

Health Committee Members
Parliament Buildings
Wellington, New Zealand

We commend the New Zealand parliament for the proposed Bill No. 110-1, the *Gene Technology Bill*, particularly its provisions related to nucleic acid synthesis (83, 149, 147). The International Biosecurity and Biosafety Initiative for Science (IBBIS), launched in 2024, is a Geneva-based foundation that works collaboratively with global partners to strengthen biosecurity norms and develop innovative tools to uphold them. Much of our work to date focused on the governance of nucleic acid synthesis, including the development of open-source resources to facilitate sequence and customer screening.

Accessible and affordable synthetic nucleic acids are an essential input into biomedical, agricultural, and conservation research. However, for over 15 years, policy and industry leaders have recognized that nucleic acid synthesis raises biosecurity concerns: some sequences can be used to reconstruct pathogen genomes or engineer dangerous biological agents, and it's necessary to ensure those sequences are not misused by actors seeking to cause harm.

Synthesis screening is consistent with international nonproliferation obligations. Synthetic nucleic acids were highlighted as a technological development relevant to the Biological Weapons Convention as early as 2006 [1], based on cases such as the assembly of poliovirus from synthesised DNA in 2001 and the reconstruction of 1918 pandemic influenza virus from DNA fragments in 2005. Agreements at the Sixth, Seventh and Eighth BWC Review conferences called for “effective national export controls”, which New Zealand has already implemented through item 1C353 of the New Zealand Strategic Goods Lists, which is harmonized with the Australia Group Common Control List entry on “Genetic Elements and Genetically-modified Organisms”. Both Article IV of the BWC and UN Security Council Resolution 1540 obligate states to establish effective domestic controls in addition to export controls; while New Zealand already has domestic controls on some materials that could be used to construct biological weapons (e.g. under the Terrorism Suppression Act 2002), the synthesis screening provisions of the Gene Technology Bill would strengthen these controls.

In the past two years, there has been increasing interest in harmonizing and standardizing screening approaches around the world, especially in light of concerns that advances in artificial intelligence will increase the risks that synthetic nucleic acids are misused. Since 2024, Over 175 active developers of AI technologies for biomolecular structure prediction have signed onto the *Commitments for the Responsible Development of AI for Protein Design* [2], which includes a commitment to “obtain DNA synthesis services only from providers that demonstrate adherence to industry-standard biosecurity screening practices”. The WHO *Global guidance framework for the responsible use of the life sciences* [3] includes a scenario in which synthetic nucleic acids, ordered from a provider who is not a member of the IGSC, are used to produce a chimeric virus, and highlights how biosafety and biosecurity risks could have been avoided if the synthesis company had screened the order.

Voluntary standards for sequence and customer screening have already been adopted by providers aiming to comply with their national export controls and biosecurity guidance. For example, over 40 commercial synthesis companies, benchtop equipment manufacturers, and

nonprofit biofoundries are members of the International Gene Synthesis Consortium (IGSC) and agree to screen orders according to a *Harmonized Screening Protocol* [4]. Providers and manufacturers outside of the IGSC have also publicly attested to complying with synthesis screening standards. Biosecurity provisions related to synthesis screening are also present in the newly published ISO standard for production and quality control of synthesized gene fragments, genes, and genomes (ISO 20688-2:2024).

Policymakers have an opportunity to formalize and clarify these voluntary standards. This has already been pursued by the U.S. under the 2023 Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids and UK under the 2024 Screening guidance on synthetic nucleic acids for users and providers, which also references ISO 20688-2, each of which were developed with significant industry consultation and support. Adoption of similar standards in New Zealand will further establish a harmonized international approach to synthesis screening. This will serve to level the playing field between industry actors who have already invested in biosecurity and those who have been reluctant to introduce screening.

We commend the New Zealand Parliament for its leadership and encourage passage of the Gene Technology Bill's nucleic acid synthesis screening provisions. We appreciate New Zealand's active participation in international biosecurity standards-setting, and encourage New Zealand to engage with IBBIS, IGSC, ISO, and other relevant stakeholders to ensure regulatory coherence and international information-sharing on screened sequences. Thank you for the opportunity to comment on and express our support for principles embodied in the *Gene Technology Bill*.

Sincerely,

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References

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