and leadership of, standards development; examples of value include reduced regulatory burden, accelerated innovation, and reductions in cost- and time-to market (see answer to Question 8 for other potential value propositions). Access to international collaborators is an additional value-add for U.S. private sector participation, especially if standards development activities give them easier access to international partners and understanding of international markets.

18. How should the U.S. Government share information on standards development activities for CET with like-minded partners and allies?

If the goal is for the standards themselves to be open, their development activities should also be open and transparent; this should be done to the extent possible while still ensuring participation among competing companies and interests in a secure way, e.g., non-attribution. Information on CET standards development activities should be shared through accessible, frequent, and extensive communications and updates through a variety of methods. Some avenues for information sharing include:

- Online resources, such as a website, portal, or repository (as described in the answer to Question 13).
- Invitations to join and contribute to ongoing standards development activities.
- Meetings and workshops with relevant international standards developers and overseers, aimed at reviewing and discussing standards development.

19. What standards information and tools can the U.S. government develop and promote to ensure U.S. exporters can compete in global markets for CET?

Currently, most countries' markets operate on their own standards and regulations. Clear and accessible articulation of what the CET standards are in the U.S. and other countries via a streamlined platform, where this information is regularly updated, could be helpful to exporters. Being a leader of open and public information sharing will likely result in other countries adopting the practices set by the U.S., or at least using them as a baseline, making domestic standards and best practices more relevant in global markets.

Detailed supporting information could include:

- Reference materials, supporting data, and examples of the standards across global markets.
- What standards, and relevant certifications, are recognized and used in other countries.
- How the domestic standards compare to what other countries use, and guidance on compliance, so that it is easier to move into international markets.

Tools and support in the form of a website, personnel, or a designated office to guide users on how to implement standards in countries outside of the U.S. could shorten the time to assess and adapt to global markets. Evaluations and certifications, backed by the U.S. government, indicating whether the appropriate standards have been used or met would allow for smoother entry into global markets.

20. How can the U.S. Government further advance the design and implementation of technical assistance programs for CET that enable broad and inclusive participation by developing countries in international Standards Development Organizations (SDOs)?

Similar to the answer to Question 12, funding support would enable developing countries to participate in SDOs. Federal funding RFAs could include joint programs for research and technology development for CET standards development. Additionally, the USG could develop joint-funded consulting contracts for CET standards development and implementation of CET standards adoption in developing countries.

21. How can the U.S. Government work with international partners to ensure that standards for CET are developed in a way that supports U.S. interests, including a commitment to free and fair market competition in which the best technologies come to market?

The USG should create and maintain relationships with international standards development bodies. Much like in working with the domestic private sector, the USG must coordinate shared goals and identify their value for all parties. In the interest of establishing and maintaining these relationships, the USG should be party to international standards setting organizations (e.g., ISO) consistently, and can take leadership roles within those organizations. Representatives of these organizations should be invited as participants or observers to domestic standards development activities, such as a standards advisory board, in order to increase transparency and alignment of goals. To ensure free markets and open competition, standards need to be inclusive of myriad applications and technologies, and thus available for input and collaboration from international partners.

USG should recognize the association between U.S. biotechnology standards setting and the standards and regulations set and adopted by other nations. The USG should work with international

partners to ensure that U.S. interests can be integrated into existing and developing biotechnology standards and regulations in other countries, in a way that benefits all parties involved.

22. How can the U.S. Government make the United States a more desirable location to hold international standards meetings, events, and activities for CET?

The USG should broadly promote open and collaborative relationships in science and technology development. For example, continued renewal of Science and Technology Agreements will demonstrate that the USG prioritizes alignment of technological interests and development with international partners.

The United States would also become a more desirable location to hold international standards meetings, events, and activities for CET if the logistics for travel and participation were simplified. The difficulty and lengthy processing times of acquiring a visa is a high barrier to foreign visitors who wish to participate in U.S. meetings. EBRC organized an event (https://www.engbiosgb.org/) in the D.C.area in June of this year to identify necessary engineering biology standards to accelerate the bioeconomy, a USG priority; the workshop was one of three around the world and was meant to convene private sector practitioners from the Americas. Because it takes over a year for U.S. visas to be issued to citizens of South America, some of our invited participants were not able to join us. Situations like this decrease the desirability of the U.S. as a location for international meetings. The USG should support host organizations and travelers that aim to hold inclusive meetings with multinational attendance by creating pathways and mechanisms that streamline travel and visa obtainment. Streamlined and accelerated vetting processes for people invited to CET standards meetings, especially for those who have a known history of U.S. engagement, could alleviate this issue without sacrificing security. Other resources to improve accessibility of international CET standards meetings held in the U.S. include readily available translators, support staff to help with visa applications, comprehensive event logistics for all attendees, and accommodations for physical accessibility needs.

Other nations may be distrustful of the perceived unregulated, capitalistic CET ecosystem of the U.S. Increased communication, transparency, and engagement with international partners, not only on CET and standards, but on how these are implemented and operate within a larger economic context may help (see answer to Question 21). A clear and transparent biotechnology regulatory framework in the U.S. would attract investment in U.S.-based biotechnologies and could result in the U.S. being a more desirable location for continued biotechnology standards development activities. Finally, the U.S. should become a leader in preventing IP theft and off-target technology use, in part through biotechnology standards that enforce biosafety and biosecurity. This could allay the undercurrent fears of U.S.-based bio-CET being appropriated for bioterror or as a tool of hegemony.