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International Biosecurity and Biosafety Initiative for Science

Implementing Emerging Customer Screening Standards for Nucleic Acid Synthesis

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Introduction

Screening customers who order synthetic DNA and RNA, not just the sequences they order, is central to biosecurity, but customer screening is less standardized than sequence screening. Many commercial synthesis providers use software tools to flag sequences of concern (SOCs) that could facilitate the construction of dangerous biological agents.[1] These SOCs are often used for legitimate applications such as the development of medicines, biomanufacturing, and biological research. To determine if they should send the order, providers conduct customer screening to answer the question: is the customer conducting legitimate life sciences work?

A consensus on customer screening practices has started to emerge. In 2024, both international and national-level guidance aligned on five core practices:

1. Tiered screening for all orders, with additional screening for orders that include SOCs.
2. Customer identity verification for all customers.
3. Customer legitimacy verification for customers who order SOCs.
4. Legitimate use verification for orders that include SOCs.
5. Supply chain screening to address third-party vendors and multi-party distribution.

[1] This whitepaper was written as part of the Common Mechanism project by the International Biosecurity and Biosafety Initiative for Science (IBBIS), a nonprofit that also maintains a free, open-source sequence screening tool called Commec (released 2024). Other available bioinformatic sequence screening tools include Aclid (2023), FAST-NA Scanner (2022), SecureDNA (2024), SeqScreen (2022), and UltraSeq (developed from ThreatSeq, which was released 2019).

The guidance is helpful, but the consensus now must be translated into tools, resources, and standards that support effective customer screening practices across the synthesis industry while ensuring that legitimate customers worldwide can reliably access synthetic DNA. This paper describes the emerging consensus, analyzes the implementation challenges through IBBIS's experience developing practical customer screening forms, and outlines future projects that would reduce ambiguity for providers, streamline procedures for legitimate customers, and support customer screening that is both efficient and rigorous.

The Emerging Consensus for Customer Screening Practices

A consensus on customer screening practices is emerging. In 2024 and 2025, several analyses explored practices and challenges particular to customer screening,[2],[3],[4],[5],[6] and international bodies and national governments issued guidance to support customer screening practices.[7] These new policies include an international standard for nucleic acid synthesis,[8] guidance from the U.K. Department of Science, Innovation and Technology,[9] and an updated voluntary protocol from the International Gene Synthesis Consortium.[10] New requirements were also established by the U.S. Office of Science and Technology Policy,[11] and, although the policy is under review by the current administration,[12] we anticipate that its core features will be maintained.

A comparison of these new policies shows alignment across five key areas:

1. Tiered screening should be done for all orders of synthetic nucleic acids, including customer screening for every order and additional screening when orders include SOCs.
2. Customer identity should be verified for all customers of synthetic nucleic acids.

[2] Tessa Alexanian and Sarah R. Carter. "Verifying Legitimacy: Findings from the Customer Screening Working Group, 2020–2023," (Geneva, Switzerland: IBBIS, February 2024).
[3] Sarah R. Carter. "Developing a Customer Screening Framework for the Life Sciences," (Washington, DC: Blueprint Biosecurity, March 2024).
[4] Forrest W. Crawford, Kyle Webster, Gerald L. Epstein, Derek Roberts, Joseph Fair, and Sella Nevo, "Securing Commercial Nucleic Acid Synthesis," (Washington, DC: RAND, July 2024).
[5] Tessa Alexanian and Sella Nevo, "Supporting Follow-Up Screening for Flagged Nucleic Acid Synthesis Orders," (Washington, DC: Council on Strategic Risks, May 2024).
[6] Engineering Biology Research Consortium. "Strengthening a Safe and Secure Nucleic Acid Synthesis Ecosystem: Outcomes of EBRC Stakeholder Engagement" (Emeryville, CA: Engineering Biology Research Consortium, January 2025). DOI: 10.25498/E4311B
[7] A document collecting customer screening guidance from each of the four policies referenced is available at "Customer Screening Guidance in National and International Policies: 2024 Reference," (Tessa Alexanian and Sarah R. Carter; Geneva, Switzerland: IBBIS, June 2025).
[8] International Organization for Standardization, "ISO 20688-2:2024. Biotechnology—Nucleic acid synthesis, Part 2: Requirements for the production and quality control of synthesized gene fragments, genes, and genomes," (Geneva, Switzerland: ISO, 2024).
[9] UK Department for Science, Innovation, and Technology, "UK screening guidance on synthetic nucleic acids for users and providers," October, 2024.
[10] International Gene Synthesis Consortium, Harmonized Screening Protocol© v3.0, September, 2024.
[11] Office of Science and Technology Policy, "2024 OSTP Framework for Nucleic Acid Synthesis Screening," April, 2024.
[12] The White House, "Executive Order on Improving the Safety and Security of Biological Research," May 5, 2025.

3. Customer legitimacy should be verified for customers who order SOCs.
4. Legitimate use of the product should be verified for orders that include SOCs.
5. Supply chain screening should consider that providers do not necessarily sell directly to the individual who will use the ordered sequences. Guidance now defines customer and end user separately and specifies screening responsibilities for non-traditional providers and third-party vendors.

Table 1 shows specific practices recommended by these policies, demonstrating substantial alignment on implementation approaches.

Despite the growing consensus on customer screening, there are persistent ambiguities around appropriate due diligence and decision-making when implementing these practices. For example, what constitutes an acceptable level of identity verification for a new customer ordering benign DNA? Is a valid email address adequate? Is it ever appropriate to ship orders to a residential address? What type of documentation is acceptable to demonstrate that a newly-established company has a legitimate use for SOCs? To what extent should a provider trust information provided by the customer?

Some differences in decision making are unavoidable and reflect the international and institutional diversity of nucleic acid providers and customers, risk tolerances, familiarity of nucleic acid providers with different types of customers, and the broader context for each order. Below, we discuss areas of consensus and remaining challenges for implementing customer screening in the context of nucleic acid synthesis. For each area, we provide perspective by highlighting the experience of the International Biosecurity and Biosafety Initiative for Science (IBBIS) in developing its openly available customer screening forms and guidance. IBBIS is a non-profit organization based in Geneva that supports nucleic acid synthesis screening globally. In many cases, additional resources and tools could support best practices, and we provide recommendations to advance this work.

Table 1: Emerging consensus in customer screening guidance in recent national and international policies.

CUSTOMER SCREENING PRACTICES	*OSTP*	*UK*	*IGSC*	*ISO*
TIERED SCREENING				
Screen customers for all orders	✓	✓	✓	✓
Screen customers based on sequence analysis	✓	✓	✓	✓
Conduct baseline screening during onboarding	✓	✓	✓	✓
Conduct additional screening for sequences of concern (SOCs)	✓	✓	✓	●
CUSTOMER IDENTITY VERIFICATION				
Verify customer identity for all orders	✓	✓	✓	✓
Collect basic information (name, organization, contact)	✓	✓	✓	✓
Perform due diligence for all orders (e.g., sanctions lists)	✓	✓	✓	●
For SOCs, conduct enhanced identity verification	✓	✓	✓	●
For SOCs, verify identity using government-issued ID	X	✓	✓	X
Use automated tools and digital identity standards	✓	X	●	X
Check shipping address for consistency and legitimacy	●	●	●	●
CUSTOMER LEGITIMACY VERIFICATION				
Verify customer legitimacy for SOCs	✓	✓	✓	✓
Check institutional affiliation and institutional legitimacy	✓	✓	✓	✓
Check individual research history (e.g., ORCID, publications)	✓	✓	●	✓
Check institution's mission or purpose relates to life sciences	✓	●	✓	●
Verify government-issued permits to possess SOCs	✓	✓	●	X
Request institutional biosafety officer/oversight information	✓	✓	X	X
Verify institutional legal status (e.g., incorporation, licenses)	✓	●	●	●
LEGITIMATE USE VERIFICATION				
Verify legitimate use for SOCs	✓	✓	✓	✓
Request written description of intended product use for SOCs	✓	✓	✓	✓
Include export control declaration and resolve licensing needs	✓	✓	✓	X
Use institutional approval process (e.g., biosafety officer sign-off)	✓	●	●	●
Evaluate in the context of research history or business plans	●	●	●	X
Apply more stringent checks if no institutional oversight exists	●	●	X	X
SUPPLY CHAIN SCREENING				
Identify whether customer is the end user or a third party	✓	✓	✓	●
For third parties, verify institutional legitimacy with documentation	✓	✓	✓	●
Require third-party vendors attest to verifying end user identity, affiliation, and use	✓	✓	✓	●

Table 1 shows customer screening practices recommended in four policies issued in 2024, the US OSTP Framework for Nucleic Acid Synthesis Screening (OSTP), the UK DSIT Screening guidance on synthetic nucleic acids for users and providers (UK), the IGSC Harmonized Screening Protocol v3.0 (IGSC), and ISO 20688-2:2024 (ISO). Each practice is coded by whether the policy explicitly mentions or requires it (✓), partially includes or implies it (●), or does not explicitly mention it (X).

Implementing emerging standards in customer screening

Drawing on the points of consensus listed above, extensive outreach with the community of nucleic acid providers,[13] and input and feedback on best practices,[14] IBBIS has developed openly available forms and decision guidance to support tiered screening of customers by nucleic acid synthesis providers.[15] The New Customer Form collects basic information to verify customer identity for each new customer and to determine whether they are part of a multi-party-supply chain. The SOC Order Form collects information needed to verify customer legitimacy and legitimate use. To support decision making by synthesis providers, IBBIS has also developed Decision Support guidance with step-by-step instructions for how the information in these forms should be evaluated.

Tiered Screening

Current guidance recommends a baseline level of screening for all customers, generally conducted during customer onboarding (i.e., the first time a customer makes an order with a provider), as well as a higher level of screening or "follow-up screening" when a customer orders a sequence of concern.

With its "New Customer Form" and "SOC Order Form," IBBIS implemented a tiered approach to ensure that the majority of customers, who neither order SOCs nor act as third-party vendors, face minimal friction. To account for different levels of risk that different SOCs may pose, decision support guidance for the SOC Order Form includes options at different levels of due diligence for verifying customer identity, customer legitimacy, and institutional oversight.

These two tiers ("all orders" and "orders containing SOCs") may not be sufficient to reflect the risk from synthesis orders. Existing guidance notes that some sequences fall under additional regulatory control, requiring government-issued licenses under programs such as the UK Specified Animal Pathogens Order (SAPO) and US Federal Select Agents Program (FSAP). The IGSC Harmonized Protocol also specifically highlights orders that include "significant portions of the genomes from regulated pathogens or toxins" for additional scrutiny.[16] At present, some sequence screening tools offer multiple tiers of SOCs (Table 2), but these risk tiers are not standardised across tools or jurisdictions, and still require specialised expertise in dual-use research to translate into customer screening decisions.

[13] Tessa Alexanian and Sarah R. Carter. "Verifying Legitimacy: Findings from the Customer Screening Working Group, 2020–2023," (Geneva, Switzerland: IBBIS, February 2024).
[14] Engineering Biology Research Consortium. "Strengthening a Safe and Secure Nucleic Acid Synthesis Ecosystem: Outcomes of EBRC Stakeholder Engagement" (Emeryville, CA: Engineering Biology Research Consortium, January 2025). DOI: 10.25498/E4311B
[15] IBBIS, "Customer Screening: Resources for Verifying the Legitimacy of Customers and Collaborators."
[16] International Gene Synthesis Consortium, Harmonized Screening Protocol© v3.0, September, 2024, pg. 15.

Table 2: Risk tiers incorporated into sequence screening tools

Tool	Sequence Risk Tiers
Aclid	SOCs may be flagged as higher concern (based on regulation by different biosecurity frameworks) or lower concern (if known to have a metabolic or housekeeping function).[17]
commec (IBBIS)	SOCs may be flagged as higher concern (due to matching a curated biorisk database) or lower concern (due to matching a curated benign database).[18]
SecureDNA	SOCs may be flagged as higher concern (due to matching an organism with known pandemic potential, or known Arthropod-to-Human or Human-to-Human transmission) or lower concern (e.g. matching against non-pathogenic or non-toxin-producing genes).[19]
UltraSEQ (Battelle)	SOCs are automatically sorted into five risk tiers, ranging from highest concern (toxins, viruses or SOCs that transfer virulence from Tier 1 Agents) to lowest concern (SOCs from non-Select Agents).[20]

The IBBIS forms do not provide guidance on how to evaluate the level of biosafety or biosecurity risk posed by different ordered sequences and instead depend on the nucleic acid providers to make their own determinations. The IGSC Harmonized Screening Protocol notes directly that, there is "no framework available for consistently categorizing specific biological risk posed by a given construct."[21] Ideally, as the level of risk increases, so would the level of confidence that a provider has in their customer. A pairing of detailed risk tiers with corresponding levels of customer screening or due diligence would be a significant asset to providers.

Customer identity verification

There is broad agreement that nucleic acid providers should verify their customer's identity, but questions remain about the level of due diligence that a provider should conduct to ensure that the customer is being truthful.

For all customers, the IBBIS New Customer Form requests basic identifying information: name, email, phone number, shipping address, institutional affiliation, and website. This is consistent with the information many providers already request, which is collected in part because it is useful when fulfilling orders. The decision guidance calls for verifying this information with "some" due diligence, including checking the individual's name against government watchlists,

[17] Kevin Flynagolts, personal communication, June 2025.
[18] Nicole E. Wheeler, Sarah R. Carter, Tessa Alexanian, Christopher Isaac, Jaime Yassif, and Piers Millet. "Developing a Common Global Baseline for Nucleic Acid Synthesis Screening," Applied Biosafety 29(2) (June, 2024).
[19] SecureDNA. "SecureDNA GitHub," (updated August 2024).
[20] Bryan T Gemler, Chiranjit Mukherjee, Patrick A Fullerton, James Diggans, and Craig Bartling. "A Sensitivity Study for Interpreting Nucleic Acid Sequence Screening Regulatory and Guidance Documentation: Toward a Foundational Synthetic Nucleic Acid Sequence Screening Framework," Applied Biosafety 29(3) (September, 2024).
[21] International Gene Synthesis Consortium, Harmonized Screening Protocol© v3.0, September, 2024, pg. 11.

verifying contact information (i.e., that the email address can be used to successfully contact the customer), checking that the email address extension matches the institution or organization listed, and verifying shipping addresses using mapping tools. Although these checks are considered best practices, government watchlists can be difficult to use successfully,[22] and email-based checks are unreliable, particularly for legitimate researchers in regions where personal email addresses are common even at established institutions.[23]

These limitations are even more pronounced when nucleic acid providers are expected to verify customer identity with a higher level of due diligence for customers who order sequences of concern. IBBIS guidance for SOC orders calls for verification of this basic information with "enhanced" due diligence, which might be achieved through real-time contact (e.g., call or video conference), third-party identity services (e.g. Veriff, Plaid, DigiLocker), or government-issued ID documents. This was a deliberate choice to rely on general approaches to verifying customer identity that do not rely directly on the customer's relationship to the life sciences, inspired by approaches described in NIST's SP 800-63 Digital Identity guidelines[24] and used by commercial entities in other contexts.[25] These approaches have not often been linked to nucleic acid synthesis screening, but could be particularly helpful when a customer's institution is less well-established or if other ambiguities arise about their legitimacy as part of the life sciences community.

Providing options for verifying customer identity with "some" or "enhanced" due diligence, rather than recommending a single approach, is a design choice that reflects a trade-off between providing streamlined, standard instructions and ensuring that legitimate customers in diverse countries and institutional settings are able to access sequences. Developing standardized approaches that account for different institutional structures and documentation practices across countries would help ensure that legitimate international customers are not disadvantaged by screening processes designed around specific national contexts.

Customer legitimacy

For orders that contain SOCs, current policies and guidance recommend verifying the legitimacy of the customer. As shown in Table 1, guidance varies on what indicators of legitimacy are requested, and reliable indicators of legitimacy are likely to differ across countries and contexts. We have heard the phrase "customer legitimacy" itself questioned by synthesis providers piloting early versions of the IBBIS forms, who worry their customers will be offended by the suggestion

[22] For example: one Global Sanctions Index reports that most countries do not have an autonomous sanctions list, and that in many countries there is no well-structured, easy-to-find sanctions list that can be referenced by providers. Additionally, verifying sanctions information can be challenging because of ambiguities in names, especially when handling non-Latin scripts.
[23] For example, personal communication with providers indicates that legitimate researchers in parts of Sub-Saharan Africa often use personal email addresses even when they have an affiliation with a well-established university.
[24] National Institute for Standards and Technology. "NIST Special Publication 800-63-3: Digital Identity Guidelines," (June, 2017), as highlighted within Forrest W. Crawford, Kyle Webster, Gerald L. Epstein, Derek Roberts, Joseph Fair, and Sella Nevo, "Securing Commercial Nucleic Acid Synthesis," (Washington, DC: RAND, July 2024).
[25] LinkedIn, "Verifications on your LinkedIn profile," (2025).

that their legitimacy is not self-evident. However, the language of "legitimacy" is used by all four policies and so we continue using it and it remains in the IBBIS guidance. One of the most common indicators of customer legitimacy, considered by every synthesis provider we consulted and recommended by every policy in Table 1, is the customer's institutional affiliation and institutional legitimacy.

The customer's institutional affiliation is requested as part of the New Customer Form, and the SOC Order Form calls for confirming that the customer's email and shipping address match the institution, or that the customer has provided a reasonable explanation for why they do not. The SOC Order Form requests that the customer provide additional documentation to show one or more of the following indicators of individual legitimacy: research history (e.g. ORCID, links to publications or conference participation), institutional affiliation (e.g. profile on institutional website), project documentation (e.g. grants, press releases), or government-issued approvals (e.g. licenses to work with regulated pathogens, export control forms, or business licenses).

The decision guidance calls for verifying that documentation is recent, consistent with other information provided in the form, and aligned with the specific SOCs ordered. This reflects guidance in ISO 20688-2 that a provider should "verify that the information obtained... is consistent with the customer's activities"[26] and in the IGSC Harmonized Screening Protocol to verify the information is both "self-consistent (in that the Customer appears to have sufficient expertise to understand the planned use for ordered sequences) and ... consistent with the nature of the ordered sequence(s)."[27]

Customers with a formal institutional approval process may use that process as an indicator of their legitimacy. The SOC Order Form requests contact information for a "biosafety officer, biorisk manager, biosafety professional, or other professional responsible for overseeing biorisk for the project" who signs the form to indicate institutional approval. However, many non-academic institutions do not have a formal institutional approval process, and practices such as research registration and review by an institutional biosafety committee are not standard in every country.[28] If the institution is unfamiliar, or when the end user cannot provide formal institutional approval, the SOC Order Form recommends verifying at least two of the following indicators of legitimacy: that the institution is an established legal entity; that it provides biosafety oversight or training; that it has a life sciences mission that it is part of the scientific community; or that it has obtained regulatory approval or official certification for work with life sciences materials.

[26] International Organization for Standardization, "ISO 20688-2:2024. Biotechnology—Nucleic acid synthesis, Part 2: Requirements for the production and quality control of synthesized gene fragments, genes, and genomes," (Geneva, Switzerland: ISO, 2024), pg 7.
[27] International Gene Synthesis Consortium, Harmonized Screening Protocol© v3.0, September, 2024, pg. 11.
[28] An early draft of the SOC Order Form requested institutional approval sign-off for any "established life sciences institution [with] ongoing, publicly documented, and well-established activities related to the life sciences", and requested alternative indicators for any "new or less-documented life sciences institution", but we received feedback that there are well-established, highly-reputable research labs (including some funded by the Institut Pasteur and CEPI) that do not have a formal institutional approval process.

Legitimate life sciences institutions range from well-established research universities to start-up companies to public health organizations to community laboratories. Customer screening systems must create clear pathways for researchers to demonstrate their legitimacy regardless of their institutional setting or geographic location.

Legitimate use

When a customer orders a sequence of concern, current guidance recommends not only verifying that customer legitimacy in general, but that the customer has a legitimate use for the specific SOCs ordered. Established guidance and policies generally require that nucleic acid providers evaluate written descriptions of how the order will be used. Such written descriptions can be difficult to interpret,[29] and customers are often unwilling to provide sufficient detail—for example, nucleic acid providers have reported that customers often write, simply, "research purposes."[30] The SOC Order Form requests a written description of intended use, consistent with other guidance, but IBBIS designed the form to supplement this with other indicators rather than relying on customer descriptions.

If a customer's work has been approved after institutional review by a "biosafety officer, biorisk manager, biosafety professional, or other professional responsible for overseeing biorisk for the project," the synthesis provider need not make an independent assessment of the planned use. Streamlined methods for communicating institutional approval would be useful; the IBBIS forms allow an institutional contact to sign, indicating approval, but it is not always easy for nucleic acid providers to make contact with the relevant institutional biosafety officials, especially in the face of impatient customers and international variance in oversight practices. Even detailed approvals do not list every individual that might contribute to a project, nor every sequence that an end user might work with.

As discussed in the previous section, much legitimate science is done in environments without an institutional approval process. If the customer is not subject to institutional oversight and approval, the SOC Order Form requests other evidence that an end user has a reason to order particular sequences, such as relevant past publications, ongoing collaborations, grants, business plans, media stories, or industry memberships. However, this process is laborious and it can be difficult to connect such diverse evidence to specific SOCs that a researcher might legitimately order.

Some sequences of concern fall under regulatory controls, such as licensing requirements and export controls, and all policies and guidance related to nucleic acid synthesis screening require that providers pay particular attention to these sequences. Regulations and licensing processes

[29] In one IBBIS workshop, a participant with a PhD in biomedical engineering, asked to evaluate biosecurity risks from sequences flagged as derived from the organisms *Xanthomonas citri*, *Plasmodium falciparum* and *Escherichia coli O157* (among several others), said he had "new appreciation for the other side" and the difficult job of screening; experts in one of these pathogens may not know much about the biosecurity risks or legitimate uses associated with the others.

[30] Contributions to a workshop under the Chatham House Rule from an industry participant. Workshop was hosted by the Engineering Biology Research Consortium, September 10–11, 2024.

vary across countries, and in some cases there is ambiguity about which SOCs are regulated. For example, 42 countries and the European Union follow export control guidance issued by the Australia Group, which calls for controls on nucleic acid sequences that "endow or enhance pathogenicity,"[31] and it is unclear exactly which sequences meet this standard. Export licenses are granted to the provider rather than the customer, but customers must often provide information as part of the licensing process. For export control, the SOC Order Form asks customers to identify potential restrictions but places responsibility on providers to resolve requirements, acknowledging that customers may not fully understand export control obligations.

Supply Chain Screening

Customers of synthetic nucleic acids are often envisioned as individuals who design and place an order for a sequence from a large, commercial provider and then receive the synthesized nucleic acids directly from that provider. However, recent guidance and policies have acknowledged the complexity and diversity of provider-customer relationships by providing definitions for "customer," "principal user," and "end user." They have also expanded the guidance for "providers" to include responsibilities for non-traditional providers (such as the U.S. policy's explicit inclusion of academic core facilities, cloud labs, and contract research organizations[32]) as well as third-party resellers of synthetic nucleic acids.

Non-traditional or third-party vendors and their business models are very diverse, and customer screening in these contexts may require more specialized guidance. In particular, the relationships between these vendors and their customers does not always follow the limited customer-provider interaction that current guidance seeks to address, and the vendors themselves may have a larger role in how the nucleic acids are used.

When synthetic nucleic acids are ordered through a third-party vendor, the nucleic acid provider who synthesizes the sequences often has limited interaction with, and sometimes is unaware of, the ultimate end user. The third-party vendor is in a better position to verify the end user's legitimacy, the legitimacy of their institution, and legitimate use. Given these multiple layers of responsibility, it can be difficult for these different types of providers to understand their roles.

In addition to basic information about the customer's identity, the IBBIS New Customer Form asks whether the customer will be the end user of the synthetic nucleic acids. If not, the form asks whether the customer is at the same institution as the end user or if they are a third-party vendor. For customers such as procurement officers at the same institution as the end user, the form requests contact information for an additional person at the institution as a minimal level of due diligence for institutional legitimacy. If the customer is a third-party vendor, the form requests documentation of institutional legitimacy similar to what is requested on the SOC Order Form, and the decision guidance suggests conducting some due diligence to verify the legitimacy of the institution.

[31] The Australia Group, "List of Human and Animal Pathogens and Toxins for Export Control," (November, 2023).
[32] "Table 2: Definitions of Non-Traditional Providers of Synthetic Nucleic Acids", Office of Science and Technology Policy, "2024 OSTP Framework for Nucleic Acid Synthesis Screening," April, 2024, pg. 7.

Table 3: Examples of diversity in non-traditional and third-party vendors

Example	Order Volume	Customer Interaction
A country-specific reseller of synthetic nucleic acids (e.g. FastBio in Brazil, Premas Life Sciences in India, or Takapouzist Co. in Iran). The company accepts customer orders, requests the orders from an international partner, then handles all the logistics of delivering from the partner to their country.	High	Low
A company specialized in creation of custom viral vectors. The company receives designs from users, orders synthetic nucleic acids from a traditional nucleic acid provider, clones the custom design into one of their proprietary vectors, then ships the assembly to their own customers.	Moderate	Moderate
An academic core facility which does not have synthesis equipment in-house, but performs complex DNA assemblies and regularly orders synthetic nucleic acids to be assembled. No researchers from outside the academic institution have access to these services.	Low	High

The IBBIS SOC Order Form also requests additional information if the customer is not the end user, including requesting that the customer obtain information from the end user to determine legitimacy, institutional affiliation, and intended use of the product. The form includes a dedicated section where third-party vendors can attest that they will conduct sequence and customer screening, following the recommendation from the IGSC Harmonized Screening Protocol to only sell to distributors or other resellers if "those companies agree to identify the end-user receiving the products and demonstrate their compliance with every requirement otherwise applicable to that end-user."[33]

Recommendations to advance implementation of customer screening

It was possible to create forms and decision guidance that reflect the emerging consensus on customer screening, but this exercise also highlighted persistent ambiguities that must be resolved to transform broad best practices into clear standards. The recommendations in this section would help to reduce ambiguity, streamline procedures for legitimate customers, and support best practices for customer screening.

Advancing implementation of customer screening will require coordination among the synthesis industry, biosecurity researchers, and policymakers. However, many of the resources proposed under the recommendations could be developed by biosecurity researchers and others.

[33] International Gene Synthesis Consortium, Harmonized Screening Protocol© v3.0, September, 2024, pg. 15.

Establish minimal globally-relevant baseline for customer screening

Recent national and international policies have encouraged adoption of synthesis screening through voluntary guidance and self-attestation. Eventually, however, this adoption should be strengthened by adoption of enforceable standards and real compliance requirements.

Customer screening standards are neither established nor harmonized enough that providers can be certified as compliant at customer screening. However, similar to recent definitions of a baseline set of sequences of concern,[34] which all responsible providers agree should be flagged, it should be possible to define a baseline set of customer attributes which all providers agree should merit some form of additional customer screening. A baseline could include, for example, follow-up screening for any customers that attempt to be anonymous, that request shipping to a residential address, or that have a name matching the UN sanctions list. It could also include acknowledgment that, when applicable, export controls and national licensing requirements should be followed.

In the case of sequences of concern, most responsible providers flag far more sequences than the baseline for which an unambiguous consensus can be achieved. The benefit of a minimal baseline is to distinguish between providers that conduct any screening and those that do not, enabling enforceable standards in advance of perfect agreement on edge cases. Customer screening practices can be refined over time and implementation can be streamlined, allowing enforceable standards to eventually expand beyond the minimum.

Clarify customer screening through practical case studies

Ambiguous customer scenarios continue to challenge synthesis providers, but systematic case studies can build shared understanding of best practices. Already, case studies of different customers, paired with specific orders, have been developed to explore screening in practice. IBBIS has developed an order screening game with a dozen customer personas[35] that have been used by synthesis providers to train customer service representatives, as well as during workshops for policymakers. In addition, six screening case studies were published in the Bulletin of the Atomic Scientists,[36] and the Engineering Biology Research Council is developing customer profiles to use in testing provider screening systems.[37]

Additional case studies would still be helpful, especially those which describe indicators of institutional legitimacy with broad geographical and sectoral representation and real-world examples of third-party vendors that provide challenges for supply chain screening, including where they conduct business and what types of services they provide.

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[34] Laird, TS et al. Inter-tool analysis of a NIST dataset for assessing baseline nucleic acid sequence screening. bioRxiv 2025.05.30.655379; doi: https://doi.org/10.1101/2025.05.30.655379

[35] Tessa Alexanian. "Customer Profiles for Screening: IBBIS Workshop Materials," (Geneva, Switzerland: IBBIS, June 2024).

[36] Steph Batalis and Vikram Venkatram. "How to stop bioterrorists from buying dangerous DNA," Bulletin of Atomic Scientists (April 2025).

[37] Engineering Biology Research Consortium. "End-to-End Stress Testing (E2EST) of DNA Synthesis Screening," (2025).

Encourage automated identity verification with clear guidance

Identity verification remains labor-intensive and inconsistent across providers, but established tools and standards from other industries could streamline these processes, as could some additional resources built specifically for the synthesis industry. Automated identity verification could be encouraged through:

- Best practices for customer screening to make use of existing software for digital identity verification (such as Veriff, Plaid, CLEAR, Persona, or DigiLocker) and sanctions screening (such as LexisNexis and LSEG World-Check).
- Transferable identity verification for life sciences customers, users, or community members. For example, identity verification could be connected to Open Researcher and Contributor IDs (ORCID),[38] which are commonly used in the life sciences community.
- Best practices for establishing the legal status of smaller or newer life sciences institutions, including lessons from the financial sector and the use of persistent identifiers such as Research Organization Registry (ROR) identifiers.[39]

Leverage existing approvals to demonstrate customer legitimacy

Rather than each provider independently assessing customer legitimacy, screening systems should build on existing institutional oversight and government approvals where they exist. Beneficial resources would include:

- Streamlined methods for communicating approvals from institutions, science funders, or other third parties for end users to work with specific biological agents, SOCs, or biosafety containment levels. One pilot project in this area is SecureDNA's Exemption Certification System[40] that integrates biosafety officer approvals with sequence screening.
- Methods to automatically collate public information about whether an individual has research history with specific biological agents or SOCs. One prototype using AI to provide an automatic summary of researcher history is Rose Scout.[41]
- A reference dataset indicating whether customers or institutions in particular countries are required to have institutional biosafety approvals or government-issued permits (such as the licenses issued the UK SAPO and US FSAP programmes) to conduct life sciences work or possess SOCs. Some of this work should be completed as part of the IBBIS Global DNA Synthesis Map.[42]

[38] Open Researcher and Contributor ID (ORCID). https://orcid.org/
[39] Research Organization Registry (ROR). https://ror.org/
[40] Baum, C et al. A system capable of verifiably and privately screening global DNA synthesis. arXiv:2403.14023v3); doi: 10.48550/arXiv.2403.14023
[41] Hanna Palya and Alejandro Acelas, Cliver: AI-Powered Customer Screening for DNA Providers, https://cliver.bio/

[42] International Biosecurity and Biosafety Intiative for Science (IBBIS). "Global DNA Synthesis Map: Creating a map of global DNA synthesis providers and policies". https://ibbis.bio/our-work/global-dna-synthesis-map/

Integrate sequence and customer screening

Tiered customer screening should include appropriate due diligence at additional tiers of risk beyond "all orders" and "orders including SOCs." IBBIS has developed a draft version of such guidance (see Appendix A), but additional refinement and feedback from the broader community is needed. Further work in this space will require closer integration of sequence and customer screening methods:

- Standardizing sequence screening outputs (see Table 2) to reflect shared tiers of risk, including standard ways to describe pathogen-related sequences that do not pose significant biosafety or biosecurity risks (e.g., metabolic or housekeeping genes).
- Cross-referencing of existing tired identity verification guidelines, such as NIST's SP 800-63,[43] to nucleic acid orders that pose different levels of biosafety or biosecurity risk.
- Government-issued guidance on which specific sequences (rather than organisms or broad categories like sequences that "endow or enhance pathogenicity") require export licences or government-issued permits.[44]

Conclusion

The consensus on customer screening practices emerging from recent policies provides a solid foundation, but does not resolve implementation challenges across the nucleic acid synthesis industry. For each area of emerging consensus, we outline specific tools and resources that would advance best practices. The IBBIS customer screening forms and decision guidance demonstrate one approach to translating policy consensus into practical tools, but significant opportunities remain to enable synthesis providers to conduct customer screening more efficiently, consistently, and confidently.

Many of our suggestions point to a future in which customer legitimacy is established more proactively. The burden of verifying customer identity could be reduced by associating existing customer identifiers, such as persistent digital identifiers (e.g., ORCID) or institutional email addresses, with a higher level of identity verification. More ambitiously, a pre-approval mechanism that acts as a trustworthy and transferable indication of customer legitimacy and legitimate use has been identified as a way to reduce the screening burden placed on individual

[43] National Institute of Standards and Technology. (2025). Digital identity guidelines (NIST Special Publication 800-63-4). U.S. Department of Commerce. https://doi.org/10.6028/NIST.SP.800-63-4

[44] The April 2023 update to France's microorganisms and toxins list, translated by IBBIS in "Policy Spotlight: French leadership defining and regulating genetic fragments," is an example that specifies controls based on sequence length and named genes of concern.

synthesis providers.[45,46,47,48] This type of pre-approval could draw on existing institutional or government oversight or be based on new third-party certifiers.

The future of customer screening also likely includes broader participation from life sciences institutions. Universities, funding agencies, and providers of life sciences products other than synthetic nucleic acids could take on larger roles in verifying customer identity, customer legitimacy, and legitimate use, reducing the burden of screening for any specific synthesis provider or sequence order. A broader support system for customer screening will reduce biosecurity risks across the life sciences, increase confidence in the legitimacy of the scientific enterprise, and help build public trust in scientific institutions.

Although recent policy development for customer screening has focused on nucleic acid synthesis screening, the verification standards, digital identity tools, and other resources discussed in this paper create precedents for securing emerging biotechnologies more broadly. Establishing streamlined, rigorous, and transparent customer screening will allow biosecurity concerns to be addressed while preserving the openness and international collaboration that enables modern life sciences research.

[45] Baum, C et al. A system capable of verifiably and privately screening global DNA synthesis. arXiv:2403.14023v3); doi: 10.48550/arXiv.2403.14023
[46] Sarah R. Carter. "Developing a Customer Screening Framework for the Life Sciences," (Washington, DC: Blueprint Biosecurity, March 2024).
[47] Sophie Rose, Tessa Alexanian, Max Langenkamp, Helena Cozzarini, and James Diggans, "Practical Questions for Securing Nucleic Acid Synthesis," Applied Biosafety 29(3) (September, 2024).
[48] Forrest W. Crawford, Kyle Webster, Gerald L. Epstein, Derek Roberts, Joseph Fair, and Sella Nevo, "Securing Commercial Nucleic Acid Synthesis," (Washington, DC: RAND, July 2024).

APPENDIX A

Tiered Customer Screening Practices in the Life Sciences

Many life sciences products and services pose very little biosafety and biosecurity risk, while others can pose significant risks. This Table is organized into tiers or levels of customer screening, with the highest tiers intended to gather information to establish that a customer and their institution can be trusted to use life sciences products or services with the highest biosafety and biosecurity risks. Providers of life sciences products and services should thoughtfully determine what level of customer verification their products require.

For customers who are the end users, we establish the following Tiers:

0. Establishing a commercial relationship *(not life-sciences-specific)*
1. Customer onboarding *(equivalent to New Customer Form)*
2. Products that pose low levels of biosecurity risk *(second approver, end use)*
3. Products that pose moderate levels of biosecurity risk *(institutional legitimacy)*
4. Products that pose higher levels of biosecurity risk *(additional individual and institutional legitimacy, equivalent to SOC Order Form)*

	Customer Identity	Customer part of life sciences community	Institutional legitimacy	Institutional responsibility or approval
Tier 0	Check government watchlists			
	Automated check of email address or phone number for successful contact			
Tier 1	Check that email address, phone, shipping address are consistent with institution	Request institutional affiliation	Check government watchlists	
Tier 2		Request information about how the ordered products will be used	Request contact information for another person at the institution, such as a biosafety officer	Check email address or phone number for successful contact with the second person

Tier 3			Request documentation to establish that the institution is legitimate	
Tier 4	Call, conduct a video conference, or otherwise establish real-time contact to verify identity **OR** Verify identification using an established third-party service (e.g. Veriff, Plaid, CLEAR, Persona, or DigiLocker)	Request documentation to establish that the customer is a member of the life sciences community	Request documentation to establish that the institution is a part of the life sciences community	Request signed approval from institutional biorisk management for ordered products
Additional verification measures for high-risk products or services	Request a copy of a government-issued ID or other identifying documents		Visit institution	Call, conduct a video conference, or otherwise contact biosafety officer (or other listed contact) to verify identity, affiliation, and approval of project
	Visit customer at their institution			