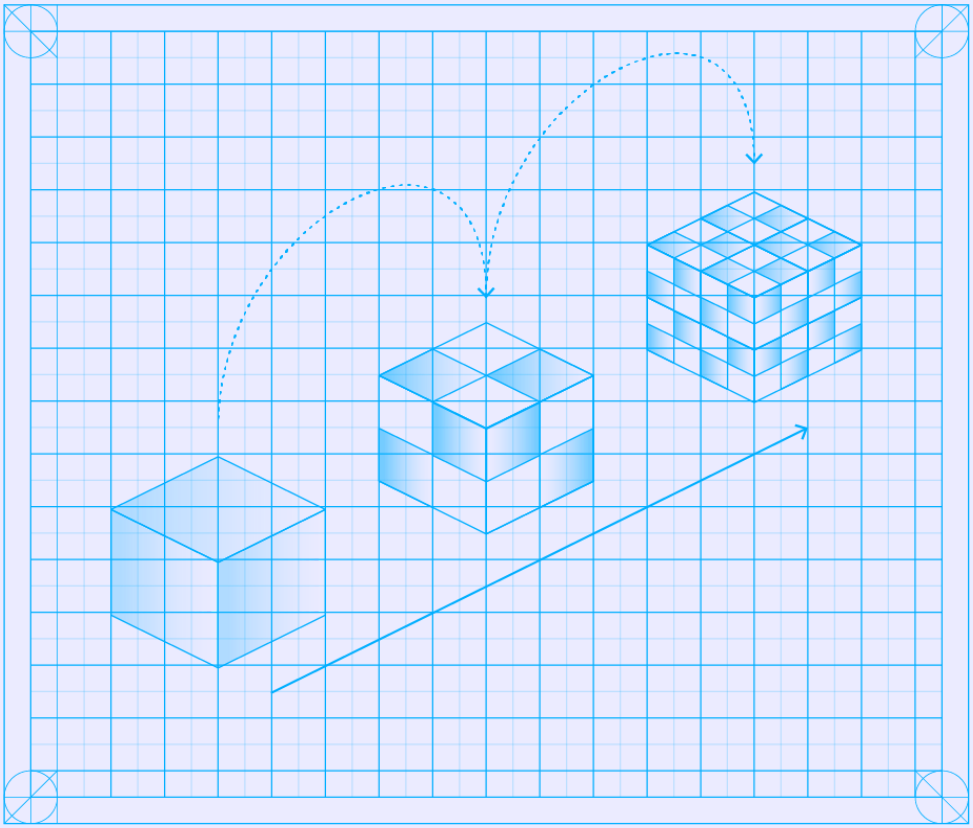
Blueprint Biosecurity



# Developing a Customer Screening Framework for the Life Sciences

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## Acknowledgements

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## About Blueprint Biosecurity

Blueprint Biosecurity is a nonprofit dedicated to achieving breakthroughs in humanity's capability to prevent, mitigate, and suppress pandemics

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# Introduction

Since the 1970's and the advent of recombinant DNA, biology has consistently become easier to engineer, and the pace of these advances is increasing. Many tools and capabilities for engineering biology are becoming more powerful, more affordable, and more widely available. These capabilities are critical for basic scientific research as well as advances in health, agriculture, and a wide range of applications in the burgeoning bioeconomy. However, access to these tools also raises the possibility that they could be accidentally or deliberately misused to cause harm by enabling development of toxins, pathogens, or other dangerous biological agents, including some not found in nature. Potential biological harms include high-consequence events such as the development and release of an engineered pathogen that causes a global catastrophe as well as a wide range of lower-consequence, higher-likelihood events. To prevent this type of misuse, policy experts have recommended expanding customer screening practices and policy frameworks to include a broad range of life sciences products, services, and infrastructure (Carter and DiEuliis, 2019a). Recent advances in artificial intelligence (AI) have increased this type of risk and have intensified these calls for action (Carter, et al., 2023; Helena, 2023).

There are a wide range of products, services, and infrastructure that scientists use for engineering biology, and they obtain these tools in many different ways. Synthetic nucleic acids with customer-defined sequences are a staple of modern molecular biology laboratories and have been a central focus of customer screening discussions to date. However, all tools that enable engineering biology could be misused to cause harm and some of these might warrant additional oversight. These include, for example, pathogen-specific bioinformatic resources, plasmids or helper viruses for generating viral particles, increasingly capable AI-enabled protein and genome design tools, platforms for genome editing or directed evolution, access to robotic laboratories ("cloud labs"), services for organism engineering, and resources for optimizing scale-up of bacterial or viral cultures. These types of products and services can be obtained from commercial vendors as well as from individual researchers, academic core facilities, non-profit repositories and biofoundries, government facilities such as national labs, and other sources. Discussions of customer screening in this context are complex. Furthermore, some companies provide high-value services (e.g., protein design, organism design, scale-up services) for which they sign long-term contracts with their customers that ensure collaboration and shared intentions, obviating the need for customer screening. For the purposes of this report, "customer screening" refers to situations in which individuals might obtain products, services, or access to infrastructure in a single interaction (or very few interactions) with the provider.

Most fundamentally, the purpose of customer screening is to reduce the risk that someone deliberately or irresponsibly misuses life sciences products, services, or infrastructure to cause harm. An effective customer screening framework will make it harder for individuals or small groups without legitimate credentials to misuse these capabilities. It also reduces the risk that a researcher accesses potentially harmful reagents or tools that they have no reason to use. Raising these barriers is important for reducing biological risk, but effective customer screening is only part of the solution. For example, in the case of a "lone wolf" actor or small group aiming to set up an illicit lab, intelligence services, law enforcement entities, and local authorities may also play a role and are better equipped to track nefarious actors, identify patterns of illegal activity, attribute harmful outcomes, and deter those with malicious intent. Customer screening also cannot prevent an otherwise legitimate researcher from deliberately or accidentally causing harm using the tools available to them. For example, Bruce Ivins, who was implicated in the anthrax attacks of 2001, was an esteemed scientist at a military lab, held a security clearance, and had received funding and institutional approval for work with dangerous pathogens (FBI, n.d.). These limitations illustrate how customer screening will always exist in a broader context of individual actions, cultural norms, and legal frameworks beyond the life sciences community.

Any biological harm that results from the misuse of life sciences products, services, or infrastructure can also cause significant harm in the form of reduced trust in scientific institutions, decreased funding, or undue restrictions on legitimate research. Therefore, in addition to reducing biological risk, an important goal of customer screening is to protect the life sciences community itself. It provides an opportunity for companies and institutions to show that they are responsible and can shield them from liability and perceptions of blame. If an individual misuses the tools of engineering biology to cause harm, it can be made clear that they were doing so despite some level of oversight. If a company fails to participate in customer screening and this negligence causes harm, it can be made clear that they were doing so outside of established best practices in the community. The life sciences community currently benefits from norms that support open sharing, community-building, rapid dissemination of information and resources, and commitment to democratization of the tools of biological engineering. This culture, particularly strong within academic institutions, enables progress toward worthwhile goals, but may hinder security and leave the community vulnerable. Development of new approaches, adoption of best practices, and establishment of customer screening norms that work alongside these values will take time and resources, but ultimately will support scientific and technological progress.

This paper outlines foundational questions and principles at the heart of customer screening in the life sciences. These include questions about how much confidence in a customer is needed for different types of products, what it means to be a "legitimate customer" or to have a "legitimate

use" in different contexts, and practices for verification. The most extensive discussions on these topics in the life sciences has taken place in the context of customer screening by nucleic acid providers in adherence with the HHS Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids (HHS Screening Framework; HHS, 2023) and more recently, the Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (White House, 2023). The experience of these providers offers useful lessons for the broader community. Potential paths for policy development to expand customer screening into a more comprehensive framework include strategies in support of vendor-based customer screening, development of practices at scientific institutions to verify customer legitimacy and legitimate use, and establishment of third-party customer screening entities. Central to each of these approaches is a need for engagement with the life sciences community to develop customer screening practices, build trust, and incentivize participation.

# Foundations of a Customer Screening Framework

The HHS Screening Framework provides a useful framework for understanding how customer screening could be conducted in the broader life sciences community. First issued in 2010 and updated in October 2023, this HHS Screening Framework calls on providers of synthetic nucleic acids (i.e., DNA or RNA longer than 50 nucleotides) to screen customers and the ordered sequences to ensure that nucleic acids with a sequence that matches pathogen or toxin DNA is not provided to a customer without a legitimate use for it. Although it is specific to synthetic nucleic acids, this framework has generated discussion and opportunities to compare customer screening approaches, to understand challenges, and to learn lessons that can be applied to the development of a broader customer screening framework. The HHS Screening Framework itself could be expanded to recommend that a wider range of life sciences vendors participate in customer screening, as some experts (including this author) have suggested (EBRC 2020, Carter and DiEuliis, 2019b). In addition to providing an additional incentive for screening, expanding the HHS Screening Framework could broaden efforts to establish best practices and develop tools and resources in support of screening. Life sciences vendors that do not fall under the purview of the HHS Screening Framework have reported a lack of opportunities for these discussions (Carter and DiEuliis, 2019a).

The HHS Screening Framework recommends multiple types of customer screening by nucleic acid providers. For all customers, it recommends that providers verify customer identity, and check customers against government watch lists of individuals to whom it is illegal to provide goods or services (see https://www.trade.gov/consolidated-screening-list). For customers who are purchasing nucleic acid synthesis equipment, it recommends that providers verify customer legitimacy by establishing that they are legitimate members of the scientific community. For customers who order a nucleic acid sequence that matches a sequence of concern, providers are expected to verify customer legitimacy *and* to determine that customers have a legitimate use for the specific nucleic acid sequence that they have ordered. This tiered set of recommendations points to an important principle for customer screening practices in the broader life sciences: there are many types of customer screening practices that may be appropriate for different technologies, and they will vary depending on the level of risk (Figure 1).

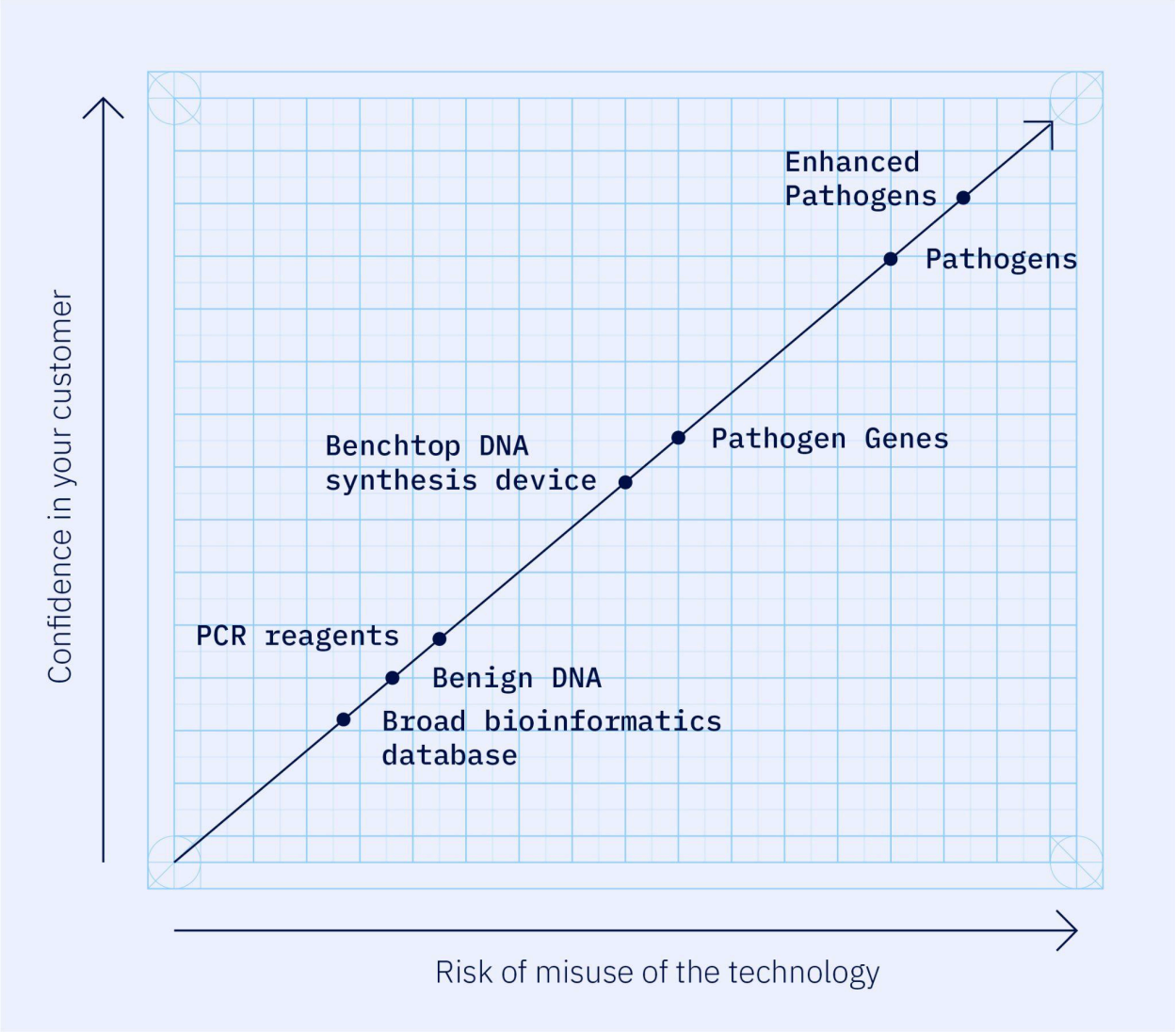


**FIGURE 1:** As the risk of misuse of a technology increases, so too should the confidence that a provider has in their customer. Examples of types of technologies are provided here for illustrative purposes.

For nucleic acid synthesis, a central metric for the risk of misuse of the technology is whether or not the ordered sequence matches a sequence of concern. Sequence screening is challenging and there are ongoing questions about the definition of "sequence of concern," but this metric provides a usable distinction that indicates when a higher level of confidence in a customer is needed. Products, services, and infrastructure in the broader life sciences community are diverse and it may be difficult to generate consensus on the risk of misuse that a technology poses and therefore what types of customer screening practices should be adopted (i.e., the question of "Where should this product be placed in Figure 1?"). Furthermore, many products or services may only pose a significant risk when

combined with a constellation of other tools or capabilities. One approach to simplify the discussion could be to generate some agreement on a baseline level of customer screening that would apply to a broad range of life sciences products. As life sciences funders and stakeholder communities seek to bolster customer screening in these different contexts, they will need to address some key questions:

- What types of products, services, and infrastructure does the policy aim to address?
- How much confidence in the customer is needed?

A comprehensive framework for expanding customer screening practices would also include methods and incentives to: 1) determine **customer legitimacy** by establishing that they are legitimate members of the scientific community; and 2) verify that customers have a **legitimate use** for the specific product or service. There are many methods for verifying customer legitimacy and legitimate use, and these can provide different levels of confidence in a customer (Figure 2). For a baseline level of potential for misuse (i.e., for products expected to be broadly used for many molecular biology applications), simple checks that a customer is a legitimate member of the scientific community may be adequate. At the highest level of potential for misuse, a customer should be verified to a high degree of confidence to be a legitimate member of the scientific community that has a legitimate use for the specific product or capability.

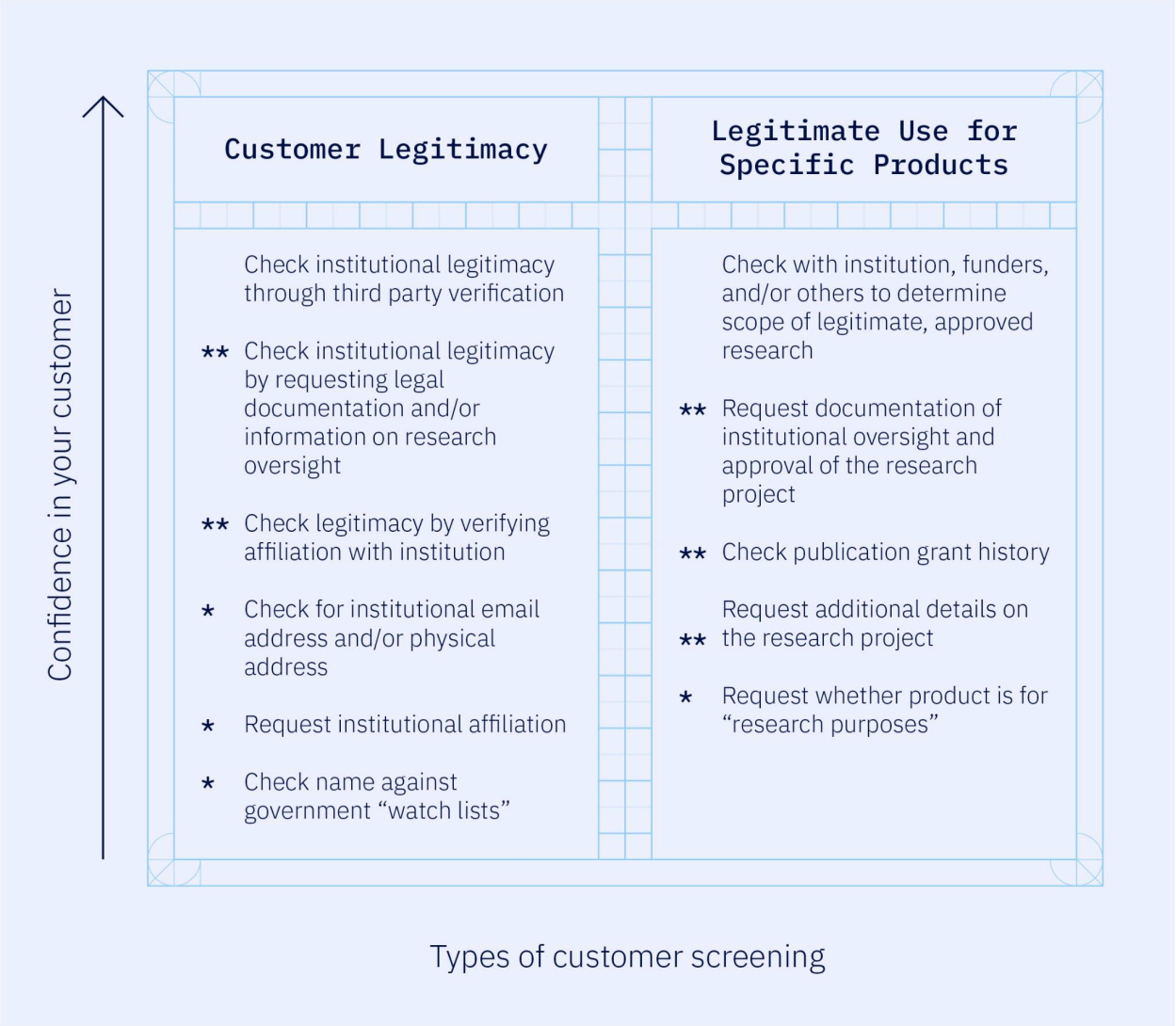


**FIGURE 2:** Examples of customer screening methods that might be used to determine customer legitimacy and legitimate use for specific products. An asterisk (*) indicates a method that many nucleic acid providers and other life sciences vendors currently use for a broad range of products. A double asterisk (**) indicates a method that responsible nucleic acid providers have used when conducting follow-up customer screening for orders that contain sequences that match pathogen or toxin DNA.

In implementing customer screening practices in adherence with the HHS Screening Framework, members of the International Gene Synthesis Consortium (IGSC) have publicly committed to some due diligence for all customers by checking that each customer is an individual with an institutional affiliation and a shipping address that is not a P.O. box (IGSC, 2018). For customers who have ordered nucleic acids containing sequences of concern, providers perform additional screening to determine that the customers are affiliated with "bona fide," legitimate institutions and that their intended use of the product is legitimate. Methods for verifying affiliation, institutional legitimacy, and legitimate use vary, though some are listed in Figure 2. To provide details on customer legitimacy and build on many

of the practices listed in Figure 2, the updated HHS Screening Framework was issued with the Companion Guide to Assist in Implementing the Recommendations of the Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids (Companion Guide; HHS, 2023) that includes additional recommendations on types of documentation or evidence that can help determine legitimacy, use-case scenarios, and red flags.

A customer screening framework for the broader life sciences community can build on the concepts of legitimate customers and legitimate use, and it is likely that many of the practices outlined in the HHS Screening Framework and used by responsible synthetic nucleic acid providers can be more widely adopted. Many responsible companies and providers already implement customer screening practices to establish customer legitimacy for products other than synthetic nucleic acids, either voluntarily or in compliance with export control rules (see Appendix). However, uncertainties and inconsistencies remain even among responsible nucleic acid providers, and expanding customer screening practices to a broader range of products, services, and infrastructure will require funders and stakeholders to grapple with some key questions, including:

- What constitutes a legitimate customer or legitimate institution in different contexts? What are their characteristics? What constitutes legitimate use of a product or service?

- To what extent or to what level of certainty should customers or their uses meet these characteristics? How should this be verified?

The HHS Screening Framework and the experience of synthetic nucleic acid providers has proved foundational for a broader customer screening framework and should be expanded to recommend customer screening by a wider range of life sciences vendors. However, it also provides critical lessons on the challenges for customer screening in the life sciences, indicating areas where additional policy work and resource development are needed. One set of lessons is about the unique role of institutions in the life sciences community. Life sciences research takes place almost exclusively within institutions, and customer legitimacy in the life sciences is closely tied with institutional affiliation and institutional legitimacy. Also, it is difficult and time-consuming for providers to determine that a customer has a legitimate use for potentially harmful products beyond just verifying that a customer is affiliated with a legitimate institution. The institution itself is often in a better position to make this determination, and responsible providers generally depend on the institution for documentation and oversight. Because they are central to customer screening in the life sciences, institutions should play a bigger role in any broader customer screening framework. Indeed, the updated HHS Screening Framework includes some roles for institutions, such as ensuring that benchtop nucleic acid synthesis devices are only accessed by those with a legitimate use, but most institutions have yet to develop robust biosecurity practices to establish legitimate use.

Some challenges for customer screening in the context of synthetic nucleic acids are similar to those seen with other types of customer screening or Know Your Customer (KYC) practices. For example, the legitimacy of some institutions can be difficult for vendors to verify, particularly new start-up companies and smaller, international institutions. It is possible that practices and methods in the financial sector or in other contexts may help provide solutions (see Appendix). The identity and legitimacy of individual customers can also be difficult to verify. Government watch lists are difficult to check because they contain little information beyond just a name, and they generate many false positives that are difficult for vendors to resolve, particularly for international customers (for example, some Chinese names are extremely common). Software such as Bridger Insight (LexisNexis, 2024) can help run this screening but does not help with false positives. If a customer's name is common and matches a name on one of these lists, a life sciences provider may check for a legitimate institutional affiliation and still sell to the customer under the assumption that the flag is a false positive (the much more likely scenario). It could be instructive to determine how vendors in other contexts conduct this screening.

The HHS Screening Framework Guidance has been critical for understanding customer screening practices in the life sciences community and provides important lessons. Policy development for expanding these practices to a broader range of products, services, and infrastructure should build on this foundation. KYC approaches in other sectors, including those used in export control and the financial sector, also may provide potential models, specific tools, and perspectives that are helpful to consider.

# Paths Forward for Customer Screening Framework Development

Advances in biosciences and biotechnologies provide profound benefits to society, and efforts to establish and improve biosecurity practices will need to ensure that these benefits are preserved. Development of a robust customer screening framework will require collaboration between policymakers, commercial vendors and other providers, and the broader life sciences community to maintain these benefits and to ensure that policies and practices are fit-for-purpose, complementary to existing frameworks, and, ultimately, implemented. In addition to providing opportunities for the life sciences community to show that it is responsible, this engagement will help raise awareness of biological risks, promote a more vigilant culture, and reduce the risk that someone misuses the tools of biological engineering to cause harm.

A successful policy approach will:

- establish collaborations with and among existing stakeholders alongside biosecurity experts;
- build on practices that are already in place, where possible;
- convene ongoing discussions to distill best practices and to look for ways to improve these practices over time; and
- provide additional incentives to adopt best practices as they are established.

Governments and funders outside of government both play critical roles in this approach. Non-governmental funders can drive progress by providing opportunities and venues for discussion of practices, best practices, and challenges, and for development of incentives for adherence. Importantly, non-governmental funders and organizations are well-equipped to broaden these discussions to include international stakeholders, which can ensure that biosecurity practices are more universally adopted and can help preserve the economic competitiveness of responsible providers. These funders may also establish and support third-party entities for customer screening (discussed in more detail below). All of this work will be ongoing and will require sustained funding.

Governments are well placed to provide direction and incentives for customer screening. These might include a simple articulation of risks and concerns (including, for example, the scope of products that might require additional oversight) that could provide a strong signal to the life sciences community that they should work to establish biosecurity practices to address those risks. Voluntary guidance to industry (e.g., HHS Screening Framework) can provide a stronger incentive and better define expectations for responsible members of the community. The U.S. government has an especially influential role as a primary funder of many research institutions in the U.S. Guidance to institutions

could include, for example, recommendations that institutions keep track of individuals who are approved for access to certain facilities or equipment (e.g., benchtop nucleic acid synthesis devices) or who work on projects that fall under dual-use research of concern (DURC) policies. To provide stronger incentives, governments can more formally incorporate biosecurity practices into funding requirements (e.g., NIH Guidelines or DURC policies; NIH, 2023) or regulations to ensure compliance. They can also signal support for customer screening frameworks in other ways, for example, by participating in international best-practices efforts or recognizing the legitimacy of third-party customer screening processes or entities.

Working with the life sciences community to develop and disseminate best practices for customer screening will improve biosecurity even in the absence of other incentives, which is particularly important in an international context where incentives can be lacking and inconsistent. However, establishing best practices also provides a critical foundation for establishment of regulations and other legal requirements. To be enforceable, regulations will often draw on established practices in the regulated community. They require some level of specificity about the elements of compliance (i.e., who it applies to, what they should do, how they should evaluate information), and it can be difficult for regulators to articulate those elements without a significant amount of experience. Also, many types of regulations allow some flexibility by incorporating a "reasonableness" standard. For example, KYC regulations in the financial sector include a requirement that banks have a "reasonable belief" that a customer is truthful (see Appendix). Enforcing these regulations depends on what is considered a "reasonable belief," which is defined in practical terms by the kinds of information that banks are reasonably able to request and receive from their customers. Similarly, in the life sciences, what is considered "reasonable" will depend on the established practices of those who conduct customer screening and the expectations of the life sciences community.

The policy process to address risks related to synthetic nucleic acids provides an illustrative example of how articulation of risks, practices, and best practices can be leveraged into wider adoption and stronger incentives. In the early 2000s, public scrutiny of the risks related to de novo synthesis of pathogen genomes generated discussion and calls for action (e.g., NSABB, 2006). These calls provided a strong incentive for the synthetic nucleic acid industry to demonstrate that they could address this concern and motivated the U.S. government to begin work on a biosecurity framework for synthetic nucleic acids (Gryphon Scientific, 2007). The launch of the IGSC in 2009 and publication of the HHS Screening Framework in 2010 established a framework of customer and sequence screening for these products. Although it was voluntary, it provided an opportunity for responsible nucleic acid providers to show some commitment to biosecurity and began the process of development of best practices to address the risk.

Screening practices have improved and evolved over time, and the updated HHS Screening Framework, released in October 2023, recommends more stringent requirements for nucleic acid sequence screening as well as additional details for customer screening. This policy framework has also enabled development of tools and resources that help expand the adoption of these practices internationally, for example, through the International Biosecurity and Biosafety Initiative for Science (IBBIS, 2024). Additional incentives can build on this voluntary framework, including opportunities for public recognition, reputational credentials, seals of approval, and voluntary certifications. As sequence screening tools have been developed, as customer screening best practices have become more established, and as customers and others in the community have become familiar with screening practices, they have paved the way for stronger requirements. These requirements include those from governments, for example, the October 2023 Executive Order on AI, which establishes a requirement that U.S. government funds can only be used to purchase nucleic acids from providers who screen. Those working within the U.S. government to implement this new requirement are drawing heavily on the collaborative communities that have been built under the voluntary framework. Legislation establishing regulatory requirements for screening has been drafted in the U.S. Congress, but has not yet been passed (Congress.gov, 2023).

This type of collaborative, best practices-focused approach to policy development will help ensure that reasonable biosecurity practices are developed and implemented and will also form a foundation upon which additional incentives (up to and including regulatory requirements) can be layered. Possibilities for investment in building this more comprehensive customer screening framework for the life sciences include a range of activities that could be pursued in parallel, and many of these are outlined below. Vendor-based customer screening will continue to be a central component, and efforts to expand these practices to a wider range of life sciences providers could yield meaningful results in the near-term. A key lesson from the experience of nucleic acid providers is that institutions should also play a role, particularly in determining whether individual researchers are legitimate customers and if they have a legitimate use for specific types of products or services. Institutions have generally not engaged in this type of biosecurity screening to date, but the renewed attention on biological risks in the AI Executive Order and the new roles for institutions outlined in the updated HHS Screening Framework provide an opportunity to reevaluate their participation. Another limitation of vendor-based screening is a misalignment of incentives. The goal of commercial companies is to make money, and they are, by nature, deferential to their customers. Customer screening and other types of biosecurity practices can be costly. Philanthropies and governments should prioritize efforts not only to improve customer screening practices, but also to reduce this burden. In some cases, establishment of a trusted third-party customer screening entity could fill this need.

Each of these approaches—supporting vendor-based customer screening, expanding institutional participation, and establishment of third-party entities—will require creative thinking about how they can best contribute to an overarching framework to ensure a safer and more secure future.

## Supporting vendor-based customer screening

Reducing the burden for vendors to conduct customer screening is one central approach to bolstering the adoption of these practices across the life sciences industry. Many commercial vendors and other providers already conduct some level of customer screening to verify customer legitimacy, and providing resources and reducing barriers will support those vendors, enable a wider range of providers to participate, and help instill a customer screening norm grounded in best practices. This type of norm, even absent additional frameworks or incentives, can help support biosecurity. Resources could include, for example:

- tools or software for verifying customer identity;
- checklists of potential documentation for customer or institutional legitimacy;
- templates or examples of customer onboarding forms for commercial vendors;
- case studies and “red flag” guidance; and
- training modules on customer screening.

These types of resources can build on what is already available in the HHS Screening Framework and its Companion Guide and would be particularly useful if they are international in nature. Engagement of scientific institutions in development of these resources, discussed in more detail later, would increase their utility. Other “gatekeeping” organizations in the life sciences community, beyond just commercial providers, could also be encouraged to use these resources and participate in customer screening, including:

- academic or government foundries and core facilities;
- resellers of products or equipment;
- repositories for physical reagents such as plasmids and other vectors (e.g., Addgene or ATCC) or for bioinformatic resources (e.g., virology databases);
- academic communities developing tools (e.g., GP-Write for synthetic genomes, Rosetta Commons for AI protein design); and
- Individuals who share reagents or tools with others.

Supporting vendor-based screening with additional resources represents the “lowest hanging fruit” for expanding customer screening in the life sciences and would require the least amount of effort to see meaningful progress. Activities could include:

- **Development of customer screening resources and tools for nucleic acid providers.** As discussed above, many nucleic acid providers already have years of experience in implementing customer screening practices in adherence with the HHS Screening Framework. The Nuclear Threat Initiative (NTI) has already worked to distill some of the best practices among responsible providers internationally, and IBBIS is developing customer screening resources for these vendors (Alexanian and Carter, 2024). Funding could directly support these activities at IBBIS in the near-term.

- **Development of customer screening best practices, resources, and tools for a wider range of life sciences vendors and providers.** This development should begin with a series of meetings with government stakeholders, biosecurity experts, and a broad range of life sciences vendors, providers, and other gatekeepers to share best practices and to discuss the foundational questions outlined above—i.e., What types of products should require what level of customer screening? What constitutes a legitimate customer and legitimate institution? To what extent should legitimacy be verified? These meetings should draw heavily from the experience of nucleic acid providers and it is likely that many of the tools and resources developed for nucleic acid providers could also be used by other types of providers. Resources from other types of vendor-based customer screening (e.g., KYC practices in the financial sector or from export control) could also prove useful.

  Many larger life sciences companies and other types of providers (e.g., Addgene, the plasmid repository) already conduct customer screening, and these convenings should highlight the perspectives of these responsible providers. A key challenge for this approach will be to engage smaller and newer providers, so it will be important to conduct outreach, ensure resources are readily available, and provide positive feedback and credit for participation.

To support ongoing development and improvement of best practices, dissemination of these tools, and norm-building for customer screening across the life sciences community, there is a critical need for an organization or other entity that serves as a centralized venue for vendors and other providers to discuss, learn, and collaborate on these practices. Therefore, one key opportunity to support vendor-based customer screening is:

- **Support for a normative entity to support customer screening in the life sciences.** This entity would convene discussions on customer screening practices by vendors and other providers; serve as a clearinghouse for best practices, resources, and tools; and identify

and address customer screening challenges that arise. It could also provide incentives such as public recognition for engaged participants, opportunities to sign voluntary pledges, or processes to earn seals of approval or certifications. This type of third-party entity could also be tasked with additional duties in support of vendor-based customer screening, discussed in more detail below, such as verifying institutional legitimacy.

IBBIS launched in February 2024 and will support customer screening by nucleic acid providers by developing resources that will be provided as part of its Common Mechanism for DNA Synthesis Screening alongside nucleic acid sequence screening software. It will also be a venue for ongoing collaboration and updating of best practices through its technical advisory bodies that will include commercial providers and others. IBBIS itself could be supported to expand its customer screening purview to include a wider range of life sciences vendors and providers, as it is likely that many of its resources could be adapted for broader use.

Extensive outreach within the life sciences community to raise awareness of these resources and this entity would help ensure the success of these efforts. Vendors and providers of all types should be included, whenever possible, in discussions of best practices and prioritization of development of customer screening tools and resources.

## Expanding roles of scientific institutions in customer screening

Life sciences research and development takes place almost exclusively within the context of institutions, such as academic institutions or companies. This is particularly true of work related to pathogens, which may pose the greatest risk of misuse. As nucleic acid providers have learned, establishing a customer's affiliation with a legitimate institution is a fundamental part of customer screening in the life sciences. Institutions are also well-positioned to help resolve the challenging question of whether an individual has a legitimate use for specific products, services, or infrastructure. However, to date, institutions have not adequately participated in supporting these types of customer screening practices.

Changes at scientific institutions can be difficult due to cultural factors, complex and diverse organizational structures, and administrative bureaucracy. However, recent and urgent discussions, including those on AI, present an important opportunity to reevaluate their roles in biosecurity. Policy experts have repeatedly raised concerns about the links between AI and the potential for misuse of life sciences products, services, and infrastructure. The October 2023 Executive Order on AI includes a requirement that government funding, which supports much of the life sciences community, only be used to purchase nucleic acids from providers that conduct both customer and sequence screening.

This requirement will draw heavily from the HHS Screening Framework, which was updated in October 2023 to include roles for institutions in verifying the legitimacy of recipients of nucleic acids that contain sequences of concern and of users of benchtop nucleic acid synthesis devices. These developments have put some pressure on scientific institutions, and it is likely that many are exploring new approaches for establishing customer legitimacy and legitimate use.

There are important ways that institutions could contribute to a customer screening framework. Most fundamentally, they could verify that customers (individuals) have a life sciences-related affiliation with their institution. It is likely that institutions could build on existing resources and infrastructure, for example, enrollment and employment records, systems for physical security (e.g., badges for access to buildings), or methods to track that life sciences researchers have participated in required basic training (e.g., laboratory biosafety, use of human materials, etc.). Another unmet need is tools or systems to share this type of information securely with external entities. Given funding constraints and high rates of administrative turnover, particularly at academic institutions, automated systems for gathering and sharing this information would be particularly valuable. It is possible that a third-party entity, discussed in more detail later, could collect information from institutions on specific individuals who have been deemed to be legitimately affiliated with them.

Institutions could also verify that customers have legitimate use for specific types of products, services, or infrastructure. As noted above, the determination of legitimate use is a key customer screening challenge for vendors or third-party entities. Institutions already spend significant resources to evaluate life sciences research projects and plans through their institutional biosafety committees (IBCs) and other types of oversight. High-consequence pathogen research, which may have a high potential for catastrophic misuse, is often subject to additional oversight, for example, through DURC Institutional Review Entities. Therefore, institutions are uniquely well-placed to establish and verify that customers have a legitimate use for the products or tools that might be needed to conduct their specific line of research. SecureDNA is working on tools that could fill this need, including cryptographically secure certification methods for automatically tracking whether individual researchers have been approved for work with specific products (SecureDNA.org).

Some scientific institutions have personnel reliability programs that aim to ensure that individuals within their institutions are trustworthy, for example laboratories affiliated with the U.S. Department of Defense, or large companies with valuable intellectual property. These institutions are more likely to have systems in place to establish an individual's affiliation and may also be better equipped to track whether they have a legitimate use for a specific type of product. Although personnel reliability programs can be onerous and so may not be a good model for most life sciences institutions (NSABB,

2009), there may be resources or lessons to be learned from these institutions (see, e.g., www.dhra.mil/perserec).

There is an important opportunity and a role for outside funding to facilitate discussions among institutions to explore challenges, distill lessons learned, and establish best practices for institutions to support customer screening. To date, there have been virtually no collaborative discussions of this type focused on foundational topics, including:

- what it means for an individual to be "affiliated" with an institution as a "life sciences" practitioner;
- Infrastructure and approaches for tracking and updating affiliated, life sciences personnel;
- processes to establish that specific researchers have been approved for specific research projects;
- methods to define and track what types of reagents and resources (e.g., pathogen DNA sequences) a research project might legitimately use;
- how to securely interface with vendors and other outside entities to provide information on customer legitimacy or legitimate use; and
- roles and responsibilities within institutions for these activities.

As noted above, participation in efforts to improve biosecurity practices is an opportunity for institutions to demonstrate that they are responsible members of the scientific community, and the updated HHS Screening Framework and policy developments related to AI provide additional incentives for institutions to participate. However, there could be some hesitancy because institutions do not feel confident about their biosecurity oversight practices and do not have good guidance or models (Greene, et. al., 2023). Furthermore, this challenge cuts across many parts of institutional bureaucracy, particularly at academic institutions, and durable solutions might require significant changes to underlying administrative procedures. Outreach and engagement with institutions on this topic will need to be done carefully so that it shows progress toward solutions, gives institutions credit for participating, and does not raise alarms that could jeopardize life sciences funding and drive otherwise willing collaborators away. Activities could include:

- **Identification of challenges for institutional participation in customer screening.** Because there are few models and no established best practices for how customer screening could be conducted in this context, institutions might be unsure how to proceed and hesitant to discuss it openly. Outreach and small, directed conversations or interviews could help identify these challenges, generate initial ideas for best practices, and begin to establish a community of practice. This process could also identify other types of challenges, such as lack of funding or prioritization, inadequate administrative

infrastructure, privacy concerns, or questions of liability, that could be flagged for additional policy work. It is likely that challenges will reflect the diversity of scientific institutions, so it will be important to hear perspectives from large and small academic institutions and companies, non-academic research institutions, and entities that are publicly traded, privately financed, and government-supported.

- **Development of best practices, principles, case studies, or models for successful customer screening.** Given the diversity of institutions and the challenges that institutions may face, it is likely that "best practices" will also be diverse. A series of convenings with institutional representatives could share successful approaches, identify models that could be more widely adopted, explore tools that could be helpful in this context, and provide opportunities for responsible institutions to be recognized. It is possible that different types of institutions (e.g., academic vs. large pharmaceutical companies vs. start-up companies) should have more targeted discussions.

- **Support of a third-party entity (or entities) to convene ongoing discussions and disseminate successful practices.** It is possible that the normative entity discussed above to support development and dissemination of vendor-based best practices (potentially, IBBIS) could convene these discussions among institutional stakeholders as well. However, there may be other organizations that could host these types of activities, for example, those that convene biosafety professionals (e.g., ABSA international), support academic institution administration, or provide resources for human resources professionals at large companies. Small companies and start-ups may be more likely to engage with organizations associated with funding opportunities or other sources of support (e.g., SynBioBeta, venture capital networks, or incubators). Determining the most effective means of engagement and dissemination of customer screening resources will sometimes require a better understanding of which types of individuals within institutions are likely to be tasked with customer screening responsibilities (e.g., institutional biosafety officers, individuals in purchasing, training and compliance, or personnel reliability offices) as well as the organizations they are likely to join or use for guidance.

- **Development of incentives for adoption of good customer screening practices.** As the range of activities and practices among institutions becomes clearer, it will be important to identify successful approaches and find ways to incentivize them. For philanthropic or other non-governmental funders, these approaches might take the form of funding for implementation or recognition, for example, with a seal of approval by a third-party entity. Governments could also provide incentives such as guidance or requirements that

institutions adopt certain practices to receive funding or to comply with DURC or related policies.

Developing practices and best practices for scientific institutions in support of customer screening for biosecurity will take significant investment of time and resources. These institutions have not proactively participated in this type of customer screening in the past, and there are few established communities and collaborations to draw on. Furthermore, because institutional roles in supporting customer screening have not been fully explored, it is likely that unexpected challenges and limitations will arise. Still, because institutions are at the heart of the life sciences community, it is critical that they participate more fully and proactively in ensuring biosecurity.

## Establishing third-party customer screening

Multiple types of third-party organizations can support a customer screening framework for the life sciences (see BOX with some existing examples). One key role for third parties, discussed earlier, is to convene discussions among life sciences stakeholders, establish best practices in different domains, and provide incentives for following those practices. However, a third-party entity could also be established to play a more direct role in customer screening of life sciences customers or institutions. One basic approach for third-party screening is an entity, either governmental or non-governmental, that verifies customers (i.e., individuals) or institutions as legitimate – sometimes called a "white list" approach. This verification can help determine that customers are legitimate members of the scientific community or that they have a legitimate use for tools and resources needed for a specific type of research. In this model, customers and institutions would provide documentation to the entity, the entity would evaluate that documentation, conduct any necessary follow-up, and then keep track of which customers and institutions are verified as legitimate. A commercial vendor or other life sciences provider could then check with the entity to see if their customers or their customers' institutions are legitimate or if the customer has a legitimate use for a product.

The advantage of third-party customer screening is that it can ensure consistent customer screening practices across the community and can provide some efficiency by enabling customers to become verified only once rather than by each vendor separately. Furthermore, it can be supported with funding external to the life sciences and can therefore limit the costs to vendors and the broader community. It also provides a venue for customer screening that is independent of profit motives and other misaligned incentives.

However, there are significant challenges that this type of third-party approach would face and key questions that will have to be answered when establishing a third-party customer screening framework. Importantly, in this model, the third-party entity will face all the same challenges that

vendors have identified in verifying customer legitimacy, institutional legitimacy, and legitimate use of products. Those conducting customer screening at this type of entity will draw on the same best practices, tools, and resources developed in the context of vendor-based screening (and will likely participate in the same "best practices" organizations). Institutional roles in support of customer screening will still need to be better developed. Establishment of a third-party entity to conduct screening does not reduce the need for engagement with the community. In fact, in addition to the collaborative work of developing best practices as described earlier in this document, an entity of this type would require additional effort to develop efficient means of interfacing with vendors, institutions, and customers. In the absence of strong incentives, such as government funding requirements or regulations, a third-party entity would have to work to earn the trust of the community. Given that a customer screening entity may have some power over who can conduct life sciences research, the community will have to trust that this power will not be misused.

One critical consideration is the scale and scope of the entity. The broader the scope of products, services, or infrastructure that the entity aims to address, the broader the community that it will have to engage. There are also more practical challenges. It would be very difficult to establish a third-party customer screening entity to solicit documentation from and verify all life sciences institutions, particularly on an international scale, as there are likely to be tens of thousands (see, e.g., Nature Index, 2024) (and all individual customers would be even more difficult). Furthermore, an approach that attempted to do so would be likely to capture primarily those institutions that are well-resourced, well-documented, and easy to verify (i.e., those that pose the fewest challenges for traditional customer screening approaches). The U.S. Department of Commerce's Validated End-User Program (DOC, 2020), which pre-clears companies for export control purposes, has struggled in this way. Keeping lists of verified institutions up to date would pose its own set of challenges. One consequence of a broad approach of this type is that the screening itself could suffer; what constitutes a legitimate institution, for example, could resort to a lowest-common-denominator standard.

Third party entities that are more narrowly focused on high priority areas could improve customer screening practices and be an important part of a comprehensive framework for the life sciences, and there could be roles for both governmental and non-governmental entities. Progress toward a successful third-party entity would require:

- Prioritization and scoping. This scoping should identify the types of products, services, or infrastructure that should fall under the entity's purview, as well as the existing stakeholders, gatekeepers, processes, and policies that the entity aims to support. This process should include engagement with the community to identify challenges, establish

initial partnerships, and get buy-in from key stakeholders. Possibilities for narrowing the scope of a third-party entity might include limiting it to:

- A specific type of research (e.g., high-consequence pathogen research). This type of entity would verify that customers or users have a legitimate use for a specified list of reagents, tools, or services that are necessary to conduct the research. It could also (or instead) verify that institutions are equipped to house or oversee such research.
- A defined research community or set of tools (e.g., AI biodesign tool developers). The entity could verify that users or customers are a legitimate member of that community, and so would have a legitimate use for that community's tools or resources.
- Geographic regions, particularly for areas with less-established life sciences communities. In addition to providing biosecurity benefits, this type of entity could enable legitimate customers and institutions in these parts of the world to more easily gain access to reagents, tools, and services.
- Types of institutions (e.g., start-ups or small companies, which are currently difficult for vendors to verify).

- Development of customer screening practices. The entity should determine, in collaboration with its partners and the broader community, criteria for what constitutes a "legitimate customer" or a "legitimate institution" for the products that fall within the entity's purview, as well as the practices that will be used to verify customers or institutions. These criteria and procedures could draw on customer screening best practices already established in other contexts but would also need to include development of practices for securely interfacing with vendors or providers as part of the entity's workflow. These discussions will be a key opportunity for the entity to generate trust and gain partnerships within the community, particularly for non-governmental entities.

- Establishment of partnerships and potential users. It is likely that this type of entity will require an initial phase or "pilot" users to demonstrate the value of this third-party screening and to ensure that screening proceeds smoothly. This pilot phase would have to include both customers or institutions that are screened as well as vendors or other providers who use the entity to determine customer legitimacy. The results of this initial phase can be shared with the broader stakeholder community to help generate interest and additional buy-in. If successful, over time, the screening entity could expand its purview to cover additional types of life sciences research, geographic areas, customers, or institutions.

Examples of third-party entities in the life sciences or related areas that could be used as models, expanded, or adapted for broader use.

- Open Researcher and Contributor ID (ORCID.org) provides a unique identifier to researchers that is linked with information submitted by the researcher about their affiliations and research. The ID then can be linked with funders, institutions, and publishers to streamline sharing of information and credentials. This system could be expanded to include a wider range of life sciences providers and linked with verification methods to provide a method to ensure that customers are affiliated with a legitimate institution.

- Good Financial Grant Practice (GFGP; globalgrantcommunity.com), a collaboration between the Global Grant Community and the African Academy of Sciences. Institutions in Africa can be certified for GFGP by submitting documentation that they meet certain criteria for financial management, human resources, procurement and governance. Then, grantors can check for GFGP certification when making decisions about whether to provide funding to that institution. Although the criteria for GFGP are financial, this framework could provide a good foundation for establishing the legitimacy of scientific institutions. Its development process could also serve as a model for the development of similar certification processes for institutions in Africa or elsewhere.

- Global Alliance for Genomics and Health (GD4GH.org), a non-government entity that uses a "passport" system to verify legitimate use of specified genomic databases and provides "visas" that enable individual researchers to access those resources. This system has already been implemented for some use cases (Voisin, et. al., 2021). A similar visa system could be developed for use in other life sciences contexts. Developers of tools, resources, or infrastructure could work with the third-party entity that provides visas to establish criteria, and then could depend on that entity to provide visas to legitimate researchers. SecureDNA is working on tools for cryptographically secure certificates for individual researchers that could be adapted for this context (SecureDNA.org).

- Addgene, a non-profit plasmid repository that distributes research plasmids to non-profit and academic institutions around the world (Addgene.org). Researchers provide their plasmids to Addgene to facilitate sharing and to reduce the administrative burden of distributing plasmids themselves. To meet its non-profit obligations, Addgene conducts screening of its customers to ensure that they are affiliated with legitimate non-profit or academic institutions. A third-party screening entity could partner with repositories like Addgene or ATCC (a repository for standardized microbes, cell lines, viral vectors, and other resources; ATCC.org) to develop customer screening best practices. Alternatively, the screening entity itself could act as a steward for some resource that is developed by the academic or non-profit community (e.g., bioinformatic databases or tools) and distribute that resource to customers that meet some criteria for legitimacy.

- iGEM, a worldwide synthetic biology competition (igem.org), and other well-defined life sciences communities such as Rosetta Commons (for AI protein design) (rosettacommons.org), GP-Write (for synthetic genomics) (engineeringbiologycenter.org) and many community labs. Although these communities are sometimes open and often do not consider themselves to be practitioners of "customer screening," their boundaries can be well-defined and participation in these communities could be used as an indicator of customer legitimacy. A third-party customer screening entity may be able to partner with some of these communities to further develop legitimacy criteria for membership.

# Conclusion

Expanding customer screening practices to a broader range of products, services, and infrastructure in the life sciences will require extensive engagement with vendors, institutions, and the broader community of life sciences practitioners. It is unlikely that such a diverse set of stakeholders will find consensus on issues such as the level of risk that a product might pose, what constitutes a legitimate customer in different contexts, or how to best verify whether an individual has a legitimate use for some tool. However, these conversations are critical, not only for establishing reasonable biosecurity practices, but also to raise awareness, form partnerships, and generate trust in the outcomes. The experience of nucleic acid providers in the context of the HHS Screening Framework has shown that some level of agreement can be reached, sensible practices can be developed, and best practices can be articulated and evolve over time. These best practices can then form the foundation for additional incentives for adoption.

Expanding vendor-based customer screening practices to a broader range of providers should be achievable in the relatively near-term. Institutional practices in support of customer screening are less developed and will require more time and resources to establish but will be essential to ensuring customer legitimacy and legitimate use of life sciences capabilities. Third-party entities can support ongoing development of best practices by providers and institutions and could also play an important role by providing customer screening services directly. The engagement-focused, bottom-up approach described here will yield a comprehensive customer screening framework that respects the community, is trusted and implemented, and helps ensure that life sciences products and services are not misused. Ultimately, this framework will reduce the risk of biological harm and protect the life sciences community itself.

# Appendix: Customer Screening and KYC frameworks in other contexts

Customer screening and Know Your Customer (KYC) frameworks exist in many other contexts, and these may provide models, resources, or perspectives relevant to the life sciences.

### KYC practices for export control

Export control regulations provide frameworks and guidance for customer screening that are highly relevant to the life sciences, particularly for products and services that have the highest potential for misuse. Some life sciences technologies are explicitly listed as export controlled and require an export license, including listed pathogens or genetic elements that may endow or enhance pathogenicity (Export Control Classification Number 1C353), nucleic acid synthesis devices capable of synthesizing or assembling nucleic acids into strands 1,500 nucleotides or longer (2B352j), and technologies for the production, development, use, or disposal of controlled biological agents (e.g., 1E001, 1E351, 2B352) (CCL, 2020). However, the U.S. government also enforces "Catch-All Controls," including the enhanced proliferation control initiative (EPCI), which prohibits "the export without a license of any dual-use commodities, software, or technology (other than publicly available information) that would contribute to projects of proliferation concern" (State Department, 2011). These rules require that exporters get a license for any product if they "know or have a reason to know" that the item will be used for a prohibited end use, including biological weapons purposes (Keller, 2012).

In recent years, ECPI has led to a proliferation of guidance and tools specific to many different industries for evaluating potential end-users. For example, the U.S. government released guidance in July, 2023 to exporters of products related to unmanned aerial vehicles that included information on end-user red flags and implementing effective due diligence (DOJ, 2023). Non-governmental, third-party guidance (e.g., from the James Martin Center for Nonproliferation Studies, 2022) and tools (e.g., the Chinese Defense Universities Tracker from the Australian Strategic Policy Institute, 2021) have also been developed for a variety of sectors, and boutique consultancies (e.g., Kharon.com, Sayari.com) have been established to help companies determine if end users of their products may have ties to adversarial militaries or terrorist organizations. It is possible that these tools and approaches could be adapted for life sciences providers. These resources could build on the customer screening provisions of the HHS Screening Framework Guidance, which closely mirror KYC guidance for export compliance in other sectors and could serve as industry-specific, due diligence guidance for a broad range of life sciences providers (Shaw, 2016).

There may be an opportunity for responsible life sciences companies to develop principles or best practices for broader compliance with end-user provisions of ECPI. Such an effort might be similar to the development of principles by nuclear power plant exporters in 2012 (CEIP, 2012). However, KYC practices for export control are likely to be most relevant to life sciences products, services, and infrastructure that pose the highest misuse potential, and it is unclear which products warrant this additional oversight (beyond those explicitly listed in export control regulations). Processes to identify such products may be difficult. For example, in recent years, the U.S. Department of Commerce has issued requests for information multiple times to identify additional emerging and foundational biotechnologies (Federal Register, 2018; Federal Register, 2020) that should be listed, but it has not made significant revisions. It is possible that a voluntary, more international effort led by a trusted third party could be more successful.

### KYC practices in the financial sector

Tools and approaches for KYC in the financial sector could also be relevant to the life sciences. KYC practices in this sector have expanded in recent years, following regulatory requirements added in the wake of the September 11, 2001 terrorist attacks and the 2008 global financial crisis. U.S. regulations require that banks establish a customer identification program that obtains from each customer, at a minimum, the customer's name, date of birth, address, and identification number (e.g., a social security number, taxpayer identification number, or passport number with country of issuance). Practices to verify this information are not specified, but banks are expected to conduct enough due diligence that they have a "reasonable belief" that the information is accurate (Treasury, n.d.). This requirement has yielded a wide variety of practices and tools across the financial sector that could be used or adapted for customer screening in the life sciences.

These approaches should be explored, for example, methods to efficiently check government-issued identification of individuals or checklists and other resources to establish the legitimacy of institutions (as noted earlier, smaller companies and international institutions currently pose the greatest challenges for nucleic acid providers). However, it is possible that these types of practices, which are used for all or nearly all customers in the financial sector, may not be appropriate for or accepted by all life sciences customers and so should be used in a more targeted way. For example, the University of California has policies against providing documentation to third parties that indicates the citizenship status of its researchers (UC, n.d.). Also, although these KYC practices can help verify customer identity, they do not resolve the central questions whether a customer is a legitimate member of the scientific community, their institutional affiliation, or if they have a legitimate use for life sciences products or services.

### Other types of KYC and Customer Screening Frameworks

There are regulatory requirements for customer screening for a variety of products, for example, ammonium nitrates, which can be used to make explosives. The Ammonium Nitrate Security Program is run by the Cybersecurity and Infrastructure Security Agency and requires registration of ammonium nitrate facilities and customers (CISA, n.d.). This program requires that customers submit photo identification, checks names against the State Department's Terrorism Screening Database (one of the government's watch lists), and provides a registration number to those who are approved. This regulation is specific, unambiguous, and highly enforceable. However, the trade-off is that the vetting process is extremely limited, requiring only that an individual not be listed on a terrorism database.

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