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International Biosecurity and Biosafety Initiative for Science

VERIFYING LEGITIMACY

FINDINGS FROM THE CUSTOMER SCREENING WORKING GROUP, 2020-2023

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Customer screening is a critical component of the Common Mechanism for DNA synthesis screening, hosted by the International Biosecurity and Biosafety Initiative for Science (IBBIS). During the initial development of the Common Mechanism, the Customer Screening Working Group of the Technical Consortium worked to develop a shared understanding of best practices and a framework that could be applied by a wide range of DNA providers and providers of benchtop DNA synthesis devices. This document aims to summarize the findings of this working group between 2020–2023.

The working group proposed a two-stage system which verifies legitimacy for all customers during onboarding and requires a stronger level of confidence if the customer wishes to obtain flagged DNA. A central challenge is in verifying legitimacy of customers and their intended end uses for synthetic DNA.

Findings to inform the design of a customer screening framework

1. **Customer screening occurs across many parts of the order process**, but the most intensive verification of legitimacy should occur during initial customer onboarding and if an order is identified as posing an elevated biorisk.

2. **Benchtop devices require a higher standard of customer screening** for initial ordering, especially if sequence screening occurs on-device. Recurring orders of proprietary reagents provide an opportunity to re-verify legitimacy, and benchtop device manufacturers should also establish record-keeping to allow auditing of the device if misuse is suspected.

3. **Once a customer has established legitimacy, they should re-verify periodically**, but should not need to fully re-verify their legitimacy for each order. For example, the framework should allow for pre-approval of certain flagged sequences for specific customers.

4. **Not all legitimate customers are working in well-established institutions,** and customer screening must be flexible enough to allow customers to establish legitimacy in multiple ways (e.g. accepting additional documentation to establish affiliation when a customer does not have an institutional email address; accepting documentation of funding when incorporation documentation has not yet been filed; allowing customers to be endorsed by legitimate institutions without official affiliations).

Defining Legitimacy

The working group arrived at definitions for a legitimate customer and legitimate institution. A **legitimate customer** for any synthetic DNA is an individual who has:

1. No red flags associated with individual identity

2. A reason to use life sciences products

   For orders of flagged biorisk DNA: A reason to use the specific sequences ordered

5. Affiliation with or endorsement from a legitimate institution

   For orders of flagged biorisk DNA or purchases of benchtop devices: Approval through the institution's biosafety process

A **legitimate institution** is an organization that has:

1. Legal standing
2. A mission or purpose that includes life sciences
3. Biosafety oversight (e.g. biosafety committee, biosafety officer, health & safety officer)

   For orders of flagged biorisk DNA or purchases of benchtop devices: strong biosafety oversight, i.e. a committee-based approvals process

How can legitimacy be verified?

Each of the criteria in the definitions above can and should be verified. We propose initial verification as well as actions that can be taken if questions about legitimacy remain.

Verifying customer legitimacy during onboarding

When an individual sets up an account with a provider, they must be verified as a legitimate customer. This legitimacy should be periodically re-verified when orders are placed.

Requirement	Initial verification	If questions remain
No red flags associated with individual identity	• Check customer name against national sanctions lists	• Follow-up call or communication with customer
A reason to use life sciences products	• Ask how the product will be used • Informal check of whether customer or institution conducts relevant activities	• Follow-up call or communication with customer • Request documentation (e.g. funding documents, publications)
Affiliation with or endorsement from a legitimate institution	• Request affiliation • Request email and shipping address associated with institution	• Follow-up call or communication with customer • Contact institution to verify affiliation / endorsement • Verify shipping address against public databases • Visit the customer at the institution

Verifying institutional legitimacy during onboarding

Customers may be affiliated with or endorsed by institutions that the provider is not familiar with, in which case the legitimacy of the institution must also be verified

Requirement	Initial verification	If questions remain
Legal standing	• If unfamiliar, conduct informal research (e.g. internet search for company or university website)	• Request documentation (e.g. incorporation papers for companies) • Verify using public databases or queries to the institution
A mission or purpose that includes life sciences	• If unfamiliar, conduct informal research (e.g. internet search for company website or scientific publications from university)	• Request documentation (e.g. funding documents, publications) • Contact institution to verify
Biosafety oversight (e.g. biosafety committee, biosafety officer, health & safety officer)	• Request information about oversight (e.g. presence of IBC, name of biosafety officer or biorisk manager)	• Request documentation of oversight (e.g. IBC process, approval of projects) • Verify by contacting biosafety officer or others at the institution

Verifying legitimacy for orders of flagged sequences or purchases of benchtop devices

When a customer orders DNA or RNA sequences that pose a biorisk, or purchases a benchtop synthesis device, it is important to verify that they have adequate risk management in place.

Requirement	Initial verification	If questions remain
Strong institutional biosafety oversight, i.e. a committee-based approvals process	• If unfamiliar, conduct informal research (e.g. internet search for company or university website)	• Verify using public databases or queries to the institution
Approval through the institutional biosafety process	• If not done previously, request documentation of institutional biosafety oversight • If not done previously, verify approval by contacting the biosafety officer or others at the institution	• Verify using public databases or queries to the institution

For orders of flagged biorisk DNA: a reason to use the specific sequences ordered.	• Request written description of the proposed end use of the sequences • If applicable, request evidence of export control licenses • Request documentation (e.g. funding, approval through institutional biosafety process, publications) • Informally check that the customer conducts relevant activities	• Verify documents using public databases, queries to the institution or queries to funders • Conduct follow-up call or communication

Open Challenges and Planned Resources

The working group identified a number of key challenges for customer screening and resources that could address them:

Challenge	Resource
No shared understanding of "legitimate" or "affiliation".	**Flowcharts with indicative processes for verifying legitimacy of both customers and institutions**. These charts should include both default information to gather and alternatives for building confidence in a customer (e.g. if a customer does not have an institutional email address).
Customer screening relies on subjective judgments and ad-hoc information-gathering.	**Structured templates for requesting information** about customers and institutions, e.g. a template for collecting information on an institution's biosafety officer or biorisk manager. This resource could also help to set industry standards and customer expectations.
No consistent documentation across countries or institutions.	**Database of official documents from different countries**, particularly for incorporation of companies. This resource is important because it helps companies verify the legitimacy of customers from other countries and jurisdictions that they are not familiar with.
Customer screening practices for benchtop devices are less established.	**Case studies specific to benchtop devices**, including investigation of options for auditing how the device is used and mitigating errors likely to occur with on-device authentication, such as failure to log out of devices, sharing passwords, and misuse of two-factor authentication.

The working group did not identify a need for decision-support software for customer screening. Two additional resources that were proposed, but not recommended for the initial wave of development, were **whitelists of institutions or entities** (e.g. based on recommendations by peer institutions or a third party verification system) and a **user interface for understanding and tracking a customer's research** (e.g.

publication topics, work history, authorship network), which would make it easier to understand if a customer has worked with certain types of pathogens when an order is flagged during sequence screening.

Next Steps

These resources are still under development, but initial versions of them will be provided along with the production release of the sequence screening software in 2024.