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Brief on Nucleic Acid Synthesis and Biosecurity

Medical diagnostics, biomanufacturing, and many other parts of the bioeconomy rely on synthetic nucleic acids (NAs). Clinicians and researchers order custom DNA and RNA sequences from companies or, less commonly, print NAs on devices in their own labs. Increasingly accessible and affordable NA synthesis both enables beneficial biotechnology and raises biosecurity concerns. Some NAs can be used to construct pathogens, toxins, or other dangerous biological agents. If such sequences are misused, whether accidentally or deliberately, it could create catastrophic outcomes of pandemic proportions impacting population health and economic prosperity and resilience.

Key Risks:

Currently, **there are no universal regulations** requiring NA synthesis companies to screen their orders to prevent sequences which could potentially be weaponised from being sent to malicious actors. Some companies screen voluntarily, but the lack of enforceable standards burdens security-conscious companies with a competitive disadvantage, while leaving security gaps among those who do not screen.

AI could further lower the barrier to biological threats, as emerging AI systems may be able to guide individuals through the synthesis of dangerous organisms, suggest ways to evade synthesis screening, or automate steps of bioweapons development. While LLMs - that provide detailed, accessible information on synthetic biology techniques - and automated labs, can drive innovation in synthetic biology, their potential to make biological attacks more feasible poses a serious threat to biosecurity.

Current Landscape:

Gene synthesis providers are not obliged by law to perform customer and sequence screening. The **International Gene Synthesis Consortium (IGSC)** provides voluntary guidelines for screening both customers and sequences to prevent misuse. However, this framework excludes smaller companies, and compliance is not mandatory.

The **US Executive Order on Artificial Intelligence** directed all recipients of federal research funding to use only NA synthesis providers that adhere to a screening framework. Given that institutions internationally receive grant funding from the US, this has shaped a shift towards more universal screening. In the past year, additional voluntary screening standards have emerged, including the Responsible AI x Biodesign Commitments, the ISO 20688-2 standard on nucleic acid synthesis, and the UK screening guidance on synthetic nucleic acids.

However, for global standards to be upheld, the landscape requires that:

- **Major market players such as the EU** implement strong incentives for screening adherence. This will serve to create regulatory alignment, making it increasingly unfeasible for gene synthesis companies to avoid performing screening, while facilitating operations for global companies.

- **Standards for screening set out comprehensive, harmonised workflows** for flagging NA sequences that pose security concerns, determining which customers have legitimate use for flagged sequences, and reporting illegitimate orders.

- **Mechanisms are in place for verifying and certifying compliance** by the relevant EU regulator.

To safeguard global biosecurity, it is crucial to implement standardised screening protocols for synthetic nucleic acid synthesis. By aligning major markets like the U.S. and EU and involving international stakeholders, we can reduce the risks posed by the misuse of synthetic biology while supporting its vast potential for positive impact.

Leaders within the NA synthesis industry have issued strong calls for regulations and safeguards. These voices have been joined by academics, researchers and industries that use synthesis technology. On the international stage, synthesis screening standards support disarmament obligations set out in UN Security Council Resolution 1540 and BWC Article IV, as well as ongoing efforts to galvanise BWC compliance and verification mechanisms.

Why should the EU act?

NA synthesis screening strengthens the EU's Preparedness Union, ensuring better resilience against future health crises and national security challenges. Current EU priorities, such as the Political Guidelines 2024-2029, focus on national, social, health, and economic security. Enhancinng safeguards for NA synthesis technology aligns with existing initiatives, including the EU risk assessment of biotechnologies, the Chemical, Biological, Radiological and Nuclear (CBRN) Action Plan, and the EU Biotech Act. Ensuring NA synthesis technologies is vital to ensuring the EU:

1. Remains at the forefront of **innovation and economic growth**

2. Has **supply chain security** for technologies that are likely to be critical for manufacturing vaccines, medications and other essential products into the future

3. Acts as an **effective standard-setter,** and consequently enhances the global safety of NA synthesis research and technology

4. **Establishes biosecurity safeguards** which will effectively reduce the risk of biological weapon development and deployment

NA synthesis screening will also help the EU to implement the regime for the control of exports and transfer of dual-use items set out in Regulation 2021/821 of the European Parliament, which encompasses NAs through the inclusion of the Australia Group Common Control Lists in its annex of dual-use items.