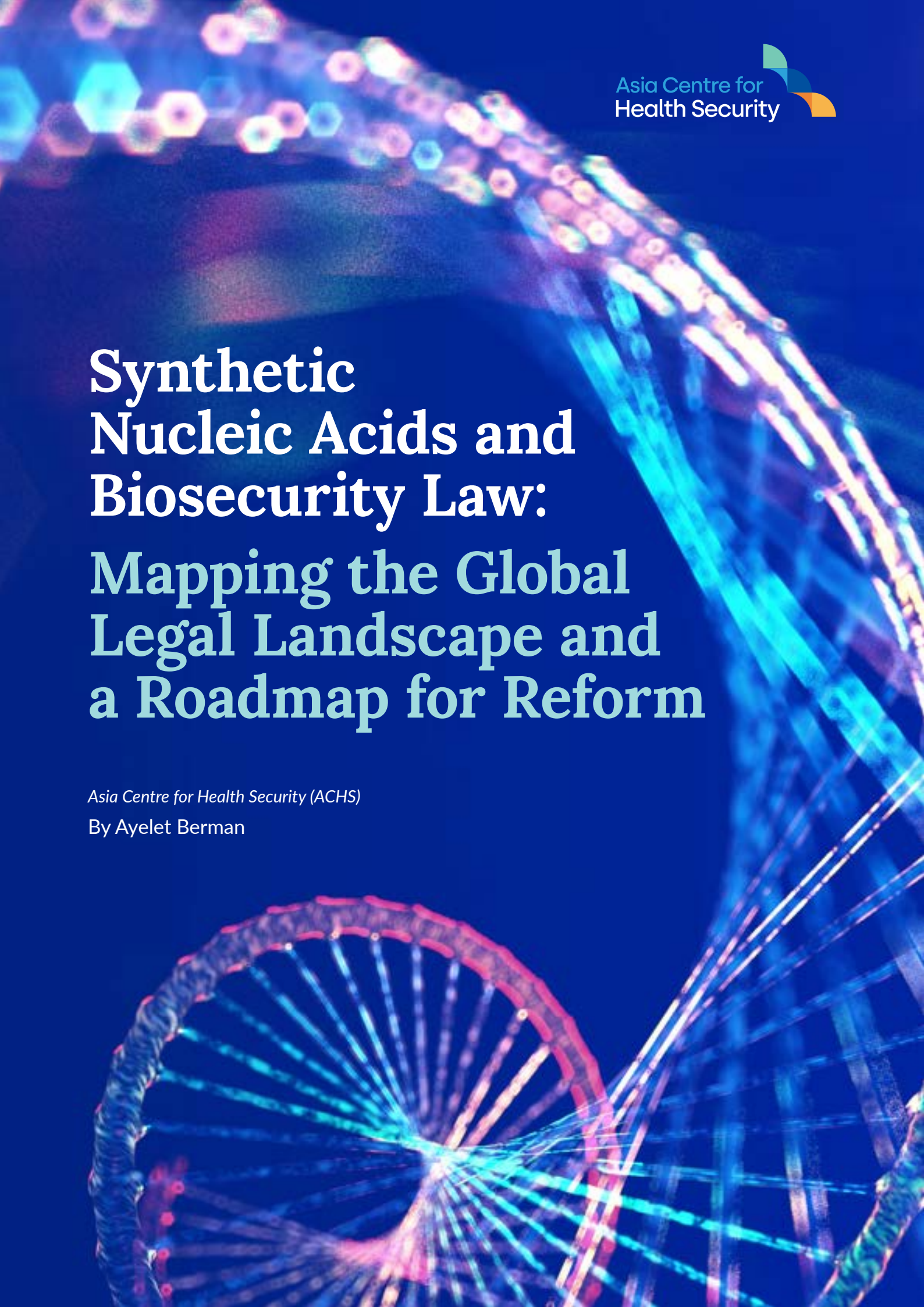


Asia Centre for Health Security

Synthetic Nucleic Acids and Biosecurity Law:

Mapping the Global Legal Landscape and a Roadmap for Reform

Asia Centre for Health Security (ACHS)

By Ayelet Berman



Foreword

We are living through a period of profound global change. One domain undergoing particularly rapid transformation is biology. Its convergence with advanced technologies is generating unprecedented opportunities for medicine, agriculture, and biotechnology. At the same time, these developments introduce new categories of risk.

As in many technological fields, legal and regulatory frameworks have not kept pace with scientific progress. The core principles of biosafety and biosecurity were developed in an earlier era, when the primary concern was the handling and containment of naturally occurring pathogens. Today, the technological landscape has changed. Synthetic nucleic acids (SNA), artificial intelligence (AI)-assisted biological design, and the growing accessibility of biotechnology are expanding both the capabilities of legitimate research and the potential avenues for misuse. The challenge for the legal and regulatory community is therefore to close this governance gap.

In recent years, the biosecurity community has devoted attention to developing and advancing voluntary DNA synthesis screening standards to mitigate the risk that dangerous SNAs fall into the wrong hands. By contrast, the legal and regulatory dimension has received far less systematic analysis. Yet, if the risks associated with SNA are as significant as many experts suggest, reliance on voluntary practices alone will not be sufficient. Law and regulation should play a central role in establishing clear, consistent, and enforceable responsibilities.

Encouragingly, awareness of this challenge is growing. Over the past few years, a few countries have begun to consider legally mandated screening requirements. Nevertheless, many jurisdictions have yet to address the issue, and the need for informed policy development will likely expand in the years ahead.

Moreover, order screening addresses only the point of acquisition and does not govern the subsequent possession, storage, transfer, use, or disposal of SNAs. As a result, controls that have long applied to dangerous pathogens across their lifecycle may be circumvented by obtaining or reconstructing them through SNAs. Determining the extent to which existing legal frameworks apply to SNAs is therefore a central regulatory question.

It is against this backdrop that this report was researched and written. It aims to provide a comprehensive overview of the global legal and regulatory landscape governing SNAs and associated biosecurity risks. It also offers recommendations for reform and outlines a range of regulatory tools that governments may consider when developing future frameworks and adapting or updating existing ones.

While countries differ in their legal systems, capacities, and policy priorities, the report seeks to provide a conceptual and structured foundation for policymakers, regulators, and other stakeholders confronting this challenge. In doing so, it seeks to contribute to a broader effort to ensure that governance frameworks evolve alongside new biological technologies.

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Executive Summary



5

Introduction

Synthetic nucleic acids (SNAs)—DNA or RNA produced from digital sequence information—have become a foundational technology in medicine, agriculture, biological research, and biotechnology. Commercial synthesis services and benchtop synthesis devices have made synthetic genetic material easier and cheaper to produce.

These developments also create significant biosecurity risks. Greater access to synthesis technologies makes potentially hazardous genetic material easier to obtain. Smaller genetic fragments can be assembled into dangerous pathogens, while artificial intelligence (AI) can reduce the expertise and time required to design hazardous sequences, including novel sequences that may fall outside traditional pathogen lists. The decentralisation of synthesis through benchtop devices further weakens centralised regulatory oversight.

Policy responses within the biosecurity community have focused primarily on strengthening nucleic acid synthesis screening—commonly referred to as DNA synthesis screening—by commercial SNA providers. Sequence screening seeks to identify sequences of concern, while customer screening assesses the legitimacy of the purchaser and of the intended use. These measures play an important role in preventing the acquisition of hazardous genetic material.

However, order screening addresses only the point of acquisition. It does not govern what happens after an SNA has been obtained, including its possession, storage, transfer, sharing, use, or disposal. These activities—with respect to pathogens—have traditionally been strictly controlled by biosafety and biosecurity laws. Yet little attention has been paid to whether—and to what extent—such regulatory controls govern SNAs.

Law is a core component of biosecurity because it establishes the authority, obligations, and enforcement mechanisms needed to prevent, detect, prepare for, and respond to biological threats. Yet the role of law in managing the biosecurity risks associated with SNA remains underexamined in both scholarship and policy. It remains unclear whether existing international and national biosecurity laws apply to SNAs, how comprehensively they do so, and where regulatory gaps remain. Voluntary screening standards can improve practice, but they cannot substitute clear, legally binding obligations governing the management of SNA-related biosecurity risks.

Against this background, this report maps the international and national biosecurity legal frameworks most relevant to SNAs, assesses their scope and application, identifies regulatory gaps, and proposes reforms. It finds that most existing biosecurity laws were designed for an earlier technological era. As a result, their scope generally extends only to whole and/or naturally occurring pathogens or, at best, is sufficiently ambiguous that it could potentially be interpreted to cover SNAs, without doing so expressly. As a result, controls that restrict access to dangerous pathogens may be circumvented through the acquisition of synthetic components capable of recreating them. Novel sequences of concern and shorter genetic fragments also fall outside existing legal oversight.

The report therefore calls for the adaptation of biosecurity law. This does not require a new legal paradigm. Rather, it requires extending established principles governing dangerous pathogens to the synthetic components and technologies now capable of producing them.

This is the first of two reports produced under the Biosecurity Law in the Age of Synthetic Nucleic Acids Project at the Asia Centre for Health Security. This report, Report 1, examines how existing legal frameworks should be adapted for the synthetic biology era. Report 2 focuses specifically on international and national regulatory approaches to nucleic acid synthesis screening.

Context and Risk

SNAs have become a foundational technology of the modern bioeconomy, enabling the artificial production of DNA and RNA directly from digital sequence data. Their applications span health, agriculture, environmental management, and industrial biotechnology. Governments worldwide are integrating synthetic biology into national bioeconomy strategies. As costs fall and access expands, SNAs are becoming a key technology for the life sciences.

The same features that make SNAs transformative – create biosecurity risks. DNA synthesis technology enables the recreation of dangerous pathogens from publicly available sequence data — a risk that is no longer theoretical. Scientists have already demonstrated the synthesis of poliovirus, the 1918 influenza virus, and horsepox from publicly available information. Access to dangerous sequences has proven alarmingly easy: in 2006, a journalist successfully ordered a smallpox genome fragment to a private address. In 2024, researchers from the Massachusetts Institute of Technology (MIT) replicated the exercise with fragments of the 1918 influenza virus.

Four converging developments are increasing biosecurity risks.

1	Barriers to access are falling: online ordering, open genomic databases, declining synthesis costs, and the growing availability of benchtop synthesis devices are collectively easing access.
2	The integration of AI into biological design lowers the skill threshold for misuse and raises the ceiling of potential harm. AI-assisted tools can generate novel, functionally dangerous sequences that do not appear on any regulated list and may evade existing screening tools.
3	Sequences of concern—genetic sequences capable of contributing to pathogenicity or toxicity regardless of their correspondence to any known or listed agent—present a fundamental challenge to list-based regulatory models. No universal consensus exists on how to identify unknown sequences of concern, and AI-generated sequences can outpace any static cataloguing approach.
4	The ability to assemble dangerous constructs from shorter fragments across multiple providers creates an evasion pathway through order splitting.

The International Legal Landscape

Four binding international instruments form the legal foundation for biosecurity governance as it applies to SNAs:

- Biological Weapons Convention (BWC)
- UN Security Council Resolution 1540 (UNSCR 1540)
- International Health Regulations (IHR)
- WHO Pandemic Agreement (if it comes into force)

None explicitly mentions synthetic biology, but a strong argument—grounded in established principles of treaty interpretation—supports the argument that all four extend to SNAs and impose duties on states to prevent their misuse. SNA biosecurity is also governed by legally non-binding guidance:

- The WHO Global Guidance Framework for the Responsible Use of the Life Sciences. It provides authoritative, if non-binding, guidance which encourages stakeholders to implement sequence and customer screening.
- The WHO Laboratory Biosecurity Guidance. The Guidance categorises SNAs as material that requires biosecurity oversight.

The BWC prohibits biological weapons "whatever their origin or method of production" (Article I) — language that encompasses synthetically produced biological agents. Its technology-neutral character, reinforced by Article XII's requirement for periodic review in light of scientific and technological developments, confirms that the Convention was designed to remain current. Article IV's requirement that States take all "necessary measures" to prevent misuse should, in today's technological environment, be interpreted as requiring States to adopt national oversight of SNAs, including modernisation of biosecurity regulations and screening measures. What constituted necessary and effective implementation decades ago is no longer adequate.

UNSCR 1540 similarly requires all UN member states to adopt effective domestic controls preventing the proliferation of biological weapons and related materials (Article 3) to non-state actors — obligations that reasonably extend to the materials and technologies enabling SNA production.

The IHR's broad mandate to prevent the international spread of disease "irrespective of origin or source", (Article 1) together with its core capacity requirements (Articles 5, 13) and the IHR Monitoring and Evaluation Framework, supports the interpretation that states should establish preventive capacities addressing SNA risks.

The Pandemic Agreement, adopted in May 2025 and not yet in force, deliberately avoids distinguishing between natural and man-made pandemic sources, bringing synthetic biology squarely within its prevention obligations.

Read together, these instruments arguably require states to exercise effective domestic oversight over SNAs. The principal challenge lies not in the absence of legal obligations but in their interpretation and implementation.

Recommendations

- A new multilateral binding treaty focused on synthetic biology is neither required nor advisable as a new multilateral treaty would be slow to negotiate. The existing legal architecture already provides the necessary framework.
- States could pursue soft-law and interpretative tools that modernise existing frameworks without reopening treaty negotiations. Under the BWC, state parties could use the Review Conference (under Article XII) to clarify that the Convention continues to apply to relevant scientific and technological developments and activities involving SNAs. The Working Group on the Strengthening of the Convention (established under the 9th Review Conference)—and, if established, the proposed Science and Technology Advisory Mechanism—could develop recommendations and technical analysis to inform such clarifications. The Review Conference could further agree or recommend that state parties should review and, where necessary, modernise their national implementation measures to address risks arising from SNAs. Within the WHO, guidance could be adopted through the IHR's monitoring and evaluation frameworks, including the Self-Assessment Annual Report (SPAR) and the Joint External Evaluation (JEE) and, once established, the Conference of the Parties to the WHO Pandemic Agreement.
- Although these treaties lack or have weak enforcement mechanisms, they carry significant normative and reputational force: clarifying their interpretation could generate political pressure needed to drive national action.
- That said, an option worth considering would be a treaty that includes synthetic biology but also extends beyond it to encompass other emerging biotechnologies that raise transnational governance challenges and require international coordination, including mirror biology, genome editing, and AI-enabled life science applications.
- Additional international alignment strategies beyond multilateral settings are addressed in detail in Report 2.

International Legal Frameworks Governing SNAs

Instrument	Scope / SNA Coverage	Key Obligations	Gaps / Limitations	Recommendation
Biological Weapons Convention (BWC) **Binding on state parties**	Covers biological agents 'whatever their origin or method of production'. Technology-neutral. Applies to synthetically produced agents through interpretation.	Art. I: No development, production, or retention of bioweapons. Art. III: No transfer. Art. IV: States must enact domestic measures to prevent misuse.	No explicit mention of SNA. No verification or enforcement mechanism. Art. IV obligations have not kept pace with technological change.	BWC Review Conferences / Working Group / Science and Technology Advisory Mechanism should clarify that Art. IV requires states to modernise biosecurity laws and rules to prevent SNA-related biological weapons risks.
UNSCR 1540 **Binding on all UN members**	Addresses Weapons of Mass Destruction (WMD) and non-state actors. Synthetic biological agents fall within its scope through interpretation.	Article 3: Requires domestic controls over manufacture, acquisition, and transfer of biological weapons and related materials.	No mention of SNAs.	The 1540 Committee could clarify that effective domestic controls include SNA oversight. Capacity-building support should include assistance for modernisation of biosecurity frameworks.

Instrument	Scope / SNA Coverage	Key Obligations	Gaps / Limitations	Recommendation
International Health Regulations (IHR) **Binding on state parties**	Applies to public health concerns 'irrespective of origin or source', interpreted to include risks from SNAs.	Articles 1, 5, 13 and Annex 1: States develop and maintain capacities to prevent, detect, and respond to public health events. JEE and SPAR assess biosafety and biosecurity as core capacities.	No explicit mention of SNAs. JEE and SPAR do not include synthesis screening as an evaluated capacity.	Update the IHR MEF, including SPAR and JEE frameworks to include SNA oversight and synthesis screening indicators as a core element of biosecurity evaluation.
WHO Pandemic Agreement (2025) **Binding (adopted but not yet in force)**	Does not distinguish between natural and man-made pandemic sources. SNA-related risks arguably fall within prevention obligations.	Art. 4: States must develop capacities to prevent emergence of infectious diseases and manage biological risks. Art. 4(2)(i): Requires lab risk-management systems, including biosecurity training.	No explicit mention of SNAs. Implementation bodies not yet established.	Conference of Parties and implementation bodies could explicitly address SNAs and call for modernisation of national biosecurity laws to address SNA-related pandemic risks.
WHO Global Guidance Framework (Dual-Use) **Legally non-binding**	Recognises DNA synthesis as a biosecurity risk.	Recommends that member states develop national biorisk governance policies addressing dual-use research, including oversight of commercial synthesis providers. Recommends that synthesis providers implement sequence screening for sequences of concern and verify customer legitimacy before fulfilling high-risk orders.	Legally non-binding; no enforcement. No obligation on states to require private sector compliance.	States could translate guidance into national requirements.
WHO Laboratory Biosecurity Guidance (2024)	Categorises SNAs as biosecurity relevant materials.	Section 4.2.2 requires the Institutional Biosafety Committee to review protocols before work begins and, for research involving genetic modification or gene expression, to ensure that the protocol states the exact nucleic acid sequences used. Section 3.2 highlights the biosecurity risks posed by DNA synthesis and desktop synthesisers and calls for commercial sequence screening. Section 8.1.5 encourages national regulatory bodies to establish a national inventory that tracks DNA synthesisers. Regulators are urged to oversee projects utilising this equipment and require institutions to track its usage and output.	Legally non-binding; no enforcement.	States could translate the guidance into national requirements.

National Biosecurity Legal Frameworks

This report draws on the Global Health Security Index and a comparative review of more than 12 jurisdictions across the United States, Europe, and Asia. It examines the principal biosecurity regulatory regimes that may apply to SNAs, including select-agent laws, export controls, non-proliferation and counterterrorism legislation, Dual-Use Research of Concern (DURC) frameworks, Genetically Modified Organisms (GMO) laws, and laboratory biosafety or biosecurity requirements.

It finds that national biosecurity regulatory regimes are fragmented and uneven between countries as well as within jurisdictions. While many countries lack biosecurity regulatory regimes, others maintain extensive controls over dangerous biological agents and toxins.

A central question is whether these existing regulatory frameworks extend to SNAs. Most were adopted before the emergence of synthetic biology. Where SNAs fall within the scope of existing laws, established strict controls—such as licensing, access restrictions, transfer requirements, oversight, and enforcement—may apply. Where they do not, SNAs capable of reconstructing or contributing to regulated biological agents may escape controls that have governed those agents for decades. Assessing and closing these gaps is therefore central to adapting national biosecurity frameworks for the synthetic biology and AI-bio era.

Select agent laws are the main domestic mechanism for controlling access to dangerous biological agents and toxins. They typically establish stringent controls governing their possession, use, storage, transfer, transport, and disposal.

Three regulatory approaches emerge across jurisdictions.

1	**Traditional frameworks:** Define the biological agents, toxins, and biological materials subject to regulation by reference to natural and/or whole biological agents and toxins. The schedules list pathogens. As a result, SNAs fall outside the statutory definitions and schedules and therefore escape regulatory controls.
2	**Ambiguous frameworks:** Define covered biological agents, toxins, and biological materials as including biological "components" which are "capable of causing disease". Because this threshold is neither scientifically nor legally defined, the application of controls to SNAs remains uncertain. This is further complicated by the fact that the schedules commonly list pathogens but do not list nucleic acids.
3	**Express frameworks:** Define regulated biological agents, toxins, or covered biological materials to expressly include SNAs. In practice, this means that SNAs are subject to regulatory controls. Even these more advanced frameworks, however, often capture only a narrow subset of SNAs as their schedules commonly list genetic elements of listed pathogens. They, therefore, may not address sequences of concern or shorter fragments.

Recommendations:

Statutory definitions of "biological agents", "toxins", and related biological materials should be updated to expressly cover SNAs, with corresponding schedules revised to include relevant categories of SNAs.

Because select-agent laws impose extensive controls on possession, use, transfer, storage, and disposal, applying the full regime to all SNAs would be disproportionate. Instead, regulation should adopt a tiered, risk-based framework that calibrates oversight to the functional risk posed by different categories of sequences. They should also include a judgement-based catch-all provision to capture high-risk sequences that fall outside predefined schedules.

Select Agent Laws: Three Approaches to SNA Coverage

Approach	Definition of Biological Agent	SNA Explicitly Covered?	Schedules Include Genetic Elements?	Example Jurisdictions	Regulatory Gap
Traditional	Limited to whole, naturally occurring pathogens and toxins. No reference to genetic material, nucleic acids, or synthetic components. Example (Indonesia): 'a virus, bacteria, fungus, or parasite, either living or dead, that can cause a disease.'	No	No	Australia (Security Sensitive Biological Agents [SSBA] Scheme) India (Hazardous Microorganisms Rules) Indonesia (Health Law)	SNAs fall entirely outside statutory definitions. No licensing, transfer controls, or screening obligations apply to SNAs.
Ambiguous	Extends to whole pathogens and their 'components … capable of causing disease or biological malfunction.' Functionality test introduced. Example (Singapore Biological Agents and Toxins Act [BATA]): 'any microorganism, infectious substance, or any component … capable of causing death, disease, or other biological malfunction in a human.'	No (implied only)	No	Singapore (BATA) Thailand (Pathogens and Toxins Act) Canada Human Pathogens and Toxins Act German Infektions-schutzgesetz	Implicit coverage of SNA. No authoritative guidance clarifies which SNAs meet the functionality threshold. Operative schedules do not list genetic elements. Significant legal uncertainty persists.
Express	Expressly includes SNAs. Example (U.S.): 'any … naturally occurring, bioengineered, or synthesised component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction.'	Yes	Yes (for select agents only)	United States (42 CFR Part 73; 18 U.S.C. §178 + FSAP Guidance) France (Ministerial Order 2023, with size/function thresholds) United Kingdom (Anti-terrorism, Crime and Security Act [ATCSA] 2001, Sch. 5) Indonesia (MOH Reg. 85/2020 — RNA/DNA sequences) Australia (Biosecurity Act 2015 — import permit for nucleic acids)	Coverage remains limited to SNA linked to listed pathogens meeting defined functional criteria. Sequences of concern, novel/AI-generated sequences, and shorter assembled fragments are not captured. Benchtop devices escape oversight.

Export controls — particularly those aligned with the Australia Group Common Control Lists (AG CCL)—provide the most legally robust existing basis for SNA oversight. The AG CCL expressly covers genetic elements, including SNAs that encode genes specific to listed pathogens and could endow or enhance pathogenicity. This scope exceeds that of most select agent laws and creates a de facto screening obligation for exporting providers.

Yet, this produces a structural asymmetry: international transfers to non-AG member states may be controlled while equivalent domestic transactions (and exports to AG member states) remain potentially unregulated, creating the opportunity for regulatory arbitrage. While the policy objectives of select agent laws and export control regimes differ and may justify variations in the

scope of controlled sequences, the relationship between these frameworks and the appropriate degree of alignment between them warrant further examination. Export controls also leave significant gaps for sequences of concern (SOC) not derived from listed pathogens, and the 1.5 kb threshold means benchtop devices fall within AG controls only for longer sequences.

Recommendations:

- The scope of genetic elements controls should be clarified and expanded to cover SOC under a tiered, risk-based framework.
- The divergence between select agent laws and export controls should be systematically assessed.
- Benchtop devices should be subject to periodic review as synthesis lengths evolve.
- Export licence conditions regarding benchtop devices could potentially impose downstream oversight obligations, including post-shipment end-user and end-use verification or monitoring programmes, that create continuous oversight after the export.

Counter-terrorism and non-proliferation laws criminalise the development, acquisition, or possession of biological weapons and related materials. Most jurisdictions do not expressly mention SNAs. The definition of biological weapon in these statutes, which usually directly implement the BWC, is similar to that of the BWC with references to biological weapons "whatever their origin". This means SNAs are likely to be covered if their intended end-use is non-peaceful, but in almost all cases this is left implicit, creating uncertainty. The clearest exception is the United Kingdom's Anti-terrorism, Crime and Security Act (ATCSA) 2001, Schedule 5, which expressly covers nucleic acids—whether synthetic or naturally derived—that encode infectious or replication-competent forms of listed pathogens, or that enhance an organism's capacity to cause harm. As with other frameworks, coverage in this category remains tied to listed pathogens and does not extend to SOC. These laws would need to be aligned, too.

Dual-use research of concern (DURC) frameworks govern research that has the potential to be misused to cause harm. Many countries lack DURC rules altogether. Where they do exist, they generally follow traditional whole-agent approaches or apply only ambiguously to SNAs, as under Singapore's BATA. In contrast, the 2026 U.S. Government Policy for Stopping High-Risk Life Sciences Research can apply to qualifying research involving SNAs. Even here, however, coverage remains limited: the framework does not extend to sequences of concern or shorter SNA fragments. DURC frameworks should therefore be adopted and/or updated to ensure that research involving functionally concerning SNAs is captured where it could reasonably be expected to contribute to harmful outcomes.

Genetically modified organism (GMO) laws may regulate SNAs once they are incorporated into a biological entity and result in a genetically modified organism. They are therefore relevant to certain downstream uses of SNAs, but generally do not regulate access to, possession of, or transfer of isolated SNAs themselves. GMO frameworks are thus an important but downstream component of the broader legal landscape governing SNA-related biosecurity risks.

Order screening guidance remains the exception rather than the rule. Only two countries—the U.S. and the U.K—have adopted governmental screening guidance. The 2023 U.S. Department of Health and Human Services (HHS) Guidance updated the 2010 HHS Screening Guidance to address SOC, shorter sequences down to 50 nucleotides, and benchtop devices, and extended obligations to manufacturers and end users. The 2024 U.K. guidance similarly covers providers, users, and benchtop manufacturers. Legislative proposals in the European Union, New Zealand, the U.K, and the U.S. seek to introduce mandatory screening requirements, but none have been enacted. In all other jurisdictions, screening remains unaddressed. Screening is addressed in detail in Report 2.

The overarching recommendations are targeted modernisation across five dimensions:

1. Establishing baseline frameworks in low- and middle-income countries (LMICs)
2. Adapting definitions of "biological agents" and schedules to expressly cover SNAs
3. Extending coverage to SOC and shorter fragments through tiered, risk-based frameworks supplemented by judgement-based catch-all provisions
4. Systematically assessing the asymmetry between export controls and select agent law
5. Adopting screening requirements as part of any regulatory modernisation effort. The available regulatory approaches for screening are addressed in detail in Report 2.

National Legal Frameworks Governing SNAs.

Framework	Legal Nature	SNA Coverage	Key Obligations	Gaps / Limitations	Recommendation
BIOSAFETY & BIOSECURITY: CORE FRAMEWORKS					
Select Agent Laws	National (binding)	Varies by jurisdiction. Three approaches: (1) traditional — no SNA; (2) ambiguous — 'components capable of causing disease'; (3) express — explicit SNA inclusion. Even express frameworks cover only SNAs linked to listed pathogens.	Licensing, registration, access controls, biosafety/biosecurity plans, record-keeping. Transfers only between licensed entities in certified facilities.	Most jurisdictions exclude SNAs entirely. Ambiguous definitions create legal uncertainty. Operative schedules rarely list genetic elements. Sequences of concern, shorter fragments, and benchtop devices are not covered in most jurisdictions.	Modernise definitions and schedules; adopt tiered, risk-based approach; extend coverage to SOC and fragments; require benchtop device registration; introduce screening requirements.
Export Control Laws (Australia Group CCLs)	National (binding); multilateral harmonisation through Australia Group (~70 states)	Expressly cover 'genetic elements' — chromosomes, plasmids, vectors, transposons, recoverable nucleic acid fragments, whether genetically modified or chemically synthesised — coding for listed pathogen genes that represent a significant hazard or endow/enhance pathogenicity. Broader scope than most select agent laws.	Transaction-specific export licences required before cross-border transfer of controlled items to specified end-users for specified end-uses. Providers assess whether sequences match listed pathogen genes and whether function endows pathogenicity.	Controls apply only to cross-border transfers; intra-AG transfers and all domestic sales are unregulated. No coverage of de novo sequences, AI-generated sequences, unlisted SOC. Most jurisdictions lack dedicated SNA screening guidance. Catch-all provisions exist but are insufficient for systematic oversight.	Clarify scope of 'genetic elements' at AG level; adopt tiered risk framework for SOC; introduce supporting screening guidance; align with domestic select agent regimes; attach end-use conditions to benchtop device export licences.

Framework	Legal Nature	SNA Coverage	Key Obligations	Gaps / Limitations	Recommendation
Counter-Terrorism / Non-Proliferation Laws	National (binding)	Generally implicit; application to SNA arises through broad language (e.g., 'components of biological weapons', 'whatever their origin') and link to the BWC. U.K. ATCSA 2001 Sch. 5 is the clearest express example: covers nucleic acids encoding infectious/ replication-competent forms of listed pathogens or altering pathogenicity.	Criminalise development, acquisition, transfer, or use of biological weapons and related materials. May impose notification duties and due-diligence obligations on providers. U.K.: Secretary of State notification required for listed SNAs.	SNAs not explicitly mentioned in most jurisdictions. Coverage, where inferred, is limited to SNAs linked to listed pathogens. SOC not captured. Modernisation needed in parallel with other frameworks.	Expressly extend counter-terrorism and anti-proliferation laws to SNAs; clarify due-diligence standards for providers; address SOC beyond listed pathogen linkage.
COMPLEMENTARY FRAMEWORKS					
Dual-Use Research of Concern (DURC) Policies	National (varies; often institutional/policy-based)	Applies where research meets DURC thresholds (e.g., enhances pathogenicity) and where scope covers SNAs.	Institutional review, risk–benefit assessment, risk mitigation planning during research projects.	Many countries lack dedicated DURC rules. Frameworks do not govern procurement of SNAs or mandate screening of providers. Centre of gravity is research conduct, not material access.	Ensure DURC policies also capture research that involves high-risk SNAs.
GMO Laws	National (binding)	Applies only once SNAs are incorporated into a living organism. Standalone SNA falls outside the scope unless it constitues a full-length viral genome copy.	Risk assessment, authorisation, containment, labelling, and monitoring obligations for GMOs.	Does not govern SNA synthesis, access, or transfer as such. Mitigates downstream risks only.	
Laboratory Biosafety Rules	National (binding)	Governs safe handling, storage, use, and disposal of biological materials. Primarily protects personnel and environment.	Biosafety-level containment requirements, handling, and disposal protocols.	Biosafety focus; does not address biosecurity or dual-use risks.	Adopt Laboratory Biosecurity Rules.
Medicinal Products Laws	National (binding)	Regulates development, authorisation, manufacture, and distribution of medicines.	Safety, quality, and efficacy obligations through regulatory approval processes.	Not designed to address biosecurity risks of SNAs. Applies only in pharmaceutical/ medicinal context.	
GOVERNMENTAL SCREENING GUIDANCE					
U.S. HHS Screening Guidance (2010, revised 2023)	Non-binding guidance; supports compliance with select agent and export control laws	2010: whole sequences screened against Federal Select Agent Program (FSAP) and CCL lists. 2023: extended to SOC, shorter sequences (≥50 nt by 2026), RNA, benchtop devices, and end users.	Sequence and customer screening by providers; record-keeping by end users; benchtop manufacturers should screen customers and monitor use.	Non-binding; compliance is voluntary. Screening methods and databases for SOC still developing.	Adopt binding screening requirements.
U.K. Screening Guidance (Department for Science, Innovation and Technology [DSIT]. 2024)	Non-binding guidance; supports implementation of ATCSA 2001 and related laws	Covers providers, users, and benchtop equipment in the U.K. Recommends built-in screening functionalities for benchtop devices.	Sequence and customer screening; benchtop devices distributed only to legitimate users.	Non-binding. No mandatory legal requirement to screen.	Adopt binding screening requirements.

Private Governance: Screening Standards

In the absence of comprehensive governmental regulation, private governance has emerged as the principal framework for setting screening standards for SNAs. These instruments—issued by industry bodies, international standard-setting organisations, non-governmental organisations (NGOs), and scientific communities—are non-binding and lack legal enforceability, but create expectations of compliance and impose reputational and market-based accountability on participating members. Four broad approaches can be distinguished.

Industry standards: The most significant private instrument is the Harmonized Screening Protocol, developed by the International Gene Synthesis Consortium (IGSC) and most recently updated in its 3.1 version in 2026. Membership of the IGSC creates de facto compliance obligations through market and reputational mechanisms. In practice, however, implementation varies significantly across members, and large segments of the market—including non-IGSC providers—fall entirely outside its scope. Voluntary, membership-based standards are not a sufficient governance model for risks of this magnitude.

ISO standards: In 2024, the International Organization for Standardization (ISO) issued ISO 20688-2 on nucleic acid synthesis. It requires producers to implement biorisk management systems, including sequence and customer screening protocols, and states that producers should use a DNA sequence screening mechanism to prevent intentional or inadvertent misuse of synthesis technologies. A complementary ISO standard specifically covering benchtop devices is under development.

Civil society standards: The Engineering Biology Research Consortium is developing international screening best practices.

Scientific community: Within the scientific community, self-regulatory initiatives have emerged, including the Guiding Principles on Responsible Use of AI for Protein Design and the International Genetically Engineered Machine Foundation (iGEM)'s responsible synthetic biology guidelines. At the subnational level, California's AB 1963 requires the California State University (CSU) system to develop guidance on procuring gene synthesis products from providers that mitigate misuse risks, and the resulting University of California (UC) guidance recommends that purchasers verify that providers meet IGSC criteria or equivalent safeguards before placing orders.

Taken together, these private instruments have made a meaningful contribution to biosecurity culture and have driven practice in the absence of governmental mandates. They remain, however, structurally insufficient: they are voluntary, bind only willing participants, lack enforcement mechanisms, and leave non-members entirely unregulated. Moreover, they only address screening at the point of acquisition o production, while other controls across the SNA lifecycle remain unaddressed. Private governance has, thus, only filled part of the gap. Translating these screening standards into legally binding screening requirements is a necessary next step. Report 2 examines the regulatory approaches available to governments.

Private Standards

Instrument	Issuing Body	Type	Binding?	SNA / Screening Coverage	Key Requirements	Limitations
1. INDUSTRY STANDARDS						
IGSC Harmonized Screening Protocol (v1: 2009; v3: 2023, v. 3.1: 2026)	International Gene Synthesis Consortium (IGSC) Industry association of major providers	Industry protocol	No (membership condition only)	Sequence and customer screening for orders of SNAs. Updated in 2023 to address emerging risks.	Members should comply as a condition of IGSC membership. Creates de facto obligations through market and reputational mechanisms.	Applies only to IGSC members; significant market segments remain outside scope. No external enforcement; implementation varies widely among members. Voluntary, membership-based model insufficient as a standalone governance mechanism given high-consequence risks.
2. INTERNATIONAL STANDARD-SETTING ORGANISATION STANDARDS						
ISO 20688-2: Biotechnology — Nucleic Acid Synthesis, Part 2 (2024)	International Organization for Standardization (ISO)	International technical standard	No (voluntary adoption)	Covers production and quality control of synthetic gene fragments, genes, and genomes. Includes explicit biosafety and biosecurity requirements, including sequence and customer screening protocols. A companion standard specific to benchtop devices is under development.	Producers should implement biorisk management, including sequence and customer screening. Expressly requires providers to use a DNA sequence screening mechanism to prevent intentional or inadvertent misuse. Aimed at SNA producers, academic labs, and other users evaluating SNA quality.	Non-binding; adoption is voluntary. Primarily a quality and production standard; biosecurity requirements are embedded but not the central focus. Benchtop device standard not yet finalised.
3. NGO STANDARDS						
International Screening Best Practices (in development)	Engineering Biology Research Consortium (EBRC) Non-profit organisation	NGO guidance	No	Developing international best practices for screening of SNAs.	Best practices for sequence and customer screening across providers and users.	Still under development; not yet finalised or publicly released. Non-binding; no enforcement mechanism.
4. USER AND SCIENTIFIC COMMUNITY SELF-REGULATION						
Guiding Principles on Responsible Use of AI for Protein Design	Scientific community / multi-stakeholder	Voluntary principles	No	Commitments to procure synthetic sequences only from providers that conduct screening.	Researchers commit to use only screened providers. Extends biosecurity expectations upstream to procurement decisions.	Voluntary; relies on individual researcher commitment. No monitoring or enforcement mechanism.

Instrument	Issuing Body	Type	Binding?	SNA / Screening Coverage	Key Requirements	Limitations
Responsible Synthetic Biology Guidelines	iGEM Foundation (International Genetically Engineered Machine Foundation)	Voluntary guidelines	No	Guidelines on responsible synthetic biology practices, including screening expectations.	Community-level standards for biosafety and biosecurity in synthetic biology projects.	Applies primarily to iGEM community participants. Voluntary; no legal force.
California AB 1963 (2022) + University of California (UC) Procurement Guidance	State of California (AB 1963); UC (implementing guidance)	State law (requires guidance) + institutional policy	Partial (AB 1963 requires California State University (CSU) guidance; UC guidance voluntary)	Requires CSU to develop guidance on procuring gene synthesis equipment and products from providers that mitigate misuse risks. UC guidance recommends procuring only from providers meeting IGSC criteria or equivalent safeguards.	Purchasers — researchers, lab managers, procurement officers— should ensure providers meet IGSC criteria or equivalent before placing orders. Extends screening expectations to institutional procurement decisions.	AB 1963 requires CSU guidance but only encourages UC adoption; not mandatory for the UC system. Applies only within California. Relies on IGSC criteria as the benchmark, inheriting the limitations of that voluntary framework.

Conclusion and Recommendations

SNAs present both extraordinary opportunity and growing risk. The capabilities driving innovation—rapid synthesis from digital sequences, falling costs, decentralised production, and AI-enabled biological design—simultaneously lower barriers to deliberate misuse and expand the threat landscape beyond what existing governance systems were built to address. The legal frameworks meant to govern these risks are lagging behind: designed for an earlier era of biology organised around natural or whole pathogens, they fail, with few exceptions, to regulate SNAs expressly at all. Where coverage exists, it is either ambiguous or narrow and structurally misaligned with emerging risks including SOC, AI-generated sequences, fragment assembly, and benchtop synthesis devices. Private governance has partially filled this gap, but voluntary, membership-based standards are not sufficient for risks of this magnitude. Moreover, private standards have only focused on screening, while all other aspects of SNA control have remained largely unaddressed by private governance.

On international law, the report finds that no new treaty is required. The BWC, UNSCR 1540, the IHR, and the Pandemic Agreement (once it comes into force) already provide the necessary legal foundation, each applying to SNAs under established principles of treaty interpretation. The principal deficit is one of interpretation and implementation, not legal authority. Under the BWC, states parties could use the Review Conference to adopt agreed understandings, informed by recommendations from the Working Group on the Strengthening of the Convention and, if established, the Science and Technology Advisory Mechanism. Complementary action could be pursued through the UNSCR 1540 Committee, updates to the IHR Monitoring and Evaluation Framework (IMF MEF), including SPAR and JEE, and, once established, the Conference of the Parties to the WHO Pandemic Agreement. Regarding other international strategies, see Report 2.

Recommendations

- Soft-law tools can modernise existing frameworks without reopening treaty negotiations.
- Pathways to international harmonised screening rules are addressed in Report 2.

On national law, the regulatory landscape is fragmented and uneven, both across and within jurisdictions. Many LMICs lack dedicated biosecurity regulatory frameworks. Among countries that do regulate biological agents and toxins, three broad approaches emerge: traditional, ambiguous, and express. Traditional frameworks exclude SNAs, while ambiguous frameworks may capture some SNAs only through statutory interpretation. Even the most advanced express frameworks remain limited in scope and often fail to address SOC and shorter fragments. Regulatory fragmentation also exists within countries, where export control regimes may cover categories of genetic material that fall outside domestic select-agent and other relevant biosecurity laws.

The central finding of this report is that the current global legal architecture is structurally insufficient to govern the biosecurity risks posed by SNAs. Modernisation reform is required across international instruments, national laws, screening obligations, and baseline frameworks in underregulated jurisdictions. This report provides the legal and regulatory roadmap for that reform. National regulatory approaches to screening measures are addressed in Report 2.

The report sets out **ten recommendations** for national reform, which can be grouped into four priorities.

1	**Baseline frameworks** should be established in LMICs, supported by international technical and financial assistance.
2	**Select agent laws and export control regimes and other applicable laws** should be modernised in coordination to expressly cover SNAs, extended to SOC and shorter fragments, and supplemented by tiered, risk-based frameworks that calibrate oversight to functional sequence risk through structured lists and residual judgement-based catch-all provisions. They should also cover benchtop devices.
3	**Screening requirements** should be adopted in support of any regulatory modernisation: screening is the only practical mechanism by which providers can determine whether orders contain regulated sequences, and it is currently required in only two jurisdictions. Report 2 elaborates on regulatory approaches to screening.
4	**Private governance instruments**—the IGSC protocol, ISO 20688-2, and community-led procurement initiatives—should inform binding legal requirements rather than substitute for them. Governments should translate voluntary best practice into enforceable law.

Key Takeaways

The following key takeaways summarise the report's principal findings across all sections.

1 The global biosecurity regulatory landscape is fundamentally misaligned with emerging biotechnology. Existing biosecurity rules were designed for natural and/or whole biological agents and toxins. SNAs—and in particular, SOC, shorter fragments, and benchtop-synthesisers—fall outside or only partially within the scope of most existing legal frameworks. This is a structural deficiency across the majority of jurisdictions examined. The consequence of this gap is significant: While access to dangerous pathogens has traditionally been tightly controlled, such controls can now be legally circumvented by reconstructing pathogens from SNAs.

2 Many jurisdictions—particularly LMICs—lack domestic biosecurity regulations altogether. Because actors can exploit jurisdictional arbitrage, the effectiveness of advanced national regimes depends on the strength of the weakest regulated jurisdiction. Establishing baseline legal frameworks in LMICs should, therefore, be a global biosecurity priority.

3 The existing international legal framework provides a sufficient foundation—but requires urgent clarification and implementation. The BWC, UNSCR 1540, the IHR, and the Pandemic Agreement each apply to SNAs under established principles of treaty interpretation. The principal challenge is interpretation and implementation. Treaty bodies should adopt authoritative clarifications confirming that existing obligations encompass SNAs and specify what effective domestic implementation requires.

4 Select agent laws were not designed for SNAs and should be expressly amended. Most domestic frameworks are anchored in whole or natural pathogen models. Where coverage can be inferred from vague statutory language, it rests on interpretation, generating uncertainty and likely leading to uneven compliance. Express legislative amendment or clarification is recommended across the majority of jurisdictions.

5 Coverage should extend beyond listed pathogens to SOC and shorter fragments. Even advanced domestic regimes with express frameworks capture only sequences closely linked to listed agents. Effective oversight should cover SOC and should address shorter fragments which could be reasonably assembled into harmful constructs.

6 Oversight should be tiered and risk based. SNAs are not functionally equivalent to the pathogens to which they relate, and the stringent access, possession, use, transfer, and export controls applicable to select agents will not necessarily be justified for all corresponding SNAs. Extending the full suite of such controls indiscriminately to SNAs would therefore be disproportionate and could unnecessarily impede legitimate research and innovation. Reform should instead calibrate both the scope and stringency of oversight to the level of functional sequence risk, using tier-based lists supplemented by residual catch-all provisions. Higher-risk SNAs may warrant controls approaching those applicable to the corresponding pathogen, while lower-risk sequences may justify more limited safeguards. Developing scientifically robust criteria for both assigning SNAs to risk tiers and determining the appropriate controls for each tier is an urgent task for policymakers.

7 Export controls are currently the most legally robust layer of SNA oversight—but their reach is structurally limited. Through Australia Group-aligned frameworks, many states regulate cross-border transfers of specified genetic elements more broadly than most domestic select agent regimes. However, export controls apply only to international transfers to non-AG members, do not govern domestic sales or use, and leave significant gaps with respect to SOC not derived from listed pathogens. The resulting asymmetry creates regulatory arbitrage. Systematic assessment of this divergence is recommended.

8 Benchtop synthesis devices represent an emerging and largely unregulated vector of risk. AG export controls cover devices capable of synthesising sequences above 1.5 kb, but only for international transfers. Domestic sales, use, and next-generation devices remain largely outside regulatory scope. States should require domestic registration or licensing of devices, and attach conditions to export licences. Export licence conditions could impose downstream oversight obligations that require end-user and end-use monitoring after the export.

9 Screening is an essential compliance mechanism—and it is almost entirely absent from domestic law. Screening is the only practical means by which providers can determine whether an order contains a regulated sequence. Only the U.S. and the U.K. have adopted dedicated screening guidance. Without screening requirements, providers cannot realistically meet existing obligations under select agent, export control, or other laws regulating access to SNAs. Screening requirements should accompany any regulatory modernisation effort.

10 Screening standards have been set largely by non-governmental bodies—and voluntary compliance is insufficient. The principal standards governing provider behaviour have been developed by industry bodies, most notably the IGSC. These voluntary frameworks have made a meaningful contribution to biosecurity culture, but bind only willing participants, lack enforcement mechanisms, and leave non-members entirely unregulated. Governments should translate voluntary best practice into screening requirements. Report 2 sets out the regulatory approaches available for doing so.

1. Introduction

Synthetic nucleic acids (SNAs)—DNA or RNA molecules produced from digital sequence information rather than extracted from biological material—have become an important technology of the life sciences. The ability to synthesise DNA and RNA is transforming biological research, medicine, agriculture, and biotechnology. Processes that once depended on extracting genetic material from physical samples can now be completed more quickly and at lower cost through commercial synthesis services and, increasingly, benchtop synthesis devices. SNAs are now embedded throughout the global bioeconomy and feature prominently in national biotechnology strategies.

Despite the many scientific and economic benefits of SNAs, nucleic acids of pathogens can be deliberately misused to harm humans, animals, plants, or the environment, and therefore present biosecurity risks. These risks are increasing as barriers to access continue to fall. Moreover, advances in assembly techniques now make it easier to combine smaller fragments of DNA or RNA into genes. Artificial intelligence (AI) may further lower the expertise and time required to design hazardous sequences and could enable the creation of new sequences that do not correspond to known pathogens and therefore fall outside traditional list-based controls. The growing availability of benchtop synthesis devices adds another layer of risk by decentralising production and escaping oversight.

International policy responses to these risks have focused primarily on advancing nucleic acid synthesis screening by commercial providers, often referred to as DNA synthesis screening. Screening is intended to prevent potentially hazardous synthetic genetic material from being supplied to users who may misuse it. It generally involves two related processes. Sequence screening assesses whether an order contains a regulated pathogen, listed genetic element, or another sequence of concern (SOC) associated with pathogenicity or toxicity. Customer screening examines the user's legitimacy by verifying the purchaser's identity, institutional affiliation, and intended use. Together, these measures position commercial synthesis providers—and, increasingly, manufacturers of benchtop synthesis devices—as gatekeepers within the biosecurity system.

DNA synthesis screening is an important means of controlling access to SNAs. However, order screening addresses only the point of acquisition. It does not govern what happens after an SNA has been obtained, including its possession, storage, transfer, sharing, use, or disposal, or the associated security, reporting, and oversight obligations. In many countries, comparable activities involving whole or naturally occurring biological agents and toxins have long been subject to stringent legal and regulatory controls governing who may possess, use, transfer, store, or otherwise handle such materials, and under what conditions. Yet comparatively little policy or scholarly attention has been paid to whether, and to what extent, these legal and regulatory frameworks apply to SNAs.

Advances in SNA technologies make this gap increasingly consequential. Regulatory regimes designed around access to whole or natural biological agents may be circumvented where dangerous pathogens can instead be reconstructed from SNAs that fall outside, or only ambiguously within, existing controls. A person may therefore be able to obtain and use SNA sequences needed to reconstruct a regulated pathogen without triggering controls that would have applied had the pathogen itself been used, transferred or handled. It is therefore essential to determine whether, and to what extent, existing legal frameworks apply to risky SNAs and, where coverage is absent, partial, or ambiguous, how those frameworks should be adapted to address the risks posed by such materials.

This report addresses this gap. It maps the international and national legal frameworks most relevant to the biosecurity governance of SNAs, assesses their scope and application, identifies regulatory shortcomings, and proposes reforms. It focuses on biosecurity: measures aimed at preventing the ***deliberate*** misuse, theft, diversion, or unauthorised access to SNAs. It does not specifically consider biosafety, which concerns the prevention of accidental exposure to, or ***unintentional*** release of, SNAs. That being said, the two fields overlap, and many legal and regulatory measures serve both biosafety and biosecurity objectives.

Biosecurity regulatory frameworks already exist at the international and in many national jurisdictions. However, most were adopted in an earlier biotechnological era and their scope captures whole or naturally occurring pathogens. Synthetic biology and AI are thus placing increasing pressure on these frameworks. Such laws commonly strictly regulate access to dangerous pathogens while leaving access to the synthetic components needed to recreate them subject to weaker controls or no controls at all. Existing regimes also fail to capture shorter DNA or RNA fragments and novel sequences of concern that do not fall within traditional pathogen-based regulatory lists or schedules.

International and national biosecurity laws and regulation therefore require adaptation. This does not demand a new regulatory paradigm. Rather, it requires applying—through legislation, amendment, interpretation, or clarification—established oversight principles to contemporary technologies. The same rationales that have long justified controls over risky biological agents and toxins also justify proportionate controls over synthetic components capable of creating them and other sequences or fragments that present comparable risks. As biotechnology becomes more digital, synthetic, and decentralised, legal and regulatory frameworks must translate established oversight principles into clear and operational requirements suited to current technologies.

Biosecurity in the Age of SNAs Reports

This report is the first of two reports produced under the Biosecurity Law in the Age of Synthetic Nucleic Acids Project. This report (Report 1) explains the benefits and risks of SNAs and examines the current international and national legal frameworks, alongside existing forms of private governance. It analyses how these frameworks apply to SNAs, identifies their gaps and shortcomings, and sets out recommendations to modernise biosecurity regimes for the AI and synthetic biology era.

The second report (Report 2) focuses on DNA synthesis screening, international alignment of screening rules, and national regulatory tools for screening.


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2. SNAs: Innovation and Risk

SNA technologies lie at the heart of the modern biotechnology system. They enable the artificial creation of DNA and RNA strands directly from digital sequences, allowing scientists to synthesise genetic material without relying on natural samples. What once required the extraction of genetic material from biological organisms—a slow and costly process—can now be done digitally and synthetically in a matter of days. This technological leap has transformed the way biological research and innovation are conducted, making genetic synthesis faster, cheaper, and more widely accessible than ever before.[1]

2.1. Innovation and Economic Opportunity

The applications of SNAs span nearly all sectors of the bioeconomy. In health, SNAs accelerate vaccine development, enable low-cost production of synthetic insulin and therapeutic proteins, and support advances in gene and cell therapy. In agriculture and food systems, synthetic organisms are used to develop crops with improved resilience and produce food ingredients such as synthetic yeast. In the environmental and industrial domains, engineered microorganisms are being designed to degrade plastics, capture carbon, and generate sustainable biofuels and biodegradable materials.[2]

These capabilities are not just scientific breakthroughs — they are economic drivers. Many governments are integrating synthetic biology into national bioeconomy strategies or initiatives to promote innovation-led growth.[3] Recent examples include the European Union's Building the Future with Nature: Boosting Biotechnology and Biomanufacturing in the EU (2024) and the U.K.'s National Vision for Engineering Biology (2023).[4] In Asia, several governments have adopted bioeconomy strategies (Box 1). The global gene synthesis market alone is projected to exceed USD 10 billion by 2030, with the U.S., China, Japan, the U.K., and South Korea currently leading global demand.[5] As access expands and costs fall, SNAs are becoming a foundational technology for biotechnology.

Box 1: Bioeconomy Strategies in Asia

Asia's bioeconomy strategies and initiatives include China's Bioeconomy Strategy,[6] Japan's Bioeconomy Strategy (2024),[7] India's Bioeconomy report,[8] Singapore's RIE (Research, Innovation, Enterprise) Plans,[9] Malaysia's Biotechnology Policy,[10] Thailand's Bio-Circular-Green (BCG) Strategy, and more.[11]

2.2. Emerging Biosecurity Risks of Synthetic Nucleic Acids

The same features that make SNAs transformative also create new biosecurity challenges. Because SNA technology enables the synthesis of genetic material from digital sequence data, it can be misused to recreate dangerous pathogens or to enhance the harmful properties of existing ones. While DNA in itself is harmless, it can be used to create functional and potentially dangerous pathogens. Despite these clear risks, access to SNAs has often been alarmingly easy. In 2006, a Guardian journalist successfully ordered a fragment of the smallpox virus genome to a private address.[12] In 2024, researchers from the Massachusetts Institute of Technology (MIT) replicated this by ordering fragments of the 1918 influenza virus online.[13]

Recent technological and economic trends have amplified these risks by lowering barriers for malicious actors and increasing the likelihood that dangerous pathogens can be produced. As laid out below, several developments are simultaneously contributing to this outcome: the growing accessibility of synthesis technology, the integration of AI into biological design, the emergence of novel SOC that fall outside established regulatory lists, and the ability to stitch pathogens from shorter DNA or RNA fragments.[14] We examine each in turn.

2.2.1. *Lowering Barriers of Access*

Several converging technological and market trends have made it increasingly easy to obtain, produce, and assemble synthetic genetic material. Together, these developments lower barriers to access and increase the risk that individuals seeking to cause harm may obtain dangerous genetic sequences or the means to synthesise them.

Online ordering of sequences	DNA and RNA sequences can be ordered online from commercial gene synthesis providers with minimal oversight.
Open genomic databases	Repositories such as GenBank and GISAID are essential for scientific collaboration but also expose pathogen sequence data to potential exploitation.
Falling synthetic costs	Declining costs enable more laboratories and startups to access powerful synthesis capabilities.
Benchtop synthesisers	Compact devices now allow users to synthesise short DNA or RNA sequences in-house, directly on a laboratory bench, rather than ordering from commercial providers. These devices decentralise control and make it harder to monitor who is producing genetic material and for what purpose.[15]
Artificial intelligence	AI can lower barriers to biological misuse by making specialised knowledge and analytical capabilities accessible to a broader range of actors. Tasks that previously required substantial expertise, time, and institutional support may therefore become faster and easier to perform.

2.2.2. *Artificial Intelligence*

The growing integration of AI with the life sciences holds substantial promise, from accelerating the development of vaccines and therapeutics to improving surveillance over infectious disease outbreaks. At the same time, the expansion of AI-enabled tools heightens the risk of misuse, including the creation of more dangerous or transmissible sequences that are difficult to detect with current tools.[16] Two dimensions of risk are particularly salient:

Lowering the Information Barrier

Generative AI platforms can provide technical guidance on synthesis processes, lowering the skill threshold for misuse. They make it easier for individuals to access and operationalise information that could enable harm.[17]

Raising the Ceiling of Potential Harm

AI-assisted biological design tools (BDTs) go further: they could be misused to create novel pathogens or to develop sequences that enhance virulence, transmissibility, or immune evasion—including entirely new SOC that do not appear on any regulated list. While the precise timeframe remains uncertain, this form of misuse is increasingly plausible in the near term if appropriate governance and risk-mitigation measures are not put in place.[18]

These risks are not theoretical.[19] Researchers recently used such tools to design de novo viral sequences and then synthesised them into functional bacteriophages that successfully infected and killed *E. coli* in the laboratory. Microsoft researchers separately demonstrated that AI-generated sequences bypassed existing screening tools.[20]

The implications for oversight are significant. Traditional oversight has relied on listed pathogens. When AI generates new sequences that are functionally dangerous but structurally unknown, this oversight fails. The threat landscape is no longer bound by what is known and listed.

2.2.3. *Sequences of Concern*

Biosecurity regimes, particularly select agent and export control frameworks, have generally regulated pathogens through tiered systems in which legal controls are calibrated to assessed levels of risk. These regimes typically rely on schedules or control lists that classify specified viruses, bacteria and toxins into categories subject to different regulatory requirements, as discussed in later sections of this report on select agent and export control laws.

This list-based model rests on an increasingly fragile assumption: that dangerous sequences will resemble known pathogens. In practice, however, with the emergence of AI, it is now possible to produce genes, DNA, or RNA sequences that do not correspond to any regulated listed agent yet are functionally capable of causing serious harm. Sequences capable of causing harm, whether or not they correspond to any listed agent, are broadly referred to as “sequences of concern” (SOC) (Box 2).

Box 2: What Qualifies as a Sequence of Concern (SOC)?

No agreed-upon definition exists, but most approaches converge around functional risk categories such as pathogenicity, immune evasion, and transmissibility. The Framework for Nucleic Acid Synthesis Screening issued by the U.S. Office of Science and Technology Policy (OSTP) defines an SOC as a nucleotide sequence (or corresponding amino acid sequence) that is a best match to a sequence of federally regulated agents—the Biological Select Agents and Toxins List (BSAT) or the Commerce Control List (CCL)—except when the sequence is also found in an unregulated organism or toxin. The OSTP Framework instructs providers to expand this definition by 13 October 2026 to include sequences known to contribute to pathogenicity or toxicity, even when not derived from or encoding regulated biological agents.

Identifying currently unknown SOCs remains a significant scientific and technical challenge. No universal consensus exists on which sequences merit concern beyond those already catalogued. Determining which genomic regions are functionally concerning—and how to assess risk in novel sequences—remains under development.

Several policy instruments have begun to acknowledge this shift—including the U.S. Department of Health and Human Services (HHS) Screening Framework Guidance (2023),[21] the U.S. Executive Order-mandated Framework for Nucleic Acid Synthesis Screening,[22] the International Gene Synthesis Consortium (IGSC) Harmonised Screening Protocol,[23] and the EU Biotech Act proposal.[24] However, translating that recognition into technically and legally workable solutions remains a central challenge. The Sequence Biosecurity Risk Consortium (SBRC) is developing classification frameworks for SOC.[25] The White House AI Action Plan[26] and the EU Biotech Act Proposal both call for the establishment of dedicated databases. The Gene Synthesis Safety and Security Act—introduced before the U.S. Congress in 2023—proposed a public docket process for the HHS Secretary to solicit recommendations on potential SOC and update the list accordingly.[27]

Yet even well-maintained databases will face inherent limitations. They will require continuous updating, raise difficult questions of data security, and can only capture sequences that have already been identified. With AI generating novel sequences, a static cataloguing approach will always lag behind the capacity to engineer new threats. An element of expert ad hoc judgement will therefore remain essential.

This is a legal report, and resolving technical questions regarding the identification of SOC falls beyond its purpose and scope. They must nevertheless be acknowledged at the outset. Any effort to adapt existing legal frameworks for the AI-bio age will require close and continuous collaboration with scientists to determine how and which SOC should be defined and controlled.

Box 3: SOC under the EU Biotech Act Proposal

The EU Biotech Act proposal[28] defines “biotechnology products of concern” as “a limited set of biotechnology products with significant potential for misuse” (paragraph 85) and explicitly includes benchtop devices and “sequences of concern” (paragraph 87). Such sequences are to be listed in Annex I (paragraph 89). The proposal acknowledges the need to calibrate thresholds carefully: overly stringent parameters may capture more risks but at the cost of increased false positives and higher compliance burdens. Oversight obligations are therefore limited to sequences presenting the highest risk of misuse (paragraph 89).

2.2.4. *Assembly of Fragments*

A further risk arises from the ability to assemble dangerous pathogens from smaller components. Rather than ordering a complete genome, actors can request individual genes or short DNA and RNA fragments and stitch them together into functional—and potentially dangerous—pathogens. Scientific advances have made this increasingly feasible, including with sequences derived from pathogens not currently listed under select agent or export control regimes (see the discussion in later parts of this report). This capacity creates a direct evasion pathway. By splitting a dangerous sequence across multiple synthesis providers, an actor evades current oversight.[29]

2.3. Implications and Conclusion

All these developments—falling access barriers, AI-enabled biological design, the ability to generate SOCs that do not correspond to listed pathogens, the ability to assemble dangerous pathogens from fragments and benchtop devices—reveal the rising biosecurity risks posed by SNAs. Each challenge is significant on its own. In combination, they undermine oversight models in select agent and export control regimes (as elaborated in later parts of this report) built around whole and/or natural pathogens, static lists, and the assumption that biothreats correspond to known biological agents and toxins. Any effort to adapt existing legal and regulatory frameworks for the synthetic biology and the AI-bio age will have to grapple with these scientific developments.

Synthetic Nucleic Acids: Innovation and Risk

Key Takeaways

1. Converging developments—lower access barriers, AI-driven design, novel potential new SOC, fragment assembly and benchtop devices—increase SNA biosecurity risks.
2. Current frameworks (as elaborated in further sections of this report) largely rely on static pathogen lists and known-agent assumptions, which these developments collectively undermine.
3. Any meaningful legal and regulatory reform (elaborated in further sections of this report) will require collaboration with scientists and need to contend with these scientific and technical realities.



3. The Intergovernmental Legal Landscape: Current Frameworks and Gaps

The previous section established that SNAs are integral to scientific and economic innovation, yet they also introduce distinct biosecurity risks.

This section maps the international legal and regulatory frameworks governing biosecurity and defines their scope as applied to SNAs. It assesses the extent to which they address SNA-related risks, identifies gaps, and sets out recommendations for reform.

Several international legal instruments provide a strong legal foundation for biosecurity governance and pandemic prevention. Together, they make up the international legal regime for governing biosecurity and SNA:

Biological Weapons Convention[30]

UN Security Council Resolution 1540[31]

International Health Regulations[32]

The WHO Pandemic Agreement[33]

WHO Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-Use Research[34]

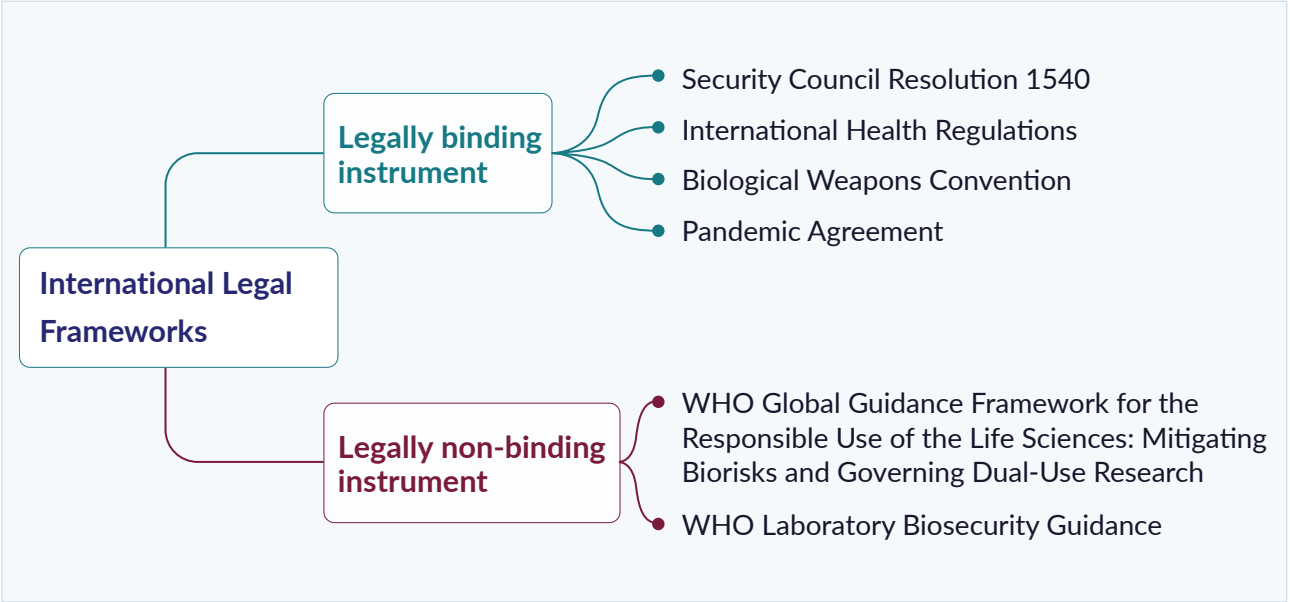
WHO Laboratory Biosecurity Guidance[35]

The first four are legally binding international agreements which set out clear legal obligations for states to prevent and control biological risks — whether natural, accidental, or deliberate. None of these major international agreements explicitly mentions synthetic biology, and this silence has contributed to uncertainty about how or whether these instruments govern SNAs.

A strong argument can be made—as set out below—that these international agreements apply to SNAs under well-established principles of treaty interpretation. However, these instruments do not provide operational clarity on how relevant stakeholders should act in practice with respect to SNAs. In contrast, the WHO Guidance Framework encourages screening by providers, and the WHO Laboratory Biosecurity Guidance recognises SNAs as material that requires biosecurity oversight. These guidance documents are, however, legally non-binding instruments.

Several additional international instruments relevant to synthetic biology fall outside the scope of this report because their primary focus is biodiversity, access and benefit-sharing, or the regulation of organisms incorporating SNAs rather than SNAs as standalone materials.

- The Cartagena Protocol on Biosafety to the Convention on Biological Diversity governs the transboundary movement of living modified organisms (LMOs). It regulates the products of synthetic biology once an SNA is incorporated into an LMO, but does not regulate SNAs as stand-alone materials.[36] Thus, the Cartagena Protocol requirements relating to the safe transfer, handling, use, and release of LMOs may be relevant at a later stage in the SNA lifecycle, once an SNA has been incorporated into an organism that qualifies as an LMO.
- The Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. Both are increasingly engaged with synthetic biology and digital sequence information, but their focus is on the conservation of biodiversity and the fair and equitable sharing of benefits from genetic resources.
- The WHO Laboratory Biosafety Manual, in turn, addresses laboratory containment.



The following sections set out these instruments in detail.

3.1. Biological Weapons Convention

3.1.1. *Overview*

The Biological Weapons Convention (BWC) is the central international treaty prohibiting biological weapons. It obliges each state party never to develop, produce, stockpile, acquire, or retain biological agents or toxins—whatever their origin or method of production—that lack justification for prophylactic, protective, or other peaceful purposes, nor weapons or delivery systems designed to use such agents for hostile purposes or armed conflict (Article I).

Under the Vienna Convention on the Law of Treaties (Articles 31–32), treaties should be interpreted in good faith in accordance with the ordinary meaning of their terms, in context, and in light of their object and purpose.[37] The object and purpose of the BWC is to prevent biological weapons, irrespective of how they are created. The explicit reference to agents "whatever their origin or method of production" confirms that synthetically produced biological agents fall within the Convention's scope, a point repeatedly reaffirmed by BWC Review Conferences, the principal periodic review decision-making forum of the BWC.[38]

This interpretation is reinforced by the technology-neutral character of international law, which applies unless a treaty expressly limits its technical scope.[39] The BWC reflects this principle not only in Article I, but also in Article XII, which requires periodic review of the Convention in light of scientific and technological developments. This provision was included precisely because states anticipated rapid advances in biotechnology.

The BWC imposes binding obligations of conduct. Article III prohibits the transfer of biological weapons to any recipient, while Article IV requires states parties to take all "necessary measures" to prohibit and prevent the development, production, acquisition, or retention of biological agents for non-peaceful purposes. These duties are implemented through national legislation.

In today's technological environment—where SNAs can be rapidly designed, ordered, and transferred—Article IV should arguably be interpreted as requiring states to adopt measures that prevent their misuse.[40] Measures that were sufficient decades ago are no longer adequate. The content of what is "necessary and effective" should evolve with the threat landscape.[41] In practice,

this requires states to adopt national rules for preventing the misuse of SNAs and could arguably be understood as requiring states to require providers to screen domestic and international orders. Failure to do so creates serious biosecurity risks and would arguably place states in breach of their BWC obligations.[42]

Within BWC meetings, conferences, and working groups, states have acknowledged synthetic biology and emerging technologies as relevant, though they have not addressed specific measures for overseeing this new technology. For example, in a recent Working Group on the Strengthening of the Convention (8-12 December 2025)—an intergovernmental body established by the Ninth Review Conference in 2022—states parties drafted recommendations stating that national implementation measures should encourage national actors or stakeholders to "uphold biosafety and biosecurity standards" in their operations.[43] Further, under its agenda to "Draft specific and effective measures, including possible legally-binding measures, to strengthen and institutionalize the Biological Weapons Convention" it has recommended "all States Parties to develop guidelines and regulations to manage the risks of possible intentional misuse of biology arising from emerging and converging technologies, such as AI, synthetic biology, and quantum computing, filling a gap not currently covered by any other international processes".[44]

3.1.2. *Recommendations*

Because SNAs capable of creating biological weapons fall within the scope of the BWC, domestic implementation measures should be updated to regulate the use, transfer, and export of SNAs. Yet, as laid out in greater detail below, most states have not addressed the biosecurity risks of nucleic acid synthesis within national laws. This regulatory gap is difficult to reconcile with a Convention that is explicitly technology-neutral and capable of governing synthetic biology.

1. It would be beneficial for the BWC institutional framework to clarify specific measures that would mitigate the risks of synthetic biology. This could be done through the Review Conference (taking place in 2027), based on the recommendations of the Working Group on the Strengthening of the Convention. In addition, discussions are currently underway on establishing a Science and Technology Advisory Mechanism which could address the application of the BWC to emerging technologies. For example, by encouraging states to adapt their biosecurity laws to adequately control the risks of SNA, and/or by adopting screening requirements for providers (see Report 2).
2. Such clarifications or declarations, even in legally non-binding form, would represent a meaningful advance in policy by translating the Convention's technology-neutral prohibitions into clearer expectations for national implementation. Although the BWC lacks formal compliance or enforcement mechanisms, it plays an important role in facilitating coordination and cooperation among states parties. Addressing these issues within the BWC would raise awareness across its membership. Clarifying the Convention's application to screening and related measures could also strengthen normative expectations and provide a forum for sharing best practices.

3.2. United Nations Security Council Resolution 1540

3.2.1. *Overview*

United Nations Security Council Resolution 1540 (UNSCR 1540) establishes a binding international legal framework to prevent the proliferation of weapons of mass destruction to non-state actors. It legally requires all UN member states to adopt and enforce effective domestic controls prohibiting the manufacture, acquisition, possession, development, transport, or transfer of nuclear, chemical, and biological weapons and related materials, as well as their means of delivery, and attempts to engage, participate as an accomplice, assist, or finance any of those activities.[45] High-risk SNAs could be understood as "related materials" enabling the production of biological materials. As such, SNAs arguably fall within the Resolution's scope.

3.2.2. *Recommendations*

The UNSCR 1540 Committee established under the Resolution could clarify that domestic controls over SNAs, including adopting or adapting biosecurity laws and/or adopting screening requirements, are needed.[46] Technical and capacity-building support provided under UNSCR 1540 could include assistance for states to establish and enforce measures to prevent misuse of SNAs, such as through the adoption of screening requirements.[47]

3.3. International Health Regulations

3.3.1. *Overview*

The purpose of the International Health Regulations (IHR)[48] is to prevent the international spread of disease,[49] and they require states to address such risks "irrespective of origin or source".[50] As this language clearly covers all risks, it should be understood to include outbreak risks that may arise from SNAs.

Further, Articles 5 and 13, together with Annex 1, require states to develop and maintain core capacities to prevent, detect, and respond to public health events. An "event" is defined broadly as "a manifestation of disease or an occurrence that creates a potential for disease".

Read together, these provisions support the interpretation that states are under an obligation to establish and maintain capacities that prevent outbreaks resulting from SNAs.

These obligations are reinforced in practice through the IHR Monitoring and Evaluation Framework, which includes an Annual Self-Assessment Reporting Tool (SPAR) and a Joint External Evaluation (JEE). These are voluntary IHR monitoring tools that assesses national capacities to prevent, detect, and respond to public health events, and set out a list of indicators that member states can self-assess under SPAR or have externally assessed under the JEE.[51] These frameworks treat biosafety and biosecurity as essential components of required core capacities, with an explicit focus on reducing dual-use risks, mitigating biological proliferation and deliberate use threats, and ensuring the safe handling and transfer of biological agents.[52] States are assessed on whether they have adopted comprehensive national biosafety and biosecurity frameworks, including biosecurity monitoring activities.

Although neither the IHR itself, nor the SPAR or JEE indicators, explicitly refer to synthetic biology, the IHR's purpose of preventing the international spread of disease—including public health events arising from deliberate biological threats, and its legally binding obligations to adopt and maintain core capacities for this purpose – are sufficiently broad to encompass measures for preventing SNA misuse.

This interpretation is reinforced by the JEE and SPAR indicators, which expressly treat biosafety and biosecurity as components of national core capacities.

3.3.2. *Recommendations*

To strengthen global preparedness, the IHR MEF, including the SPAR and the JEE assessment frameworks, could be updated to explicitly include overview of dangerous SNAs as a core element of biosecurity evaluation.

3.4. Pandemic Agreement

3.4.1. *Overview*

In May 2025, WHO member states adopted a new pandemic agreement establishing multilateral legal obligations on pandemic prevention, preparedness, and response.[53] Although not yet in force, the Agreement deliberately avoids distinguishing between naturally occurring and man-made sources of pandemics, thereby bringing risks associated with synthetic biology within its scope.

Article 4, which addresses the prevention pillar, requires states to develop and strengthen their capacities to prevent the emergence and re-emergence of infectious diseases and to manage biological risks. It further obliges states, under Article 4(2)(i), to develop or strengthen laboratory risk-management systems, including biosafety and biosecurity training and practices, and to ensure the safety and security of transport.[54]

Given the potential for SNAs to be misused in ways that could trigger a pandemic, SNA-related risks should be treated as a core component of states' prevention obligations under the Agreement. In practice, this places SNA governance squarely within the treaty's biosecurity requirements.

3.4.2. *Recommendations*

Once the Conference of the Parties and other implementation bodies are established under the Pandemic Agreement, they should explicitly address the Agreement's application to SNAs and emphasise the need to modernise national biosecurity laws to prevent pandemic risks associated with SNAs.

3.5. WHO Global Guidance Framework for the Responsible Use of the Life Sciences: Mitigating Biorisks and Governing Dual-Use Research

The WHO Global Guidance Framework is a legally non-binding document but provides authoritative guidance on responsible life science practices.[55] It determines that providers should implement sequence and customer screening. In a checklist for the private sector, it expressly calls on providers to adopt screening protocols and to develop "red flag" systems for suspicious orders.[56]

3.6. WHO Laboratory Biosecurity Guidance

This WHO Laboratory Biosecurity Guidance provides a framework for managing laboratory biosecurity.[57] It specifically addresses the potential threats posed by emerging technologies like artificial intelligence and synthetic biology. It mentions SNAs across multiple sections, recognising it and related sequence data as biosecurity-relevant materials.

The Guidance addresses SNAs across several core pillars:

Institutional Oversight: In Section 4.2.2 (Institutional biosafety activities), the guidance explicitly mandates that the Institutional Biosafety Committee (IBC) must review research protocols prior to initiating work. Specifically, it requires that:

> *"The rationale and/or hypotheses are provided for protocols that include genetic modifications and/or gene expression (genome editing, synthetic nucleic acid molecules, recombinant proteins) of biological agents."*

Sequence Data Documentation: Protocols involving modified pathogens must fully describe the genetic modifications, including exact nucleic acid sequence data (including primers), vectors, and organisms to be used.

Screening: In Section 3.2 (Synthetic biology), the guidance highlights concerns surrounding DNA synthesis and the proliferation of desktop DNA synthesisers. Because shorter synthesised fragments can be combined to reconstitute full genomes or create high-consequence pathogens, it underscores the need for commercial screening to prevent misuse.

Benchtop Devices: In Section 8.1.5, national regulatory bodies are encouraged to establish a national inventory that tracks not only dangerous biological agents but also biosecurity-relevant equipment, specifically highlighting DNA synthesisers. Regulators are urged to oversee projects utilising this equipment and require institutions to track its usage and output.

Cybersecurity of Sequence Data: In Section 6.5, sequence data—including whole genomes, specific genes, primers, and RNA guide sequences—is classified as sensitive information that requires cybersecurity protections.

Risk-Based Handling: Under Section 8.1.4, when determining risks for import, export, possession, or sharing, authorities and institutional biosafety committees (IBCs) must evaluate the physical or digital form of the material, explicitly distinguishing between living organisms, isolated DNA, sequence data, and synthesised DNA.

The Guidance is significant because it clearly recognises SNAs as a biosecurity concern requiring oversight. However, as a guidance document, it is not legally binding.

3.7. Summary and Recommendations

The obligations contained in these four international treaties can be interpreted to extend to SNAs and as imposing legal duties on states to prevent the misuse of synthetic biology. Read together, these provisions arguably require states to exercise oversight over SNAs, as regulatory gaps could enable misuse for the development of biological weapons or the international spread of disease and pandemics.

In this sense, no new treaty obligation is required to bring SNAs within the scope of existing international law. This is arguably advantageous, as the current geopolitical environment makes the negotiation of a new multilateral biosecurity instrument both difficult and unlikely to achieve broad participation among key states.

The principal challenge lies in interpretation and implementation. Strengthening these elements within existing treaty frameworks—and explicitly clarifying that their obligations encompass SNAs—would substantially enhance global biosecurity without requiring a new legal instrument. Although all of these treaties lack effective enforcement mechanisms, they carry significant normative and reputational force. Clarifying their interpretation could therefore be a powerful avenue for advancing SNA regulation, improving awareness among member states, and by generating reputational and political pressure on states. Accordingly, it is recommended that:

1 **A new multilateral treaty is not required to govern SNAs.** The existing legal landscape already provides the necessary framework. States should instead pursue soft-law tools that do not require reopening treaty negotiations. Such an approach would enable modernising existing treaties while avoiding the political and legal costs of reopening negotiations.

2 For example, treaty bodies could **adopt authoritative clarifications** on the application of existing obligations to SNAs. In the case of the Biological Weapons Convention, for example, this could be achieved at the 2027 Review Conference based on recommendations of the Working Group on the Strengthening of the Convention and/or guidance by a newly established Science and Technology Committee. Similar clarifications could also be pursued within the WHO regime.

3 **In parallel**, treaty bodies could clarify that effective domestic implementation in the age of SNAs requires States to adopt appropriate national oversight—through modernised biosecurity laws and/or screening measures for SNA—thereby reinforcing prevention at the operational level.

The Intergovernmental Legal Landscape

Key Takeaways

1 The BWC, UNSCR 1540, the IHR, and the Pandemic Agreement can each be interpreted as extending to SNAs and as imposing duties on states to prevent misuse of synthetic biology.

2 Read together, these instruments arguably require states to exercise oversight over SNAs. Regulatory gaps could enable the development of biological weapons or the international spread of disease and pandemics.

3 No new treaty is required to bring SNAs within the scope of international law — an advantage given the current geopolitical environment, which makes negotiating a new multilateral biosecurity instrument difficult.

4 The principal challenge lies in interpretation and implementation, not in the absence of legal obligations.

5 States should pursue soft tools that avoid reopening treaty negotiations to modernise existing frameworks while minimising political and legal costs.

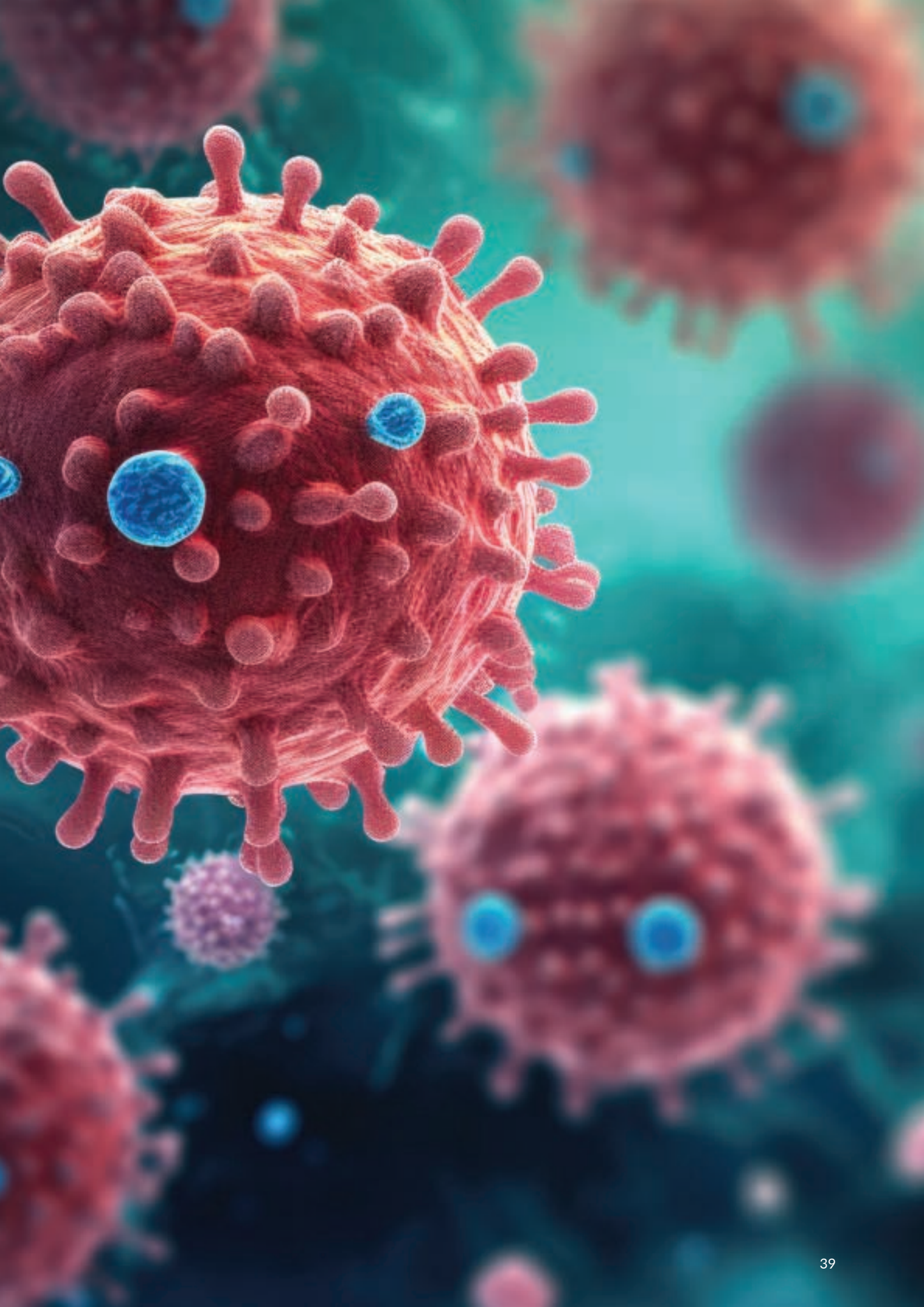
6 Treaty bodies (e.g., the BWC Review Conference, Working Group on the Strengthening of the Convention, Science and Technology Advisory Mechanism, and equivalent WHO mechanisms) could adopt authoritative clarifications confirming that existing obligations apply to SNAs.

7 In parallel, treaty bodies could clarify that effective domestic implementation requires states to adopt appropriate national oversight—through modernised biosecurity laws and/or SNA screening measures—reinforcing prevention at the operational level.

8 Although these treaties lack effective enforcement mechanisms, they carry significant normative and reputational force. Clarifying their interpretation can increase awareness among member states and generate normative or political pressure on states to act.

Table 1: International Legal Frameworks Governing Synthetic Nucleic Acids

Instrument	Scope / SNA Coverage	Key Obligations	Gaps / Limitations	Recommendation
Biological Weapons Convention (BWC) Binding on states parties	Covers biological agents 'whatever their origin or method of production'. Technology-neutral. Applies to synthetically-produced agents through interpretation.	Art. I: No development, production, or retention of bioweapons. Art. III: No transfer. Art. IV: States must enact domestic measures to prevent misuse.	No explicit mention of SNAs. No verification or enforcement mechanism. Art. IV obligations have not kept pace with technological change.	BWC Review Conferences / Working Group / Science and Technology Committee should clarify that Art. IV requires states to modernise biosecurity laws and rules to prevent SNA-related biological weapons risks.
UNSCR 1540 **Binding on all UN member states**	Addresses Weapons of Mass Destruction (WMD) proliferation to non-state actors. Synthetic biological agents fall within its scope through interpretation.	Article 3: Requires domestic controls over the manufacture, acquisition, and transfer of biological weapons and related materials.	No explicit mention of SNAs. No specific mention of synthesis screening or biosecurity law modernisation.	The 1540 Committee could clarify that effective domestic controls include SNA oversight. Capacity-building support should include assistance for modernisation of biosecurity frameworks.
International Health Regulations (IHR) **Binding on member states (almost universal)**	Applies to public health concerns 'irrespective of origin or source'. Could be interpreted to include risks from SNAs.	Articles 1, 5, 13: States must develop and maintain core capacities to prevent, detect, and respond to public health events. JEE and SPAR assess biosafety and biosecurity as core capacities.	No explicit mention of SNAs. JEE and SPAR do not include synthesis screening as an evaluated capacity.	Update the IHR MEF, including SPAR and JEE frameworks, to include SNA oversight and synthesis screening as a core element of biosecurity evaluation.
WHO Pandemic Agreement (2025) **Binding (adopted but not yet in force)**	Does not distinguish between natural and man-made pandemic sources. SNA-related risks arguably fall within prevention obligations.	Art. 4: States must develop capacities to prevent emergence of infectious diseases and manage biological risks. Art. 4(2)(i): Requires lab risk-management systems, including biosecurity training.	No explicit reference to synthetic biology or SNAs. Implementation bodies not yet established.	Conference of the Parties and implementation bodies should explicitly address SNAs and call for modernisation of national biosecurity laws to address SNA-related pandemic risks / screening.
WHO Global Guidance Framework (Dual-Use) **Legally non-binding**	Recognises DNA synthesis as a biosecurity risk.	Recommends that member states develop national biorisk governance policies addressing dual-use research, including oversight of commercial synthesis providers. Recommends that synthesis providers implement sequence screening for sequences of concern and verify customer legitimacy before fulfilling high-risk orders.	Legally non-binding; no enforcement. No obligation on states to require private sector compliance.	States could translate guidance into national requirements.
WHO Laboratory Biosecurity Guidance (2024)	Categorises SNAs as biosecurity relevant materials.	Section 4.2.2 requires the Institutional Biosafety Committee to review protocols before work begins and, for research involving genetic modification or gene expression, to ensure that the protocol states the exact nucleic acid sequences used. Section 3.2 highlights the biosecurity risks posed by DNA synthesis and desktop synthesisers, and calls for commercial sequence screening. Section 8.1.5, encourages national regulatory bodies to establish a national inventory that tracks DNA synthesisers. Regulators are urged to oversee projects utilising this equipment and require institutions to track its usage and output.	Legally non-binding; no enforcement.	States could translate the guidance into national requirements.



4. The National Biosecurity Legal Landscape: Current Frameworks and Gaps

This section turns to national law and maps how national legal systems regulate the biosecurity risks posed by SNAs. It analyses which regulatory regimes are implicated, how they apply to SNAs, and where significant gaps remain.

This study draws on examples from legal frameworks in North America, Europe and Asia: Australia, Canada, China, the European Union, France, Germany, India, Indonesia, Japan, Malaysia, New Zealand, the Philippines, Singapore, South Korea, Thailand, the U.K., and the U.S. While the examples are grounded in these jurisdictions, it develops conceptual distinctions and regulatory categories intended to clarify the broader legal landscape and inform reform efforts across a wider range of countries.

4.1. International Variation in Biosecurity Law

The global legal landscape is fragmented and uneven, marked by significant variation in scope, structure, and oversight between countries. Many low- and middle-income countries (LMICs) lack dedicated biosecurity legislation or have only partial legal frameworks addressing biosecurity risks. Reflecting this gap, the 2021 Global Health Security Index reported that 178 countries score below 50 out of 100 on biosecurity and lack adequate legal frameworks in this area.[58] In Southeast Asia, for example, several states do not yet maintain comprehensive domestic biosecurity regimes.[59] By contrast, other high-income jurisdictions have established more developed biosafety and biosecurity laws governing the possession, use, transfer, import, and export of dangerous biological agents and toxins. The result is a highly uneven and fragmented global regulatory landscape.

4.2. Biosecurity Legal Frameworks

Most states do not treat pathogens as ordinary commercial goods that can be traded and used freely. Rather, given their capacity to cause harm to humans, animals, or the environment, the possession, use, transfer, import, and export of pathogens are commonly subject to strict regulatory requirements, controls, and oversight under domestic biosafety and biosecurity laws.

Although the titles, terminology, and scope of relevant statutes vary across jurisdictions, several recurring regulatory categories of biosafety and biosecurity laws are relevant when considering the governance of risky SNAs, as listed in the diagram below.

Select agent laws	Regulate the *domestic* possession, use, transfer, and import of biological agents and toxins.
Export control and strategic goods regimes	Govern the cross-border transfer of dual-use items, including biological agents and toxins.

Non-proliferation and counter-terrorism legislation	Criminalise the possession or misuse of biological weapons or other prohibited substances for biological weapons or terrorist purposes.
Dual-use research of concern (DURC) frameworks	Regulate research that could be misapplied for harmful purposes.
Genetically modified organism (GMO) laws	Regulate the creation, safe containment, handling, transport, and release of genetically modified organisms.
Laboratory biosafety rules	Govern the safe handling, storage, use, and disposal of biological materials in laboratory settings, with the aim of protecting personnel, the public, and the environment from harm.
Medicinal products laws	Regulate the development, authorisation, manufacture, distribution, and post-market surveillance of medicines to ensure their safety, quality, and efficacy.

Because most of these laws were adopted in an earlier biotechnological era, a core question is whether, and to what extent, they directly govern SNAs or can be interpreted as governing biosecurity risks associated with them.

The consequences of this assessment are critical:

1. **If SNAs fall within the scope of existing laws:** Then the stringent controls embedded in these laws—such as licensing, access approval, and oversight and enforcement mechanisms governing the use, sale, transfer, export, and related activities of listed biological agents—also apply to SNAs.
2. **If SNAs fall outside the scope of existing laws:** Then the biosecurity controls that apply to listed biological agents and toxins do not apply to SNAs. That means that high-risk SNAs escape oversight, allowing actors to legally use SNAs to circumvent controls that have governed "traditional" biological agents and toxins for decades. All the regulatory requirements, such as licensing, access controls, and enforcement, do not apply to SNAs being used to construct regulated or otherwise harmful biological agents.
3. Regulatory frameworks that treat SNAs as an unrestricted material are thus misaligned with contemporary technological realities. Identifying these gaps is, therefore, essential to strengthening existing legal frameworks and making them fit for the synthetic biology and AI-bio era.

4.2.1. *Do SNAs fall within the Scope of the Law? The Two-Step Test*

To determine if a law in a given jurisdiction applies to and governs SNAs, a two-step test should be followed:

1 STATUTORY DEFINITION

The definition of biological agents, toxins or materials, and whether that definition encompasses SNAs.

As laid out below, legal frameworks fall into three broad categories:

1. **Traditional:** The definition setting the scope of the law clearly does not extend to SNAs.
2. **Ambiguous:** The definition setting the scope of the law could be interpreted as covering SNAs.
3. **Express:** The definition expressly includes SNAs (or certain SNAs) within its scope.

2 SCHEDULES / ANNEXES / LISTS

The schedules/annexes attached to legislation typically classify biological agents according to their level of risk and attach corresponding controls. This report examines whether the schedules include only biological agents and toxins themselves, or whether they also extend to genetic elements.

As discussed below, several approaches can be identified.

1. **Traditional:** The schedules are limited to pathogens.
2. **Express:** They expressly extend to genetic elements of listed pathogens or other nucleic acids.
3. **Catch-all:** The legislation contains judgement-based catch-all provisions or explanatory notes indicating that the schedules are not exhaustive and that additional agents, genetic elements, or related materials may be regulated. In such cases, entities may need to consult the relevant regulatory authority to determine whether a particular SNA falls within the scope of the framework.

Based on this dual test, and as the examples below will illustrate, the application of biosecurity laws to SNAs fall into three main conceptual categories:

1. **Traditional:** Traditional or legacy laws that apply to whole and/or natural biological agents and toxins.
2. **Ambiguous:** Laws whose application to SNAs depends on interpretation.
3. **Express:** Laws that expressly govern SNAs (or some SNAs).

4.3. Select Agent Laws: Domestic Oversight

In many countries, the use, transfer, or import of biological agents and toxins is regulated under so-called "biological agent" or "select agent" regimes, which impose strict controls on the possession, use, and transfer of listed pathogens and toxins *within* or *into* the country.

While the titles of the respective laws differ, they typically set out a range of requirements and controls on persons or entities that possess, use, or transfer select agents. This commonly includes registering with the relevant agency, restricting access to approved persons, implementation of biosafety and biosecurity plans, requiring laboratories or facilities working with controlled agents to obtain licences, implementing physical and personnel security measures, and maintaining detailed records of transfers. As such, transfers may occur only between licensed or approved entities that hold valid authorisations and operate within certified facilities.[60]

As mentioned above, these select agent laws typically rely on lists of pathogens subject to regulatory oversight, often organised in "annexes" or "schedules" that differentiate levels of control based on the risks posed. Examples include the U.S. Select Agent Regulations,[61] or Singapore's Biological Agents and Toxins Act (BATA).[62]

Three main regulatory approaches to the application of the laws to SNAs have been observed: *traditional, ambiguous, and express approach.*

4.3.1. *Traditional Approach: Whole or Natural Pathogens*

This category includes countries whose select agent laws cover whole and/or natural biological agents without including synthetic genetic materials. Examples include Australia,[63] and the Republic of Korea.[64] Examples of this approach are laid out in Box 4 below.

Box 4: Traditional definition of "biological agent"

Examples

Under **Indonesia's Health Law**, a biological agent is defined as "a virus, bacteria, fungus, or parasite, either living or dead, that can cause a disease that has the potential to cause an extraordinary event and outbreak".[65]

India's Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells function as India's core biosafety or select agent law and regulate the manufacture, use, and import of both "microorganisms" and "gene technological products". The definition of "microorganism" is that it "shall include all the bacteria, viruses, fungi, mycoplasma, cell lines, algae, protodoans and nematotes indicated in the schedule and those that have not been presently known to exist in the country or not have been discovered so far". Further, the "List of Infective Microorganisms" lists whole microorganisms.[66]

Australia's Security Sensitive Biological Agents (SSBA) Regulatory Scheme is Australia's framework for controlling access to and handling of the most dangerous biological materials that could be misused for bioterrorism or pose a severe threat to public health and safety. It is based on the National Health Security Act (2007) which defines biological agents as "includ[ing] bacteria and viruses...". Further, the scheme covers agents listed in two categories: Tier 1 agents – pose the highest risk to national security (e.g., Bacillus anthracis, Variola virus); Tier 2 agents – pose a lower but still significant risk. The list does not expressly regulate DNA or RNA.[67]

Conclusion: Such legal frameworks create a significant regulatory gap. Since SNAs fall outside existing select agent laws, they escape the controls that govern pathogens. This exemption leaves countries vulnerable, as SNA use, transfer, and possession can occur without legal oversight.

4.3.2. *Ambiguous Definition: Components of Pathogens "Capable of Causing Disease"*

In some jurisdictions, select agent laws define "biological agents" to include not only whole or natural pathogens but also their components, whether natural or synthetic. The reference is typically to:

> *"any component … capable of causing disease".*

This expanded scope is typically conditioned on functionality—namely, whether a component is *capable of causing disease*. As such, it introduces a functional test. This functional threshold implies that not all SNAs are regulated. Only those sequences that meet the functionality test would be covered.

Although there is no known judicial interpretation or authoritative regulatory guidance clarifying this language, ordinary principles of statutory interpretation permit a range of plausible readings. At one end, a narrow interpretation would limit coverage to components that are inherently capable of causing disease. At the other end, a broader interpretation would extend coverage to components that, either on their own or stitched with other components, could contribute to the causation of a disease.

A narrow interpretation arguably aligns with the original purpose of select agent laws: to control the possession, use, and transfer of inherently dangerous biological materials and to prevent their misuse or accidental release. Under this approach, components that lack an intrinsic or reasonably foreseeable capacity to cause disease would fall outside the scope of regulation.

At the same time, rapid advances in synthetic biology challenge the adequacy of this narrow framing. The ability to design, assemble, and functionally recombine genetic material suggests that regulatory attention may need to extend beyond inherently pathogenic components to a broader set of sequences that can enable or facilitate disease-causing functions when combined or expressed. In this context, a more expansive interpretation may be warranted to ensure that existing biosecurity frameworks remain fit for purpose.

Be that as it may, because such legal frameworks do not expressly address nucleic acids, and regulators have not addressed these interpretive challenges—at least in the jurisdictions examined in this report—significant uncertainty persists as to their application in practice, including with respect to which categories of SNAs fall within their scope. In practice, regulated entities may need to seek guidance from the competent authority regarding how the authority interprets this provision and whether it considers SNAs to fall within their scope. Conversations with regulators have also revealed divergent interpretations: some consider the statutory language broad enough to encompass SNAs, while others view SNAs as falling outside its scope.

Even where legislation adopts an ambiguous definition of "biological agent" that could potentially encompass SNAs, the schedules examined do not expressly list genetic elements or SNAs, for example in Canada's Human Pathogens and Toxins Act, in Germany's Infektionsschutzgesetz. and in Singapore's Biological Agents and Toxins Act (BATA).[68] However, in Singapore's case, a catch all provision could arguably capture SNAs. See Box 5.

Conclusion: This uncertainty underscores the need for regulatory guidance or targeted regulatory amendment to clarify whether, and which, SNAs fall within the scope of existing select agent regimes. This lack of clarity leaves countries vulnerable, as SNA use, transfer, and possession potentially operate without regulatory oversight.

Box 5: Definition of biological agent includes "components capable of causing disease."

Examples

Singapore

Singapore's BATA regulates the possession, use, import, transfer, and transportation of human pathogens and microbial toxins.[69]

Biological agents are defined as meaning:

> *"any microorganism, infectious substance, or any component … capable of causing death, disease, or other biological malfunction in a human".*

This is a broad definition. Because the term "component" is not limited to whole microorganisms, it is capable of encompassing nucleic acids, even though synthetic components are not expressly mentioned. The absence of an explicit reference to synthetic material does not, in itself, imply exclusion. At the same time, BATA does not apply to all SNAs. Its application is limited to those components that are "capable of causing disease", a threshold that is both scientifically and legally indeterminate. The statute provides no criteria for assessing when a nucleic acid meets this standard, and no publicly available guidance clarifies how regulators draw this line in practice.

Moreover, BATA establishes a risk-based classification system through five schedules, with different regulatory requirements applying to the possession, import, transfer, and transport of biological agents and toxins according to their risk level. On their face, the schedules list biological agents and toxins and do not expressly refer to SNAs. As a result, nucleic acids derived from even highly dangerous pathogens do not appear to be subject to the same controls, potentially creating a regulatory gap.

That said, the Fourth Schedule functions as a judgement-based catch-all provision. It includes "any biological agent that causes death, disease, or biological malfunction in a human, other than a First Schedule biological agent or a Second Schedule biological agent". This broad language provides the Ministry of Health with a legal basis to regulate biological agents that are not expressly listed. Nevertheless, whether and to what extent this provision applies to SNAs remains unclear and would benefit from regulatory clarification.

Thailand

Thailand's Pathogens and Toxins Act defines "pathogens" as microorganisms or biological substances that are:

> *"capable of causing diseases in humans, livestock, beasts, or other animals."*

A "biological substance" is further defined as:

> *"a culture or any part of it made or modified from animal toxins, microorganisms, or other germs."*

Read together, these definitions do not directly extend to SNAs. While the Act regulates biological substances capable of causing disease, its scope is limited to substances that are made or modified *from* animal toxins, microorganisms, or other germs. SNAs, by contrast, can be produced de novo and need not be derived from any living organism.

Even if the Act were interpreted more expansively to capture certain SNAs, its application would remain limited to sequences that are "capable of causing disease". As in other jurisdictions, this functional threshold is not further defined, leaving open questions as to whether, and under what circumstances, particular categories of SNAs would fall within the Thai regulatory framework.

Moreover, the Pathogens and Animal Toxins Act classifies pathogens into four distinct groups based on their hazard level, from Group 1 Pathogens (low risk) to Group 4 Pathogens (very high risk).[70] Thailand's pathogen list does not regulate nucleic acids, genetic elements, genetic fragments, or sequence information.[71]

4.3.3. *Express Coverage of SNAs*

A few jurisdictions expressly extend the definition of biological agents to include SNAs (see Box 6). Even in these cases, however, coverage is conditioned on a functional criterion — namely, whether the nucleic acid is capable of causing harm or disease. This limitation is arguably deliberate and reasonable. As mentioned above, select agent laws impose stringent oversight requirements, and extending them to all SNAs would unduly restrict legitimate research and innovation. Thus, it is sensible to limit strict oversight to SNAs that pose a genuine risk.

However, even such relatively advanced "express" regimes do not adequately capture the emerging problems of SOC and short fragments outlined above. In other words, frameworks that cover SNAs are only applicable to a narrow subset of SNAs. This scope no longer aligns with emerging risks posed by potentially novel or unknown SOC, let alone shorter DNA or RNA fragments.

Box 6: Definition of Biological Agent Applies to SNAs

Examples

United States

The U.S. Select Agent and Toxins Regulations (42 CFR Part 73), and the Biological Weapons Statute (18 U.S.C. §178) define "biological agent" as meaning:

> *"any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesised component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment."*

The Federal Select Agent Program's "Guidance on the Regulation of Select Agent and Toxin Nucleic Acids"[72] and its regulatory interpretation[73] clarify which nucleic acid sequences are subject to FSAP control. They determine that the following synthetically created nucleic acids would be regulated:

- Nucleic acids that can produce infectious forms of any of the select agent viruses. The guidance suggests in parentheses that this specifically refers to nucleic acids "capable of generating infectious forms of a regulated virus by utilizing host polymerases but without the need for any additional exogenous factors [proteins, nucleic acids, etc]"[74]
- Recombinant and/or SNAs that encode for the functional form(s) of select toxins if the nucleic acids:
  - Can be expressed in vivo or in vitro, or
  - Are in a vector or recombinant host genome and can be expressed in vivo or in vitro.
- Note that the interpretation guidance clarifies that the rules apply to any SNA, including unlisted SNAs, if they are used to create a listed select agent or toxin. It says: "Please note that if unregulated synthetically modified DNA sequences are used to derive a select agent or toxin the resulting agent will be regulated".[75]

The U.S. Select Agent and Toxins Regulations (42 CFR 73) also include a definition of SNAs. They are defined as "(1) Molecules that are chemically or by other means synthesised or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., SNAs) or (2) Molecules that result from the replication of those described in paragraph (1) of this definition."

France

France's domestic biosecurity framework expressly extends to SNAs.[76] The 26 April 2023 ministerial order updating the list of *micro-organismes et toxines* (MOT) under the French Public Health Code makes this explicit by:

- Referring directly to "genetic fragments, whether of natural or synthetic origin", and
- Defining quantitative and qualitative thresholds that trigger regulation.

However, it does not regulate all SNAs. Instead, it adopts a hybrid approach combining: (a) Size thresholds >500 bp for variola virus fragments, >800 bp for other viruses, >500 bp for certain bacterial genes, (b) Functional equivalence tests (for viruses): For most viruses, regulation applies only where: The translated sequence exceeds 75% of the amino acid sequence of a viral protein. This effectively captures sequences that are functionally meaningful, not just nominally related, and (c) Gene-specific controls (for bacteria): For bacteria, coverage is limited to enumerated virulence- or pathogenicity-associated genes (e.g., anthrax capsule genes, botulinum toxin genes, *Yersinia pestis* Pla).

Australia's Biosecurity Act 2015 and the Biosecurity (Conditionally Non-Prohibited Goods) Determination 2021: A permit is required for the import of microorganisms and infectious agents. The framework adopts a risk-management approach and extends to nucleic acids, meaning their import also requires prior authorisation. Permit applications are processed through the Biosecurity Import Conditions (BICON) system, which outlines the applicable import pathways. The specific permit type and conditions depend on the nature of the nucleic acid (e.g., synthetic, derived, or homologous to pathogens) and its intended use.[77]

Indonesia

MOH Regulation No. 85/2020 on the Transfer and Utilisation of Material, Information Payload, and Data (MOH Regulation 85/2020) governs the transfer and use of biological materials, information, and data—particularly those derived from health-related research and clinical activities—both within Indonesia and across national borders.[78]

Under Article 5(3) it defines "biological materials" as:

> *"biological ingredients (bahan) that are contained in clinical specimens, animal specimens, plants, virus isolates, bacteria, parasites, fungi, other microorganisms, vectors, and other natural resources, including parts or derivatives containing genetic material and sequence information, such as RNA and DNA nucleotide sequences."*

Thus, RNA and DNA nucleotide sequences are expressly included in the definition (although synthetic ones are not mentioned).

The World Health Organization's Recommendations concerning the distribution, handling, and synthesis of variola virus DNA (2005) apply the same oversight obligations to the synthesis of variola (smallpox) DNA as to the live virus itself.[79]

Conclusion: This approach extends oversight to SNAs, with the result that certain SNAs are subject to the same stringent controls that apply to listed pathogens. However, the scope of coverage typically remains limited to sequences associated with listed pathogens. As a result, SOC and shorter nucleic acid fragments that fall outside regulatory lists are commonly left unregulated.

4.3.4. *Consequences for Screening*

Where select agent laws extend to SNAs, they create a de facto screening obligation for synthesis providers. The reason is that although the legislation does not mandate providers to screen orders, this would be difficult in practice without reviewing orders to determine whether they contain controlled sequences associated with regulated biological agents.

In most jurisdictions, however, SNAs are either not regulated at all or are covered only implicitly and ambiguously. In such cases, no meaningful screening obligation can be derived from existing select agent law. Moreover, even in jurisdictions with more advanced frameworks that expressly cover SNAs, the scope of coverage generally remains narrow. Any screening obligation derived from those laws would therefore extend only to the SNAs that fall within their regulatory scope, leaving other potentially risky sequences outside the screening requirement.

Accordingly, establishing mandatory screening requires attention to the underlying scope of biosecurity legislation. Select agent and related laws should first be updated to encompass relevant categories of SNAs. Once they are legally controlled, screening becomes a necessary mechanism through which providers determine whether an order involves regulated material and whether the recipient is authorised to obtain it. The design and implementation of mandatory screening requirements are examined in greater detail in Report 2.

Table 2: Select Agent Laws: Three Approaches to SNA Coverage

How jurisdictions define 'biological agent' and the extent to which that definition captures SNAs:

Approach	Definition of Biological Agent	SNA Explicitly Covered?	Schedules Include Genetic Elements?	Example Jurisdictions	Regulatory Gap
Traditional	Limited to whole, naturally occurring biological agents and toxins. No reference to genetic material, nucleic acids, or synthetic components. Example (Indonesia): 'a virus, bacteria, fungus, or parasite, either living or dead, that can cause a disease.'	No	No	Australia (Security Sensitive Biological Agents [SSBA] Scheme) India (Hazardous Microorganisms Rules) Indonesia (Health Law)	SNAs fall entirely outside statutory definitions. No licensing, transfer controls, or screening obligations apply to SNAs.
Ambiguous	Extends to whole pathogens and their 'components … capable of causing disease or biological malfunction.' Functionality test introduced. Example (Singapore BATA): 'any micro-organism, infectious substance, or any component … capable of causing death, disease, or other biological malfunction in a human.'	No (implied only)	No	Singapore (BATA) Thailand (Pathogens and Toxins Act)	Implicit coverage of SNAs. No authoritative guidance clarifies which SNAs meet the functionality threshold. Operative schedules do not list genetic elements. Significant legal uncertainty persists.

Approach	Definition of Biological Agent	SNA Explicitly Covered?	Schedules Include Genetic Elements?	Example Jurisdictions	Regulatory Gap
Express	Expressly includes SNAs, bioengineered, and synthesised components capable of causing harm. Example (U.S.): 'any … naturally occurring, bioengineered or synthesised component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction.'	Yes	Yes (for select agents only)	U.S. (42 CFR Part 73; 18 U.S.C. §178 + FSAP Guidance) France (Ministerial Order 2023, with size/function thresholds) U.K. (ATCSA 2001, Sch. 5) Indonesia (MOH Reg. 85/2020 — RNA/DNA sequences) Australia (Biosecurity Act 2015 — import permit for nucleic acids)	Coverage remains limited to SNAs linked to listed pathogens meeting defined functional criteria. Sequences of concern, novel/AI-generated sequences, and shorter assembled fragments are not captured. Benchtop devices escape oversight.

4.3.5. *Recommendations: Modernising Select Agent Laws and Regulations*

With limited exceptions in a few jurisdictions, most select agent or biological agent laws governing the domestic use and transfer of biological agents and toxins are ill-equipped to control risky SNAs. In some jurisdictions, SNAs fall entirely outside statutory definitions of biological agents. In others, their status remains uncertain and depends on regulatory interpretation. Even the most advanced, "express" frameworks typically extend only to a narrow subset of SNAs and do not adequately address emerging risks posed by SOC, shorter fragments, or benchtop devices. The consequence is that controls of dangerous pathogens can be legally circumvented by using SNAs that fall outside, or only ambiguously within, existing controls. Regulatory reform—or authoritative clarification—is therefore warranted in many jurisdictions.

1

Modernising Statutory Definitions

Statutory definitions of biological agents should be amended to expressly include SNAs, and regulated schedules should be updated to cover the synthetic equivalents of listed pathogens. Given the growing risk posed by SOC not necessarily related to listed agents, the scope of regulated SNAs requires further clarification and policy development (see next).

2

Adopting a Tiered, Risk-Based Approach to SOC

Extending the full suite of select agent controls to all SNAs would be disproportionate. Persons or institutions that possess, use, or transfer select agents are generally required to register with, and obtain authorisation from, the competent authority, and are subject to stringent requirements governing facilities, personnel, handling, and related activities. Unlike the pathogens to which they may relate, most SNAs are not inherently harmful and typically require assembly or incorporation into a biological cell before they can pose a risk. Many fragments also lack independent functional capacity. A blanket equivalence approach would therefore impose unnecessary burdens on legitimate research and innovation.

Regulatory reform should instead adopt a tiered, risk-based framework that calibrates oversight to the functional risk posed by a sequence. Not all SOC present the same level of risk, and only a subset is likely to justify the application of the most stringent select agent controls. Oversight should therefore be graduated, with regulatory obligations increasing in accordance with the potential of a sequence to contribute to harmful outcomes.

Efforts are beginning to identify specific sequences that pose biosecurity risks. These include the Sequence Biosecurity Risk Consortium's work to develop methods for identifying high-risk sequences and the proposed European Biotech Act's provision for establishing a list of SOC (see section 2.2.3 and Box 3).

Particular attention should be given to shorter fragments. Although many such fragments may present little risk in isolation, regulation should extend to fragments that are intended, designed, or reasonably likely to be assembled into a regulated sequence or SOC. A calibrated approach is needed here as well.[80]

The point at which the regulatory balance should be struck when extending controls to SOC and fragments requires further development. A narrower approach would limit oversight to sequences with an intrinsic or reasonably foreseeable capacity to cause harm. A broader precautionary approach would permit regulation where scientific uncertainty exists regarding the potential for misuse. Determining the appropriate balance between these approaches remains an important science policy question that goes beyond the scope of this report.

3

Judgement-based Catch-all provisions

Determining which sequences, beyond those derived from listed pathogens, should fall within the scope of select agent or equivalent laws remains an unresolved question that governments and expert bodies will need to address. However, it is neither feasible nor desirable to rely exclusively on exhaustive lists, as it is impossible to anticipate all sequences that may pose a biosecurity risk. Regulatory frameworks should therefore incorporate catch-all provisions providing that any sequence reasonably capable of contributing to harmful outcomes – that is the creation, enhancement, acquisition, dissemination, or misuse of a harmful biological agent – falls within the scope of oversight, irrespective of whether it is expressly listed. Such provisions would focus on the sequence's potential functional outcome rather than solely on its identity. Schedules should be treated as illustrative rather than exhaustive, and legislation should impose a corresponding obligation on regulated persons to seek guidance from the competent authority where doubt exists as to whether a particular sequence is subject to regulation. Such an approach would help ensure that oversight remains effective in the face of rapid technological change and evolving biosecurity risks. Similar approaches already exist in international law. For example, Annex 2 of the International Health Regulations incorporates a catch-all mechanism, recognising that it is impossible to list every virus outbreak that could develop into a public health emergency of international concern. Export control laws (see below) similarly include such provisions. This is also common in national regulations. The U.S. Government Policy for Stopping High-Risk Life Sciences and the Singapore Biosafety Guidelines for Research on GMOs provide further examples of policies that require certain research to be subject to oversight and authorisation based on the risk that the research could produce specified outcomes, rather than solely on the biological agents or materials involved.

4

Regulating Benchtop Devices

The increasing availability of benchtop synthesis devices presents a significant regulatory challenge. Most existing select agent laws focus on the possession, transfer, or procurement of biological materials and therefore do not adequately address on-site synthesis.

Regulatory obligations should attach to the production or possession of regulated sequences regardless of the means by which they are obtained. Whether a sequence is acquired from a commercial provider or synthesised using a benchtop device, controls over end-user and end-use legitimacy should equally apply. States should therefore adopt legislation that requires the registration or licensing of benchtop devices and/or their users, together with continuous monitoring and record-keeping requirements.[81]

5

Adopting Screening Requirements

Extending select agent or equivalent laws to SNAs will be ineffective unless accompanied by mechanisms capable of identifying regulated sequences before synthesis occurs. Screening therefore represents a critical component of any modernised biosecurity framework.

Governments should establish clear screening requirements applicable to providers of SNAs and, where appropriate, operators of benchtop devices. The available regulatory approaches for adopting such requirements are discussed in Report 2.

Select Agent Laws

Key Takeaways

1 Most existing legal frameworks governing the domestic use and transfer of biological agents are not designed for SNAs. In many jurisdictions, SNAs fall outside statutory definitions of biological agents, remain legally ambiguous, or are regulated only in part, creating significant gaps in biosecurity oversight.

2 Statutory definitions and schedules should be modernised to expressly cover SNAs.

3 Not all SNAs warrant the same level of control. Oversight should adopt a tiered, risk-based approach that calibrates controls to the functional risk posed by a sequence, while avoiding unnecessary burdens on legitimate research and innovation.

4 Regulatory frameworks should also include judgement-based catch-all provisions to ensure that harmful or potentially harmful sequences remain subject to oversight even where they are not expressly listed.

5 Regulation should extend to shorter fragments which could reasonably be assembled into a SOC. Focusing exclusively on complete sequences would leave gaps in oversight.

6 Screening is an essential component of any modernised biosecurity framework. Effective oversight of SNAs requires mechanisms capable of identifying regulated sequences before synthesis occurs.

4.4. Export Control Laws

Export control laws regulate the cross-border transfer of dual-use goods and technologies that may serve both legitimate and hostile purposes. Their purpose is to protect or advance national security, foreign policy, or economic interests. These regimes typically require providers or manufacturers to obtain government export licences before shipping controlled items abroad. Export licences are generally transaction-specific, authorising the transfer of a defined item to a specified end-user for a specific end-use at a particular location.[82]

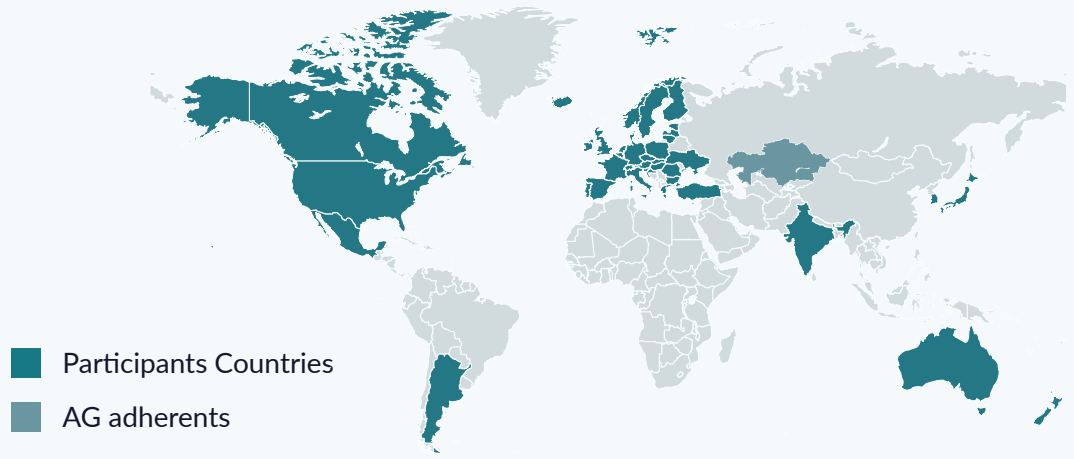
Because actors may evade national controls through jurisdictional arbitrage, states have pursued multilateral coordination to harmonise export controls and reduce opportunities for venue shopping. To this end, the Australia Group was established in 1984.[83] It now comprises approximately 43 participating members (42 states and the EU, totalling almost 70 states) and—in view of complying with the BWC and the Chemical Weapons Convention—aims to prevent the proliferation of chemical and biological weapons by aligning national export control policies (Box 7).

The Australia Group's Guidelines for Transfers of Sensitive Chemical or Biological Items (The AG Guidelines) state that the purpose of the Guidelines is to limit proliferation and terrorism risks involving chemical and biological weapons by controlling tangible and intangible transfers that could contribute to chemical or biological weapons activities, while not impeding legitimate trade and cooperation consistent with the BWC and Chemical Weapons Convention articles on peaceful cooperation.[84] Central to this effort is the Australia Group Common Control Lists (AG CCL).[85] These include lists of dual-use biological equipment and related technology and software,[86] human and animal pathogens and toxins,[87] and plant pathogens. The dual-use equipment list includes nucleic acid synthesisers, and the pathogens and toxins list includes viruses, bacteria, toxins, fungi, and genetic elements (Box 8).

Across jurisdictions, incorporation of the AG-listed items most commonly occurs through integration into national strategic goods/dual-use control lists. For example, the Singapore Strategic Goods (Control) Act 2002 and Strategic Goods (Control) Order 2025,[88] Thailand's Proliferation of WMD Act,[89] or the U.S. Export Administration Regulations (EAR).[90] The AG encourages non-members to follow the list, and several non-member states (adherents) have also aligned their national controls with the AG lists, further extending their practical reach. Other countries that are not AG members or adherents, such as China[91] and Russia,[92] have also adopted similar export rules.

In what follows, the report sets out the provisions of the AG Guidelines and lists. Although member countries generally align their national export control regimes with these standards, there are variations. Therefore, the specific legal provisions applicable in any given jurisdiction must be determined by examining that jurisdiction's domestic export control laws and regulations.

Box 7: Australia Group Members



4.4.1. *Genetic Elements*

AG- based export controls provide the clearest and most robust existing legal basis for regulatory oversight of SNAs (see Box 8). The reason is that the AG lists for biological agents expressly include genetic elements. Their provisions extend beyond whole or natural viruses, bacteria, or toxins to "Genetic Elements and Genetically Modified Organisms".[93]

The definition covers any genetic element that codes for gene(s) specific to:

> - *any listed virus*
> - *any listed bacterium or fungus — and which itself or through transcribed/translated products represents a significant hazard to human, animal, or plant health*
> - *any listed bacterium or fungus — and which could endow or enhance pathogenicity*
> - *any listed toxins or subunits*

Genetic elements are defined as including:

> *"chromosomes, genomes, plasmids, transposons, vectors, and inactivated organisms containing recoverable nucleic acid fragments, whether genetically modified or unmodified, or chemically synthesised in whole or in part".*

On a straightforward reading, SNAs constitute genetic elements as they fall into the term "chemically synthesised in whole or in part".

However, that does not mean that all SNAs are controlled. Rather, coverage is not comprehensive: export controls apply only to genetic elements that code for genes specific to listed viruses, or for listed bacteria if those either pose a significant hazard or could confer or enhance pathogenicity. Their scope is therefore broader than that of most select agent laws discussed above. Nevertheless, they do not clearly extend to other SOC or to shorter fragments that fall outside these criteria.

A useful reference for understanding the scope of "genetic elements" is an advisory opinion issued in the U.S. On 26 September 2023, the Bureau of Industry and Security (BIS) published an advisory opinion clarifying the interpretation of "genetic elements" controls under Export Control Classification Number (ECCN) 1C353 of the U.S. Export Administration Regulations (EAR). While not authoritative for other countries—and not legally binding even within the U.S.—the opinion nonetheless provides useful guidance for delineating the scope of control.

BIS noted that the term "gene" is not defined in the relevant Export Control Classification Number (ECCN 1C353) or in the EAR's definitions, and that it is considering whether and how to provide public guidance on interpreting the scope of the genetic elements control. It clarified that sequence-length is not a threshold for classification and that licensing requirements for synthetic DNA are primarily determined by the biological *function* of the resulting protein rather than a specific sequence length. The text outlines several hypothetical scenarios to help exporters identify when modified or fragmented sequences still fall under strict oversight due to their potential pathogenicity. Additionally, it warns that intentionally splitting orders to bypass these regulations constitutes a violation and should be treated as a security red flag.[94]

Finally, the AG Guidelines expressly state that participating governments may impose controls on items not included on the AG CCL and may apply additional conditions to transfers.[95] Nothing in the AG Guidelines, therefore, prevents countries from extending their national export controls by adding additional SOC.

In sum, the export of controlled SNAs may be subject to national export licensing requirements. Companies exporting SNAs should therefore determine whether the jurisdiction from which they operate maintains export control laws that apply to SNAs and, where applicable, assess whether a licence or other authorisation is required before export.

4.4.2. *Consequences for Screening*

In practice—and as discussed above in relation to screening under select agent laws—compliance with export controls can create a de facto obligation to screen orders. Providers need to screen orders to assess whether a sequence is controlled, and to determine whether export licensing requirements are required.

However, in most jurisdictions, a significant gap remains. Although export control laws specify that certain genetic elements require a licence, they do not establish screening procedures to assist exporters in identifying controlled sequences and complying with these requirements. It is largely for this reason that members of the IGSC developed voluntary screening guidance: to operationalise compliance with export control requirements.

The U.S. HHS Screening Guidance was similarly adopted to support compliance with select agent and export laws. This approach, however, remains the exception rather than the rule. Most countries with export control regimes that follow similar language regarding "genetic elements" have not adopted dedicated screening guidance for SNAs.

This absence of specific screening laws or guidance in support of export controls has likely contributed to uneven compliance. Indeed, despite the existence of export control obligations, anecdotal evidence from red-teaming exercises suggests that some companies may already be operating in ways that fall short of compliance.[96]

4.4.3. *Benchtop Devices*

The Australia Group Control List of Dual-Use Biological Equipment and Related Technology and Software (Item 10) covers partly or fully automated nucleic acid assemblers and synthesisers capable of synthesising sequences greater than 1.5 kilobases, as well as software capable of designing and building functional genetic elements from digital sequence data.[97]

As mentioned above, the AG Guidelines expressly state that participating governments may impose controls on items not included on the AG CCL and may apply additional conditions to transfers. Nothing in the AG Guidelines, therefore, prevents countries from adopting additional export licence conditions. For example, to ensure that benchtop devices remain in the hands of legitimate end users and are used only for legitimate purposes after export, exporting states could attach conditions to export licences designed. Such conditions could, for example, require manufacturers to incorporate mechanisms to authenticate authorised users, screen SOC, and maintain appropriate data security and cybersecurity protections. Cloud-connected devices may facilitate oversight by enabling remote monitoring of their use and continued compliance with applicable requirements.

4.4.4. *What are the Consequences if Controlled SNAs or Benchtop Devices are Exported without a Licence?*

Criminal and administrative sanctions are regularly imposed for violations of export controls involving regulated biological agents and toxins in jurisdictions such as the U.S., Europe, and Japan — for example, the case concerning Indiana University's unlicensed export of ricin-related material,[98] Princeton University's export of regulated pathogens,[99] and prosecutions in Germany involving the unlawful export of controlled chemicals to Russian entities (Box 9).

All publicly known cases, however, have involved the export of traditional biological agents or toxins. Although none has addressed the export of SNAs, these cases nonetheless illustrate enforcement pathways that could, in principle, be applied to providers of SNAs that fail to comply with export control requirements. There have been instances in which benchtop synthesis devices were exported without the required licences. However, it remains unclear whether authorities undertook any enforcement action.[100]

Box 8: Export Controls' Common Control List

Australia Group List of Human and Animal Pathogens and Toxins

The Human and Animal Pathogens and Toxins List begins with viruses and covers high-consequence pathogens such as Crimean-Congo haemorrhagic fever virus, Ebola virus, and Rift Valley fever virus. It then moves to bacteria, from *Bacillus anthracis* to *Yersinia pestis*, followed by toxins such as ricin, saxitoxin, and botulinum toxins. alphabetised for clarity, ensuring consistent implementation across jurisdictions and enabling exporters to determine quickly whether a biological material falls under legally controlled items.

Genetic Elements and Genetically Modified Organisms:

Any genetically modified organism which contains, or genetic element that codes for, any of the following:

1. any gene or genes, translated product, or translated products, specific to any listed virus; or
2. any gene or genes specific to any listed bacterium [3] or fungus, and which,
   a. in itself or through its transcribed or translated products, represents a significant hazard to human, animal, or plant health, or
   b. could endow or enhance pathogenicity; or
3. any listed toxins or their sub-units.

The Technical Note explicitly includes fragments. It says that "Genetic elements" include: chromosomes, genomes, plasmids, transposons, vectors, and inactivated organisms containing recoverable nucleic acid fragments, whether genetically modified or unmodified, or chemically synthesised in whole or in part.

To endow or enhance pathogenicity is defined as "when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism's ability to be used to deliberately cause disease or death. This might include alterations to, inter alia: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability."

Other Countries: AG Member Countries

All Australia Group countries have adopted this language into their respective national export control laws. These include Argentina, Australia,[101] Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, Ukraine, the U.K., the U.S., and the EU.[102]

Other Non-member Countries

There are non-members who align their export controls with the AG and whose laws follow the same "genetic elements" language. Examples include Singapore's Strategic Goods Control Act, India's SCOMET list,[103] Malaysia's Strategic Trade (Strategic Items) List under the Strategic Trade Act 2010 (e.g., 2021 list),[104] and the Philippines National Strategic Goods List, Annex 2 (dual-use list).[105]

Box 9: Export Control Cases Regarding Biological Agents and Toxins

Indiana University — Dual-Use Export Violation of Ricin Toxin (2024)

Indiana University's Bloomington Drosophila Stock Centre exported shipments of genetically modified fruit flies containing Ricin toxin (A-subunit) transgenes to 30 institutions in 16 different countries without an export licence. Ricin and all its subunits are covered by the Commerce Control List under the Export Control Classification Number (ECCN) 1C351 Human and Animal Pathogens and Toxins. Indiana University was sentenced under the Export Administration Regulations, originally issued under the Export Administration Act of 1979 (Section 766.3), as amended. In June 2024, the U.S. Bureau of Industry and Security and Indiana University concluded a settlement agreement, and the University received a one-year suspended denial of export privileges for certain controlled materials. The University also agreed to provide compliance training and present on the issue at relevant forums.[106]

Princeton University — Dual-Use Export Violations of Biological Agents

In a similar case, Princeton University exported various animal pathogens to several overseas research institutions. These pathogens are classified under the U.S. Commerce Control List (CCL) (ECCN 1C351, 1C352, 1C353). Thus, under the Export Administration Act of 1979 (Section 766.3), as amended, and the Export Administration Regulations (15 CFR Parts 730-774), they require specific licences for their export. Yet Princeton transferred them in 2021 without obtaining a licence. Princeton University reached an agreement with the BIS to pay a $54,000 fine and undertake audits of its export controls compliance programme.[107]

Japan

In 2020, Yokohama, a Japanese company, exported spray dryers without obtaining an export licence. Japanese authorities indicted company officers on the grounds that the equipment could be used in the production of biological weapons and therefore fell within Japan's export control regime, notably under the Foreign Exchange and Foreign Trade Act (Act No. 228 of 1949), the Export Trade Control Order (Cabinet Order No. 378 of 1949), and the relevant ministerial orders specifying controlled goods and technologies. The prosecution argued that the dual-use potential of spray dryers triggered licensing requirements. The company had not sought export authorisation, but the case was ultimately dropped.[108]

Belgium

Three Belgian companies—A.A.E. Chemie, Danmar Logistics, and Anex Customs—exported isopropanol to Syria and Lebanon without the required permits. Although isopropanol is widely used in pharmaceutical manufacturing, it also has potential applications in chemical weapons production. The companies were prosecuted in 2023, and several company officials received prison sentences.

The prosecutions were brought under Belgium's general export control framework established by the Law of 11 September 1962 on the import, export, and transit of goods and associated technology. While isopropanol was not restricted under that law as such, the exports violated EU sanctions against Syria, in particular Council Regulation No. 36/2012. These restrictive measures are implemented in Belgium through the Law of 13 May 2003 and the Royal Decree of 22 February 2013, as amended in 2014 and 2015.[109]

Germany

Alexander S., the manager of a trading company based in Saxony, Eastern Germany, exported chemicals and electrical equipment to entities in Russia, including institutions involved in the production of components for nuclear weapons and missile systems. Alexander O. advised and assisted him in carrying out these exports. In 2022, German prosecutors brought charges for the unlawful export of dual-use goods for the benefit of the secret services of a foreign power. Alexander S. was convicted and sentenced to three years' imprisonment for exporting controlled items without the required licence from the Federal Office for Economic Affairs and Export Controls (BAFA), in violation of EU Regulation (EC) No. 428/2009 and Section 18 of the German Foreign Trade Act (Außenwirtschaftsgesetz). The prosecution was based on general export control law.[110]

4.4.5. *Coverage of Non-Listed SOC and Fragments*

As discussed above, the AG Pathogens and Toxins List extends controls to certain SNAs, but coverage is not comprehensive. It captures genetic elements that code for genes specific to listed pathogens or toxins. Consequently, SOC and shorter fragments that do not fall within those listed categories may remain outside the scope of export controls.

However, the AG Guidelines address non-listed items. The guidelines dictate that:

> *"The Government will ensure that its regulations require the following:*
>
> *an authorisation for the transfer of non-listed items where the exporter is informed by the competent authorities of the Government in which it is established that the items in question may be intended, in their entirety or part, for use in connection with chemical or biological weapons activities;*
>
> *that if the exporter is aware that non-listed items are intended to contribute to such activities, it must notify the authorities referred to above, which will decide whether or not it is expedient to make the export concerned subject to authorisation".*[111]

Accordingly, competent authorities may impose controls on items that are not included on the AG CCL. Nothing in the AG Guidelines prevents governments from extending national export controls to additional SOC exported from their territory.

Further, where an exporter is aware that an unlisted item is intended to contribute to prohibited activities, the exporter must notify the competent authority. This catch-all provision provides a further basis for extending controls beyond specifically listed sequences to unlisted SOC, including fragments. Its reach is more limited, however, because it depends on the exporter's awareness of the intended misuse and does not itself impose broader precautionary obligations.

Two caveats are important.

First, the Australia Group is an informal and voluntary export control regime and does not itself create binding domestic legal obligations. Whether such a catch-all provision that covers non-listed items provides a legally enforceable basis for oversight therefore depends on how, and in what terms, individual states have incorporated it into national law.

Second, broad catch-all language necessarily provides limited ex ante clarity as to which specific sequences or fragments fall within its scope. Its application may therefore depend on case-by-case interpretation and enforcement. As a practical matter, such provisions are valuable as a legal backstop, but are unlikely, on their own, to provide sufficiently clear, predictable, and effective oversight of SOC and fragments.

4.4.6. *Recommendations*

1	**Closing the Gap in Application** Export controls—particularly those aligned with the Australia Group control lists—are an important mechanism for overseeing the cross-border transfer of SNAs. However, they primarily apply to transfers involving non-Australia Group participants and generally do not regulate transfers between participating states. This leaves a significant regulatory gap that requires attention.
2	**Introducing Screening Requirements** With the exception of the U.S. and the U.K., export control regimes have not been accompanied by clear screening guidance. This leaves broad discretion to providers and increases the risk of inconsistent compliance. Governments should develop supporting screening guidance as part of any export control modernisation effort. The available regulatory approaches for doing so are set out in Report 2.

3

Aligning Select Agent and Export Control Regimes

Select agent regulations and export control frameworks exhibit structural asymmetry. This divergence stems from their distinct policy objectives: select agent laws focus on domestic biosafety and biosecurity, governing the secure possession, use, and handling of dangerous pathogens within national borders, whereas export controls focus on non-proliferation and international security, restricting the cross-border transfer of sensitive dual-use items to foreign entities.

While these divergent purposes mean the scope of oversight may naturally differ, their current coverage of SNAs, SOC, and benchtop devices varies significantly. To prevent regulatory gaps where an SNA and benchtop device fall within the scope of one regime but are inadvertently excluded from the other, governments should conduct a systematic assessment of their alignment. Evaluating where these regimes should converge or diverge ensures comprehensive and consistent national oversight without introducing conflicting compliance burdens for researchers and industry.

4

Clarifying the Scope of "Genetic Elements" and a Tier-Based Approach

The U.S. has informally clarified how export controls apply to genetic elements, but most other jurisdictions have not. Moreover, the application of export controls to SOC also requires clarification or development. Both gaps create legal uncertainty and risk uneven implementation. As mentioned above, a blanket equivalence model of all SNAs would chill legitimate research and impose unnecessary licensing burdens. Reform should instead adopt a tiered, risk-based framework that calibrates national security concerns with the functional risk of the sequence in question. Coordinated clarification at the Australia Group level—or, at minimum, through national regulatory guidance—would reduce inconsistency and strengthen the overall regime.

5

Benchtop Devices

To ensure that benchtop devices remain in the hands of legitimate end users and are used only for legitimate purposes after export, exporting states could attach conditions to export licences.

Export Control Laws

Key Takeaways

1. Export control laws provide the strongest existing legal basis for regulating SNAs. Unlike most select agent regimes, export controls already extend beyond whole pathogens to certain genetic elements.
2. The scope of export controls remains uncertain for many SOC and fragments. Current controls are primarily tied to genetic elements associated with listed pathogens, leaving uncertainty regarding novel synthetic sequences that are not derived from historically controlled agents.
3. Catch-all provisions offer a potential mechanism for addressing emerging and unlisted risks. Australia Group guidelines contemplate controls on non-listed items that may contribute to biological weapons activities, but the extent to which this authority exists in domestic law varies across jurisdictions.
4. Export control obligations create a de facto need for sequence screening. Providers must assess whether a sequence falls within controlled categories and whether export licensing requirements apply. However, most countries have not issued specific screening guidance to support compliance.
5. Benchtop synthesis devices present an emerging regulatory challenge. Although certain devices and related software are already subject to export controls, export conditions for post-sale oversight should be considered.
6. Significant implementation gaps remain. The limited availability of screening guidance and uncertainty regarding the scope of controlled genetic elements create risks of inconsistent compliance and regulatory arbitrage.

4.5. Biological Weapons Non-proliferation and Counter-terrorism Laws

This category of national security laws prohibits the development, acquisition, possession, or use of biological weapons, regulates broader weapons of mass destruction proliferation activities, and/or criminalises acts of terrorism involving biological agents or toxins. Such laws often implement obligations under the BWC and UNSCR 1540, which both require states to criminalise biological weapons-related activities by non-state actors.

Across jurisdictions, such laws are framed to prohibit the development, acquisition, transfer, or use of biological weapons and related materials, but their application to SNAs is largely lacking or implicit at best. In practice, however, since these statutes implement the BWC, its definition of biological weapon likely applies to the extent that the statute's language can be read consistently with it. This is usually the case since these statutes tend to use vague language that is similar to that of the BWC. This arises through references to biological weapons "whatever their origin or method of production" (India),[112] or to "components" of biological weapons or microorganisms (Indonesia).[113] As discussed in the section on the BWC above, this means SNAs are likely covered, but only when their intended end-use is non-peaceful.

One known exception reflecting an "express" approach is found in the U.K. Anti-terrorism, Crime and Security Act 2001, which notes (Schedule 5) that pathogens and toxins that could be used in an act of terrorism include SNAs.[114] Schedule 5 on Pathogens and Toxins determines that microorganism includes "any nucleic acid deriving from a microorganism listed in this schedule (synthetic or naturally derived, contiguous, or fragmented…) that can encode infectious or replication competent forms of any of the listed microorganisms", or "any nucleic acid sequence derived from the microorganism which when inserted … alters or enhances that organism's ability to cause serious harm to human health".

U.K. law also requires notification to the Secretary of State when keeping or using pathogens and toxins listed in Schedule 5 (arts. 58–59), disclosure of persons holding such substances (art. 61), and compliance with additional requirements set out in Part 7. Compliance with these requirements could effectively entail a de facto screening obligation.

Here, too, coverage is limited to SNAs linked to listed pathogens and does not extend to unlisted SOC. Modernisation efforts should therefore also address these gaps within terrorism and national security frameworks.

To the extent that the relevant law is understood as applying to SNA, the critical question for SNA providers is whether, and under what circumstances, these criminal statutes apply when they supply SNAs to a customer with malicious intent, and whether they require providers to screen every transaction. Much turns on whether liability under the law requires actual knowledge, subjective awareness of risk, or an objective standard based on what a reasonable provider should have inferred from the information available. The answer to this question will depend on the precise wording of the relevant statute and its interpretation by the courts of the jurisdiction concerned. Thus, whether a failure to conduct screening can itself give rise to criminal liability, requires a case-by-case assessment (see the examples below).

> **Example: Indonesia.** Indonesia's Anti-Terrorism Law (Law No. 15/2003, as amended by Law No. 5/2018) establishes a legal framework that could, in principle, ground due-diligence obligations for providers of SNAs, even though SNAs are not explicitly mentioned. Article 10A(2) criminalises the intentional sale or provision of biological weapons or their components for terrorism-related purposes, while Article 12 extends liability to persons who provide or collect assets that are knowingly used—or should reasonably have been known to be used—for unlawful activities

involving biological weapons. Article 15 further expands responsibility to accomplices and facilitators, including those involved in preparatory or enabling conduct. Read together, these provisions suggest that entities supplying materials with dual-use potential may incur liability not only where intent is proven, but also where they disregard risks obvious to a reasonable person. Article 12's use of the word "reasonable" is significant because it expressly lowers the mental threshold required for criminal liability. Under Indonesian criminal law, intent (kesengajaan) is a subjective standard which includes both direct intent and dolus eventualis, where a person actually foresees the possibility of a prohibited outcome and accepts that risk. Negligence is instead an objective standard, based on what a reasonable person would have done in the same circumstances, that applies only where expressly provided by statute. Article 12 therefore likely imposes a due diligence duty on SNA providers - if they did not know the customer's intent that is not enough to avoid liability. In this context, a synthesis provider that fails to conduct basic customer screening or ignores clear red flags regarding the end use of potentially hazardous sequences could potentially be found to have recklessly facilitated a terrorism-related biological offence under general principles of Indonesian criminal law. This issue has not yet been considered by a court.

In the **U.K.**, Schedule 5 of the *Anti-terrorism, Crime and Security Act 2001* sets out a detailed list of pathogens and toxins subject to strict control for counter-terrorism purposes. Crucially, it also explains when nucleic acids are treated as part of those controlled materials.

Schedule 5 provides that:

1. "Microorganism" includes nucleic acids, whether of natural or synthetic origin, contiguous, or fragmented, where they fall within defined functional categories.
2. Coverage extends to nucleic acid sequences derived from a listed pathogen that:
    - Encode infectious or replication-competent forms of that pathogen; or
    - When inserted into another organism, alter or enhance its ability to cause serious harm to human health.
3. For toxins, Schedule 5 expressly includes any nucleic acid sequence coding for the toxin.[115]

Schedule 5 is one of the clearest national examples of explicit statutory treatment of nucleic acids. Under Section 59, any person or lab keeping synthetic DNA that encodes a Schedule 5 pathogen must notify the Secretary of State (via the National Counter Terrorism Security Office).

4.6. Dual-Use Research of Concern Policies

Dual-use research of concern (DURC) frameworks provide an additional layer of biosecurity oversight. They oversee life sciences research that may generate outputs that could be misused to cause harm. Such frameworks focus on research involving biological agents or other biological materials that could enhance harmful properties or otherwise pose significant risks to public health, safety, or security. They may require institutional review, risk assessment, risk-mitigation measures, and additional oversight before or during the conduct of high-risk research.

DURC frameworks regulate the conduct of research, rather than access to SNAs as stand-alone materials. They do not generally operate as mechanisms for controlling the sale, use, or transfer of biological agents—or SNAs for that matter—before they enter the research environment. DURC oversight should therefore be understood as complementary to controls governing the sale and use of high-risk SNAs.

Many countries lack DURC rules altogether. Where they do exist, the application of DURC rules to SNAs depends on how their material scope is defined. Where a framework applies to research involving a "biological agent", the key question is whether that term encompasses SNAs. The same distinction

between traditional, ambiguous, and express approaches therefore arises: a framework may be confined to whole or natural biological agents, may use language whose application to SNAs is uncertain, or may expressly extend the definition of a biological agent or covered material to synthetic components.

The recently issued U.S. Government Policy for Stopping High-Risk Life Sciences Research provides an example of the "express" approach. The policy, released on 28 July 2026, establishes new rules for federally supported high-risk life-sciences research.[116] It defines dangerous gain-of-function (DGOF) research as research involving a biological agent that seeks, achieves, or poses a substantial risk of achieving specified outcomes that could result in significant negative societal consequences. These include enhancing harmful consequences, disrupting beneficial immune responses or immunisation, conferring resistance to prophylactic or therapeutic interventions or facilitating evasion of detection, increasing stability, transmissibility, or dissemination, altering host range or tropism, increasing host susceptibility, or generating or reconstituting an eradicated or extinct biological agent. Federal funding for research meeting this definition is prohibited, while research that could potentially result in one or more of these outcomes and could result in significant negative societal consequences, must receive prior approval.

Importantly for SNAs, the policy defines "biological agents" by reference to 18 U.S.C. § 178 and expressly includes any naturally occurring, bioengineered, or synthesised component of a microorganism or infectious material that is capable of causing specified forms of harm. This language provides an express basis for bringing at least some SNAs within the policy's scope: an SNA may qualify as a biological agent that falls within the policy's scope where it constitutes a synthesised component of a microorganism or infectious material and is capable of causing the harms specified in the definition. Research involving such an SNA may therefore trigger the policy where the research meets the substantive criteria for DGOF or other covered research.

In contrast, DURC frameworks in many other countries in Asia and beyond remain grounded in traditional approaches and apply only to research involving conventional biological agents and toxins. Singapore's Biological Agents and Toxins Act applies an ambiguous approach.[117]

These examples illustrate the potential role of DURC and research oversight frameworks in governing high-risk SNAs. Expressly extending their scope to SNAs can help prevent a regulatory gap where research uses SNAs that could cause harm.

4.7. Genetically Modified Organisms Laws

Laws governing genetically modified organisms (GMOs) are designed to protect human health and the environment from risks arising from organisms whose genetic material has been altered through biotechnology. Under frameworks such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity[118] and corresponding national laws, however, regulation generally attaches to the modified organism or the activity involving its modification, rather than to SNAs as standalone materials.[119]

Whether a particular GMO framework is relevant to SNAs therefore depends first on how it defines its regulatory scope, including whether it refers expressly to nucleic acids and, if so, in what context.

Some frameworks address nucleic acids when they are introduced into cells or organisms as part of genetic modification. For example, Singapore's Biosafety Guidelines for Research on GMOs, issued by the Genetic Modification Advisory Committee (GMAC),[120] establish requirements for the containment, handling, transport, and disposal of GMOs used in research and provide a framework for reviewing and assessing such research. Their scope is defined by reference to research involving the manipulation of the genomic composition of biological entities, defined as cells, organisms, microorganisms, prions, viroids, and viruses.

The Guidelines do not, however, regulate nucleic acids as standalone materials. Rather, nucleic acids fall within their scope only in connection with particular research activities involving biological entities. For example, the introduction of naked nucleic acids into plants or animals is expressly excluded, whereas recombinant nucleic acids capable of giving rise to infectious agents are covered (Article 2.2.1 (v)). Similarly, synthetic and other nucleic acids are regulated in the context of their introduction into human subjects (Articles 2.3.2 and 2.3.3). The regulatory trigger is therefore not the possession or availability of the nucleic acid itself, but its use in specified research involving a biological entity or human subject.

An SNA may therefore fall within the framework once it is used to create or modify an organism, while remaining outside its scope when it is acquired, possessed, transferred, or stored in isolated form.[121]

This distinction is significant for biosecurity. GMO laws can provide an important downstream layer of oversight, including requirements relating to authorisation, containment, risk assessment, monitoring, and other safeguards once an SNA is used in regulated research or incorporated into an organism. At the same time, GMO laws generally do not regulate access to SNAs as such. They do not ordinarily govern the procurement, supply, possession, or transfer of an isolated synthetic sequence merely because that sequence could later be used to create a hazardous biological agent. GMO frameworks are therefore downstream biosecurity controls, but they do not substitute for legal measures directed specifically at access to and handling of SNAs before their incorporation into an organism.

4.8. Governmental Screening Guidance or Laws

As noted above, in several jurisdictions, select agent laws, export control, and non-proliferation or counter-terrorism regimes apply directly to SNAs. Where this is the case, providers will de facto need to conduct DNA synthesis screening to comply with licensing, transfer, and due diligence obligations. Although the legislation does not mandate providers to screen orders, compliance would be difficult in practice without reviewing orders to determine whether they contain controlled sequences. However, to date, only two countries have adopted screening guidance: the U.S. and the U.K. Report 2 addresses screening guidance and rules in detail. The following provides a brief overview.

4.8.1. *U.S. Department of Health and Human Services Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*

In 2010, the U.S. Department of Health and Human Services released the Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA. This was the first national governmental screening guidance to be published worldwide.[122] This guidance recommended baseline measures: customer due diligence and sequence screening of whole genomes against the select agent lists of the federal select agent program (FSAP) and the export common control list (CCL).

Yet the ability to reconstruct such agents from multiple fragments, and the emergence of SOC, underscored the need for more effective screening methods resulting in a 2023 revision, titled Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids (2023 HHS Guidance). The updated guidance is broader in scope and addresses several of the emerging risks identified in this report — including SOC, shorter sequences, and benchtop devices.[123] (Box 10)

Box 10: Main Changes Adopted in the 2023 HHS Screening Guidance

(i) **Regulated entities:** It is no longer addressed solely at providers, but also at manufacturers of benchtop nucleic acid synthesis devices, and users (e.g., institutions, principal users, end users, and third-party vendors).

(ii) **From lists to SOC:** While the previous recommendation was to screen strands using a "best match" approach against regulated agents, providers are now encouraged to screen for SOC that pose a risk, even if no direct match is identified in existing databases, which are based on the regulated lists. Screening should include all "sequences that are recognised to contribute to pathogenicity or toxicity as information regarding these sequences and their verified functions and improved screening methods become available (or as feasible)."

(iii) **Shorter sequences:** Under the previous 2010 guidance, sequences longer than 200 nucleotide sequences were compared against the Select Agents and Toxins List (SATL) and CCL using a best-match algorithm. The 2023 HHS Guidance recommends that the length of screening be decreased to 50 nucleotides by 2026. They also cover DNA and RNA.

(iv) **Benchtop devices:** Manufacturers must screen customers and adopt mechanisms to monitor and verify the legitimate use of the devices.

(v) **End users:** The guidance requires end users to maintain comprehensive records of SNA orders and transfers. Users must also "develop and follow best practices in biosafety, biosecurity, and responsible conduct regarding the possession, use, and transfer of SOC."

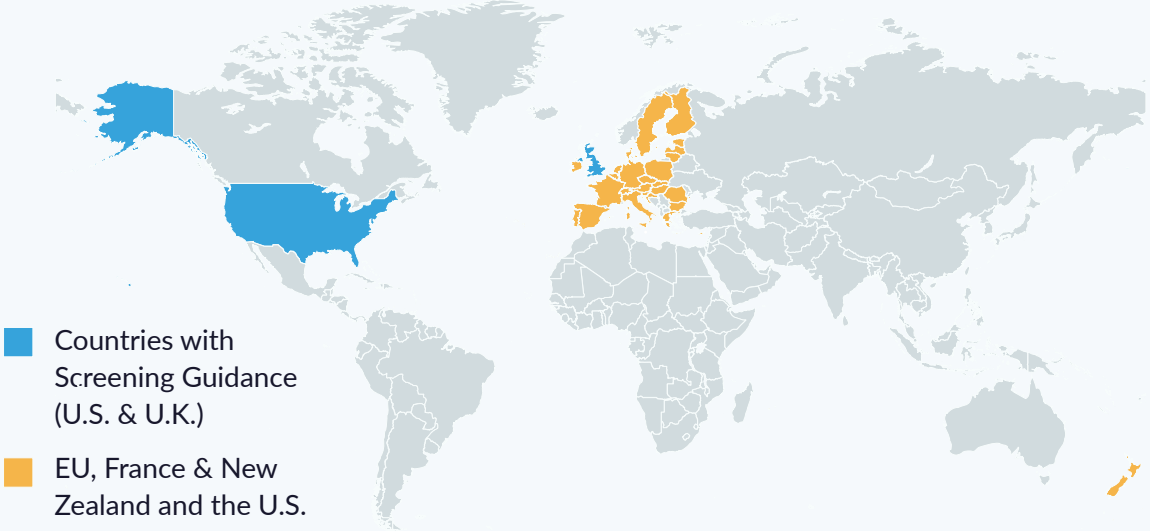
4.8.2. *U.K. Screening Guidance on Synthetic Nucleic Acids for Users and Providers*

In 2024, the U.K. adopted the "U.K. Screening Guidance on Synthetic Nucleic Acids for Users and Providers" (DSIT, 8 Oct 2024), in support of the implementation of existing domestic laws such as the Anti-terrorism, Crime and Security Act 2001 (addressed above). This guidance covers providers, users, and benchtop equipment operating in the U.K. As regards benchtop manufacturers, the U.K. Guidance recommends that manufacturers build in screening functionalities and that benchtop devices are only distributed to legitimate users.[124]

4.8.3. *Mandatory Screening Proposals*

There have been several attempts in recent years to introduce mandatory screening requirements, but none have succeeded. At the time of writing, several legislative initiatives merit attention: The European Biotech Act Proposal,[125] New Zealand's proposed Gene Technology Act,[126] the U.K. Biological Security Strategy,[127] and the U.S. Biosecurity Modernization and Innovation Act.[128] However, all remain pending in the legislative process, and none have been enacted. Report 2 elaborates on mandatory screening laws.

Box 11: Countries with screening guidance and legislative proposals



4.9. Recommendations on Adopting, Adapting, or Modernising National Legal Frameworks

Current national biosecurity legal frameworks were designed for a traditional biology era. Across jurisdictions, biosecurity regulation remains either absent or fragmented, with oversight dispersed across multiple regimes that are poorly aligned with the realities of SNAs. In the majority of jurisdictions, SNAs remain outside formal legal control or, at best, are covered ambiguously or only with respect to a narrow subset of SNAs.

What is required is not an entirely new regulatory domain, but targeted modernisation. SNAs represent a technological shift, not a shift in regulatory oversight principle. The same logic that justifies controls over dangerous pathogens applies equally to their synthetic equivalents. Extending existing frameworks to cover SNAs ensures that long-standing legal safeguards remain effective against emerging biological risks.

The analysis identifies the following gaps and recommendations.

1

Establish Baseline Frameworks in LMICs.

Many jurisdictions—particularly LMICs—lack domestic biosecurity frameworks altogether, enabling actors to circumvent stricter controls through jurisdictional arbitrage. Establishing baseline legal frameworks in these countries is a priority.

2

Modernise Domestic Select Agent Frameworks to Expressly Cover SNAs.

Where domestic select agent frameworks exist, they are typically anchored in whole/natural pathogen models focused on listed pathogens. SNAs frequently fall outside their formal scope. In some jurisdictions, coverage may be inferred from broad references to "components", "biological substances", or materials "capable of causing disease", but such implicit coverage creates legal uncertainty. Operative schedules rarely list genetic elements or nucleic acids. National laws should expressly address SNAs rather than rely on implication or strained interpretation.

3

Extend Coverage to SOC and Fragments.

Even in jurisdictions that do explicitly regulate SNAs, coverage typically remains limited to sequences closely linked to listed high-risk pathogens. Effective oversight should extend to SOC — including novel sequences that do not correspond to any listed agent. Coverage should also not be limited to full-length sequences: the ability to assemble shorter fragments into functional constructs requires that fragments be covered where their use could enable the assembly of a harmful biological function.

4

Tiered Approach and Judgement-based Catch-all Provisions.

Select agent laws and export controls impose stringent obligations: licensing, registration, inspection, and prior approval for transfer. Extending these requirements to all SNAs would prove disproportionate and chill legitimate research while creating unnecessary administrative burdens.

Reform requires a tiered, risk-based framework that calibrates oversight to functional sequence risk. Not all SOC pose equivalent risk levels or justify identical select agent/export controls. A blanket equivalence approach would stifle innovation and impose excessive regulatory burden on low-risk activities.

Defining SOC presents ongoing scientific and regulatory challenges. Some sequences can be identified and listed, while others remain unknown. Effective regulation demands a tiered approach to SOC alongside residual, judgement-based mechanisms—such as catch-all provisions—that place responsibility on actors handling potentially risky sequences to assess and manage their use.

Policymakers seeking regulatory reform should address this fundamental challenge: developing scientifically grounded criteria that distinguish among risk levels while maintaining proportionate regulatory responses.

This scientific foundation will prove essential for crafting laws that capture emerging SNA threats without undermining beneficial research and innovation.

5

Assess the Asymmetry between Export Controls and Domestic Law.

Export control regimes currently constitute the most legally robust layer of oversight. Through frameworks aligned with the Australia Group, many states regulate the cross-border transfer of specified genetic sequences and benchtop devices, particularly to non-participating countries. By contrast, most domestic select agent regimes do not extend to SNAs or to benchtop devices. This structural asymmetry—where some international transfers may be controlled while equivalent domestic transactions remain unregulated—creates regulatory arbitrage and should be assessed. The scope of oversight may differ given the distinct purposes of each regime.

6

Adopt Screening Requirements.

Where laws regulate the transfer of SNAs, order screening is de facto necessary for compliance. Screening is the only practical mechanism by which providers can determine whether orders contain regulated sequences. Most jurisdictions do not explicitly require screening, yet without it, providers cannot realistically meet existing obligations relating to licensing, authorisation, and export control. The available regulatory approaches for screening are set out in Report 2.

7

Modernise the Full Range of Domestic Legal and Regulatory Frameworks Relevant to Biosecurity.

Domestic legal and regulatory frameworks need to be updated to ensure that they expressly address SNAs where appropriate. This extends beyond select agent laws and may require amendments or clarification across DURC frameworks, GMO frameworks, biosafety and biosecurity standards, and other applicable regimes, depending on the jurisdiction.

Table 3: National Legal Frameworks Governing Synthetic Nucleic Acids

Framework	Legal Nature	SNA Coverage	Key Obligations	Gaps / Limitations	Recommendation
BIOSAFETY & BIOSECURITY: CORE FRAMEWORKS					
Select Agent Laws	National (binding)	Varies by jurisdiction. Three approaches: (1) traditional — no SNAs; (2) ambiguous — 'components capable of causing disease'; (3) express — explicit SNA inclusion. Even express frameworks cover only SNAs linked to listed pathogens.	Licensing, registration, access controls, biosafety/biosecurity plans, record-keeping. Transfers only between licensed entities in certified facilities.	Most jurisdictions exclude SNAs entirely. Ambiguous definitions create legal uncertainty. Operative schedules rarely list genetic elements. Sequences of concern, shorter fragments, and benchtop devices are not covered in most jurisdictions.	Modernise definitions and schedules; adopt tiered, risk-based approach; extend coverage to sequences of concern and fragments; require benchtop device registration; introduce screening requirements.
Export Control Laws (Australia Group [AG] CCLs)	National (binding); multilateral harmonisation through Australia Group (~70 states)	Expressly cover 'genetic elements' — chromosomes, plasmids, vectors, transposons, recoverable nucleic acid fragments, whether genetically modified or chemically synthesised — coding for listed pathogen genes that represent a significant hazard or endow/enhance pathogenicity. Broader scope than most select agent laws.	Transaction-specific export licences required before cross-border transfer of controlled items to specified end-users for specified end-uses. Providers must assess whether sequences match listed pathogen genes and whether function endows pathogenicity.	Controls apply only to cross-border transfers; intra-AG transfers and all domestic sales are unregulated. No coverage of de novo sequences, AI-generated sequences, unlisted sequences of concern. Most jurisdictions lack dedicated SNA screening guidance. Catch-all provisions exist but insufficient for systematic oversight.	Clarify scope of 'genetic elements' at AG level; adopt tiered risk framework for sequences of concern; introduce supporting screening guidance; align with domestic select agent regimes; attach end-use conditions to benchtop device export licences.
Counter-Terrorism / Non-Proliferation Laws	National (binding)	Generally implicit; application to SNAs arises through broad language (e.g., 'components of biological weapons', 'whatever their origin') and their close link to the BWC. U.K. ATCSA 2001 Sch. 5 is the clearest express example: covers nucleic acids encoding infectious/replication-competent forms of listed pathogens or altering pathogenicity.	Criminalise development, acquisition, transfer, or use of biological weapons and related materials. May impose notification duties and due-diligence obligations on providers. U.K.: Secretary of State notification required for listed SNAs.	SNAs not explicitly mentioned in most jurisdictions. Coverage, where inferred, is limited to SNAs linked to listed pathogens. Sequences of concern not captured. Modernisation needed in parallel with other frameworks.	Expressly extend counter-terrorism and anti-proliferation laws to SNAs; clarify due-diligence standards for providers; address sequences of concern beyond listed pathogen linkage.
COMPLEMENTARY FRAMEWORKS					
Dual-Use Research of Concern (DURC) Policies	National (varies; often institutional/policy-based)	Applies where research meets DURC thresholds (e.g., enhances pathogenicity).	Institutional review, risk–benefit assessment, risk-mitigation planning during research projects.	Many countries lack dedicated DURC rules. Frameworks do not govern procurement of SNAs or mandate screening of providers. Centre of gravity is research conduct, not material access.	DURC frameworks should also capture work with SNAs and not just traditional biological agents.
GMO Laws	National (binding)	Applies only once SNAs are incorporated into a living organism. Standalone SNAs are outside scope unless constituting a full-length viral genome copy.	Risk assessment, authorisation, containment, labelling, and monitoring obligations for GMOs.	Does not govern SNA synthesis, access, or transfer as such. Mitigates downstream biosafety risks only.	

Framework	Legal Nature	SNA Coverage	Key Obligations	Gaps / Limitations	Recommendation
Laboratory Biosafety Rules	National (binding)	Governs safe handling, storage, use, and disposal of biological materials. Primarily protects personnel and environment.	Biosafety-level containment requirements, handling, and disposal protocols.	Biosafety focus; does not address biosecurity or dual-use risks.	Adopt laboratory biosecurity rules.
Medicinal Products Laws	National (binding)	Regulates development, authorisation, manufacture, and distribution of medicines.	Safety, quality, and efficacy obligations through regulatory approval processes.	Not designed to address biosecurity risks of SNAs. Applies only in pharmaceutical/ medicinal context.	
GOVERNMENTAL SCREENING GUIDANCE					
U.S. HHS Screening Guidance (2010, revised 2023)	Non-binding guidance; supports compliance with select agent and export control laws	2010: whole sequences screened against FSAP and CCL lists. 2023: extended to SOC, shorter sequences (≥50 nt by 2026), RNA, benchtop devices, and end users.	Sequence and customer screening by providers; record-keeping by end users; benchtop manufacturers must screen customers and monitor use.	Non-binding; compliance is voluntary. Screening methods and databases for SOC still developing.	Adopt binding screening requirements.
U.K. Screening Guidance (DSIT 2024)	Non-binding guidance; supports implementation of ATCSA 2001 and related laws	Covers providers, users, and benchtop equipment in the U.K. Recommends built-in screening functionalities for benchtop devices.	Sequence and customer screening; benchtop devices distributed only to legitimate users.	Non-binding. No mandatory legal requirement to screen.	Adopt binding screening requirements.



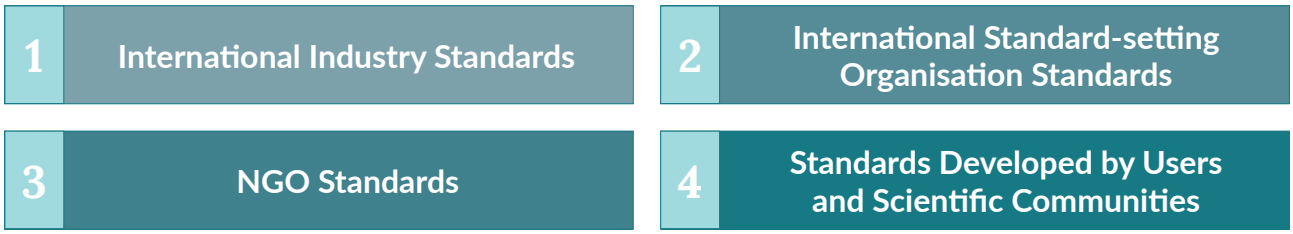
5. Private Standards

This section turns to private regulation — standards and guidance issued by private entities that do not carry the force of law and are not legally enforceable. While non-binding, these instruments nonetheless create expectations of compliance and may impose forms of social accountability on participating members.

Unlike the intergovernmental and national frameworks discussed above, which address the regulation of SNAs broadly, private governance initiatives have focused specifically on setting DNA synthesis screening standards (Box 12).

Report 2 examines screening in depth. This section therefore provides only a brief overview of the principal private instruments to complete the account of the current regulatory landscape.

Four broad approaches can be distinguished:



5.1. Private Industry Standards: IGSC Harmonized Screening Protocol

The IGSC, an industry association, adopted a voluntary screening protocol in 2009, which was most recently updated in its third version in 2023,[129] and version 3.1 in June 2026.[130]

The principal limitation of this model is that it is neither legally binding nor universally applicable: it applies only to IGSC members. However, IGSC members are expected to comply with the consortium's screening protocol as a condition of membership, creating de facto obligations through market and reputational mechanisms.[131] In practice, studies have shown that implementation by providers varies greatly.[132] As a result of many DNA synthesis providers not being IGSC members, significant segments of the global market remain outside its scope, and enforcement mechanisms are limited.

Given the high-consequence risks associated with SNAs, voluntary, membership-based standards are not a sufficient governance model on their own, as discussed in Report 2.

5.2. International Standard-setting Organisation Standards: ISO 20688-2: *Biotechnology—Nucleic Acid Synthesis, Part 2*

In 2024, the International Organization for Standardization (ISO) issued ISO 20688-2: Biotechnology—Nucleic Acid Synthesis, Part 2: Requirements for the production and quality control of synthesised gene fragments, genes, and genomes. It sets standards for producing and controlling the quality of synthetic genes, gene fragments, and genomes.[133] It is aimed at SNA producers, academic labs, and other users who need to evaluate the quality of SNAs. While much of the standard focuses on production quality, like purity and yield, it also includes explicit biosecurity requirements. Notably, providers must have "biorisk management", which includes sequences and customer screening protocols. It expressly determines that to prevent the intentional or inadvertent misuse of DNA synthesis technologies and products, producers should make use of a DNA sequence screening mechanism. An ISO standard specifically covering benchtop devices is under development.

5.3. NGO Standards

The Engineering Biology Research Consortium (EBRC), a non-profit organisation, is developing international screening best practices.[134]

5.4. Self-Regulation by Users

There has also been a movement within the scientific community toward self-regulation, including commitments to procure synthetic sequences only from providers that conduct screening. Examples include the Guiding Principles on Responsible Use of AI for Protein Design,[135] and the guidelines on responsible synthetic biology developed by the International Genetically Engineered (iGEM) Machine Foundation.[136] Further, California's AB 1963 (2022) requires the California State University system and encourages the University of California to develop guidance on procuring gene synthesis equipment and products from providers that mitigate misuse risks, including consideration of International Gene Synthesis Consortium (IGSC) criteria.[137] The resulting University of California guidance recommends that purchasers—such as researchers, lab managers, and procurement offices—ensure that providers meet IGSC criteria or apply equivalent safeguards before placing orders.[138]

Box 12: Overview of Screening Frameworks

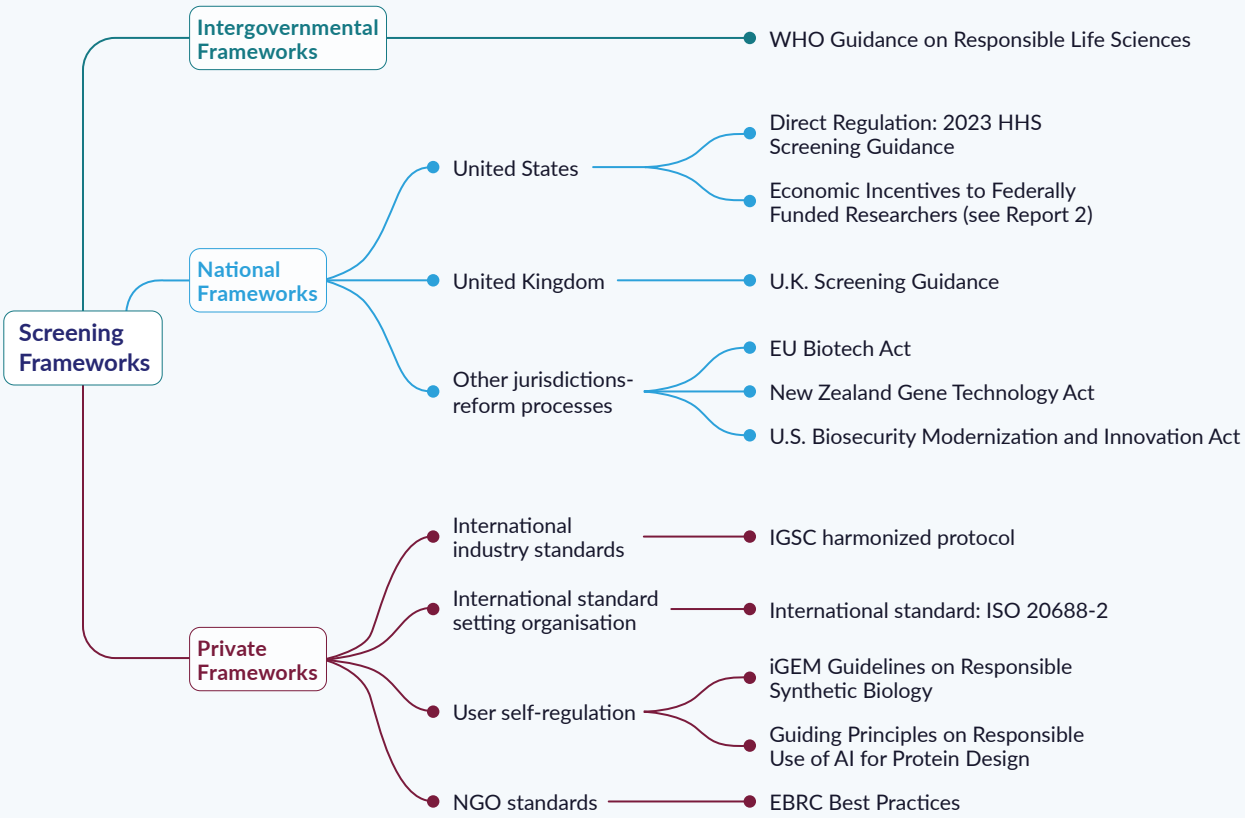


Table 4: Private Standards

Instrument	Issuing Body	Type	Binding?	SNA / Screening Coverage	Key Requirements	Limitations
1. INDUSTRY STANDARDS						
IGSC Harmonized Screening Protocol (v1: 2009; v3: 2023, and v3.1 in 2026)	International Gene Synthesis Consortium (IGSC) Industry association of major providers	Industry protocol	No (membership condition only)	Sequence and customer screening for orders of SNAs. Updated in 2023 to address emerging risks.	Members must comply as a condition of IGSC membership. Creates de facto obligations through market and reputational mechanisms.	Applies only to IGSC members; significant market segments remain outside scope. No external enforcement; implementation varies widely among members. Voluntary, membership-based model insufficient as a standalone governance mechanism given high-consequence risks.
2. INTERNATIONAL STANDARD-SETTING ORGANISATION STANDARDS						
ISO 20688-2: Biotechnology — Nucleic Acid Synthesis, Part 2 (2024)	International Organization for Standardization (ISO)	International technical standard	No (voluntary adoption)	Covers production and quality control of synthetic gene fragments, genes, and genomes. Includes explicit biosafety and biosecurity requirements, including sequence and customer screening protocols. A companion standard specific to benchtop devices is under development.	Producers must implement biorisk management, including sequence and customer screening. Expressly requires providers to use a DNA sequence screening mechanism to prevent intentional or inadvertent misuse. Aimed at SNA producers, academic labs, and other users evaluating SNA quality.	Non-binding; adoption is voluntary. Primarily a quality and production standard; biosecurity requirements are embedded but not the central focus. Benchtop device standard not yet finalised.
3. NGO STANDARDS						
International Screening Best Practices (in development)	Engineering Biology Research Consortium (EBRC) Non-profit organisation	NGO guidance	No	Developing international best practices for screening of SNAs.	Best practices for sequence and customer screening across providers and users.	Still under development; not yet finalised or publicly released. Non-binding; no enforcement mechanism.

Instrument	Issuing Body	Type	Binding?	SNA / Screening Coverage	Key Requirements	Limitations
4. USER AND SCIENTIFIC COMMUNITY SELF-REGULATION						
Guiding Principles on Responsible Use of AI for Protein Design	Scientific community / multi-stakeholder	Voluntary principles	No	Commitments to procure synthetic sequences only from providers that conduct screening.	Researchers commit to use only screened providers. Extends biosecurity expectations upstream to procurement decisions.	Voluntary; relies on individual researcher commitment. No monitoring or enforcement mechanism.
Responsible Synthetic Biology Guidelines	iGEM Foundation (International Genetically Engineered Machine Foundation)	Voluntary guidelines	No	Guidelines on responsible synthetic biology practices, including screening expectations.	Community-level standards for biosafety and biosecurity in synthetic biology projects.	Applies primarily to iGEM community participants. Voluntary; no legal force.
California AB 1963 (2022) + University of California Procurement Guidance	State of California (AB 1963); University of California (UC) (implementing guidance)	State law (requires guidance) + institutional policy	Partial (AB 1963 requires California State University (CSU) guidance; UC guidance voluntary)	Requires CSU to develop guidance on procuring gene synthesis equipment and products from providers that mitigate misuse risks. UC guidance recommends procuring only from providers meeting IGSC criteria or equivalent safeguards.	Purchasers—researchers, lab managers, procurement offices—must ensure providers meet IGSC criteria or equivalent before placing orders. Extends screening expectations to institutional procurement decisions.	AB 1963 requires CSU guidance but only encourages UC adoption; not mandatory for the UC system. Applies only within California. Relies on IGSC criteria as the benchmark, inheriting the limitations of that voluntary framework.

Key takeaway: Private standards fill a governance gap left by national and international law but are insufficient as a standalone model. Voluntary, membership-based instruments apply unevenly, lack enforcement, and cover only a subset of providers. Moreover, they address the point of acquisition by screening orders and customers, but do not regulate other stages of the SNA lifecycle, including possession, storage, transfer, use, and disposal. Mandatory screening requirements—examined in detail in Report 2—are needed to ensure consistent, enforceable biosecurity standards.



6. Conclusion and Recommendations

SNAs represent both a profound opportunity and a growing risk. SNAs are transforming medicine, agriculture, and biotechnology, and they are central to national bioeconomy strategies worldwide. Yet the same capabilities that drive innovation—rapid synthesis from digital sequences, falling costs, decentralised production, and AI-enabled biological design—also lower barriers to deliberate misuse and expand the threat landscape beyond what existing governance systems were built to address.

Most international and national legal and regulatory frameworks are lagging behind. They were designed for an earlier era of biology organised around whole, naturally occurring pathogens. With few exceptions, they do not regulate SNAs at all, or at best, implicitly. And even those frameworks that do extend to SNAs remain limited in scope—typically covering only sequences linked to listed pathogens—and are not fit for recent developments, including the emergence of novel SOC, and the ability to assemble dangerous pathogens from shorter fragments. They also do not cover benchtop devices.

To date, most of the regulation of SNA risks has come from the private sector. Several private standards on the screening of orders—the IGSC Harmonized Screening Protocol, ISO 20688-2, and community-led procurement initiatives—demonstrate that the risks are recognised and that practical screening tools exist. Yet these instruments are voluntary and legally unenforceable. They also focus on the point of acquisition, and do not address the broader range of biosecurity controls that should apply across the SNA lifecycle. Governments, by contrast, have not properly addressed these risks. Only two countries have adopted screening guidance and the vast majority of jurisdictions have not modernised their biosecurity laws to account for SNAs.

The consequence of this global legal gap is that existing controls may be circumvented through the use of SNAs without violating existing law, creating pathways for misuse with potentially catastrophic biological consequences.

It is against this background that this report has examined the current legal landscape and identified where reform is needed.

Findings on International Legal Frameworks

The report finds that the existing international legal regime—the BWC, UNSCR 1540, the IHR, and the Pandemic Agreement—provides a strong legal foundation for governing SNAs. Under established principles of treaty interpretation, each instrument arguably governs SNAs. The WHO guidance documents further demonstrate that states recognise SNAs as an issue requiring biosecurity oversight.

However, no treaty body has issued authoritative clarifications confirming that these obligations encompass SNAs or specifying what effective implementation requires in the current technological environment. This silence has contributed to uncertainty and inaction at the national level. Action through the BWC, WHO, or UN is therefore needed. Although these bodies may lack binding enforcement powers, they provide important forums for raising awareness, generating normative pressure, and sharing best practices.

Findings on National Legal Frameworks

The report finds that the national legal landscape is fragmented and uneven. Many jurisdictions—particularly LMICs—lack domestic biosecurity frameworks altogether, enabling actors to circumvent stricter controls through jurisdictional arbitrage. Where domestic frameworks exist, select agent laws in most jurisdictions do not expressly cover SNAs. In some, coverage may be inferred from

broad statutory language, but this creates legal uncertainty. Even in the jurisdictions with express SNA coverage, coverage remains restricted to sequences linked to listed pathogens and does not capture novel SOC or fragment assembly risks. And benchtop devices remain unregulated.

Export control regimes aligned with the Australia Group provide the most robust existing basis—expressly covering genetic elements, including chemically synthesised nucleic acid fragments—but they are limited to sequences of listed pathogens. Non-proliferation and counter-terrorism laws rarely address SNAs expressly. DURC policies remain designed around traditional biological agents.

Recommendations

Accordingly, the report sets out the following recommendations.

Regarding International Law

1

No new treaty is required. The existing international legal framework already provides the necessary legal basis for governing SNAs. States could pursue modernisation through protocols, annexes, declarations, or soft-law instruments that do not require reopening treaty negotiations. Other possible international strategies are addressed in Report 2.

2

Treaty bodies should adopt authoritative clarifications confirming that existing obligations encompass SNAs and specifying what effective domestic implementation requires. Specifically:

- The BWC Review Conference (in 2027), based on recommendations of the Working Group on the Strengthening of the Convention and/or input from a Science and Technology Advisory Mechanism, should clarify that Article IV obligations require states to adopt national SNA oversight, including modernised biosecurity laws and screening requirements.
- The UNSCR 1540 Committee should clarify that domestic controls over SNAs fall within states' implementation obligations and should include SNA-related capacity building in its technical assistance programmes.
- The WHO should update the IHR MEF to include SNA preparedness as a core element of national biosecurity evaluations.
- The Conference of the Parties under the Pandemic Agreement should explicitly address the Agreement's application to SNAs and the need to modernise national biosecurity laws accordingly.

3

Treaty bodies should clarify that effective domestic implementation in the age of SNAs requires states to adopt appropriate national oversight through modernised biosecurity laws and screening measures. See further discussion in Report 2.

Regarding National Law

4 **Low- and middle-income countries should establish baseline biosecurity frameworks**. The absence of domestic legislation in many jurisdictions enables actors to circumvent stricter national safeguards through jurisdictional arbitrage. International organisations and donor states should prioritise technical and financial assistance for this purpose.

5 **Governments should modernise select agent laws to expressly cover SNAs**. Statutory definitions should be amended to include SNAs, and regulated schedules should be updated to cover synthetic equivalents of listed pathogens and SOC. Governments should not rely on implied coverage, which creates legal uncertainty and leaves compliance indeterminate. U.S. law provides an example of an express approach.

6 **Coverage should extend to SOC and fragments**. Effective oversight should reach beyond sequences linked to listed pathogens to encompass novel sequences—including AI-generated sequences—that are functionally capable of causing serious harm. Coverage should also extend to shorter fragments whose use could enable the assembly of harmful biological functions. Governments and expert bodies should invest in defining which SOC require regulation and in developing scientifically grounded risk classification criteria.

7 **Reform should adopt a tiered, risk-based approach and a judgement-based catch-all provision**. Extending the full weight of select agent, export, or DURC/GMO controls to all SNAs would be disproportionate and would chill legitimate research. Oversight should be calibrated to functional sequence risk, combining tiered lists with residual, judgement-based mechanisms (catch-all provisions). Examples of a judgement-based approach exist in Annex 2 of the IHR, export controls, and the Singapore BATA.

8 **Governments should assess the asymmetry between export controls and domestic law.** Export control regimes regulate cross-border transfers of genetic elements and benchtop devices while most domestic select agent laws do not cover them. Both regimes should be reviewed and assessed in coordination so that SNAs within the scope of one are not inadvertently excluded from the other.

9	Governments should modernise **the full range of domestic legal and regulatory frameworks relevant to biosecurity** to ensure that they expressly address SNAs where appropriate. This extends beyond select agent laws and export controls and may require amendments or clarification across DURC frameworks, GMO frameworks, and other applicable regimes, depending on the jurisdiction.
10	**Regarding export controls, the Australia Group could clarify the scope of "genetic elements"**, address SOC within its Common Control Lists, and encourage all members and adherents to adopt dedicated screening guidance for SNAs.
11	**Countries should adopt screening requirements**. Where laws regulate SNAs, order screening is necessary for compliance. Screening is the only practical mechanism by which providers can determine whether orders contain regulated sequences. Without it, providers cannot realistically meet existing obligations relating to licensing, authorisation, and export control. The available regulatory approaches are set out in Report 2.
12	**Private governance instruments should complement, not substitute for, mandatory regulation**. The IGSC protocol, ISO 20688-2, and community-led initiatives inform screening practice but remain voluntary and unenforceable. Governments should treat them as informing—not replacing—binding legal requirements. See Report 2.

Report 1

Global Legal and Regulatory Landscape for Synthetic Nucleic Acids

Key Takeaways

1. **The global regulatory landscape is fundamentally misaligned with the technology it is meant to govern.** Existing biosecurity frameworks were designed for whole and/or natural pathogens. SNAs—and in particular SOC, shorter fragments, and benchtop devices—fall outside or only partially within the scope of most existing legal frameworks. This is not a marginal gap: it is a structural deficiency across the majority of jurisdictions examined.

2. **Global regulatory gaps enable actors to circumvent even well-designed national frameworks.** Many jurisdictions—particularly LMICs—lack or have weak domestic biosecurity regulations. Because actors can exploit jurisdictional arbitrage, the effectiveness of advanced national regimes depends on the strength of the weakest jurisdiction. Establishing baseline legal frameworks in LMICs is therefore a global biosecurity priority.

3. **Select agent laws, where they exist, were not designed for SNAs.** Most domestic frameworks are anchored in whole or natural pathogen models. SNAs frequently fall outside their formal scope, and where coverage can be inferred, it rests on implication or interpretation rather than express legal authority. Operative schedules rarely list genetic elements or nucleic acids. Legislative amendment or regulatory clarification is needed.

4. **Coverage should extend beyond listed pathogens to SOC and shorter fragments.** Currently, even express domestic frameworks capture only sequences closely linked to listed agents. Effective oversight should reach SOC and shorter fragments where they could reasonably be assembled into a functional construct capable of causing harm.

5. **Export controls are currently the most legally robust layer of SNA oversight — but their reach is structurally limited.** Through AG-aligned frameworks, many states regulate cross-border transfers of specified genetic elements, with a scope broader than most domestic select agent regimes. However, export controls apply only to genetic sequences of listed pathogens.

6. **Oversight should be tiered and risk-based, not blanket.** SNAs are not functionally equivalent to the pathogens they relate to. Extending full select agent or export control obligations to all SNAs would be disproportionate and would chill legitimate research. Reform should calibrate oversight to functional sequence risk through structured, tier-based lists supplemented by residual judgement-based catch-all provisions that place responsibility on actors handling potentially high-risk sequences to assess and manage their use. Developing the scientific criteria to underpin this tiering is an urgent task for policymakers and expert bodies.

7. **Select agent and export control regimes should be assessed in coordination.** The two regimes serve distinct purposes but together constitute the primary legal architecture for SNA oversight. Their current scope and coverage for SNAs and benchtop devices differ significantly, creating asymmetry in coverage. Alignment across the entire national biosecurity regime is required.

8. **Benchtop synthesis devices represent an emerging and largely unregulated vector of risk.** AG export controls cover devices capable of synthesising sequences above 1.5 kb, but only for international transfers. Domestic use remains largely outside regulatory scope. States should require domestic registration or licensing of devices, attach biosecurity conditions to export licences, and conduct post-shipment verification where feasible.

9. **Screening is the essential compliance mechanism — and it is almost entirely absent from domestic law.** Screening is the only practical means by which providers can determine whether an order contains a regulated sequence. Most jurisdictions do not explicitly mandate it. Only the U.S. and the U.K. have adopted dedicated screening guidance. Without screening requirements, providers cannot realistically meet existing obligations under select agent and export control laws. Screening requirements should accompany any regulatory modernisation effort; the available approaches are set out in Report 2.



Annex 1: List of Abbreviations

Abbreviation	Term
ACHS	Asia Centre for Health Security
AG	Australia Group
AG CCL	Australia Group Common Control List
AI	Artificial Intelligence
APHIS	Animal and Plant Health Inspection Service (United States Department of Agriculture)
BAFA	Federal Office for Economic Affairs and Export Controls (Germany)
BATA	Biological Agents and Toxins Act (Singapore)
BCG	Bio-Circular-Green Strategy (Thailand)
BDT	Biological Design Tools
BIS	Bureau of Industry and Security (United States Department of Commerce)
BSL	Biosafety Level
BWC	Biological Weapons Convention
CCL	Commerce Control List
CDC	Centers for Disease Control and Prevention (United States)
CEPI	Coalition for Epidemic Preparedness Innovations
CFR	Code of Federal Regulations (United States)
DURC	Dual-Use Research of Concern
DSAT	Division of Select Agents and Toxins (United States)
DSIT	Department for Science, Innovation and Technology (United Kingdom)
EAR	Export Administration Regulations (United States)
EBRC	Engineering Biology Research Consortium
ECCN	Export Control Classification Number
EMA	European Medicines Agency
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FATF	Financial Action Task Force
FBI	Federal Bureau of Investigation (United States)
FDA	Food and Drug Administration (United States)
FSAP	Federal Select Agent Program (United States)
GDPR	General Data Protection Regulation (European Union)
GCP	Good Clinical Practice
GENBANK	
GHS Index	Global Health Security Index
GMO	Genetically Modified Organism
HHS	United States Department of Health and Human Services
ICAO	International Civil Aviation Organization
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IGSC	International Gene Synthesis Consortium
IHR	International Health Regulations

Abbreviation	Term
INSDC	International Nucleotide Sequence Database Collaboration
ISO	International Organization for Standardization
ISO 20688-2	Biotechnology — Nucleic Acid Synthesis — Part 2: Requirements for the Production and Quality Control of Synthesized Gene Fragments, Genes, and Genomes
ISO 35001	Biorisk Management for Laboratories and Other Related Organisations
ITAR	International Traffic in Arms Regulations (United States)
JEE	Joint External Evaluation (World Health Organization)
KYC	Know Your Customer
LMIC	Low- and Middle-Income Country
MOH	Ministry of Health
MOT	Micro-organismes et toxines (France)
NBP 2.0	National Biotechnology Policy 2.0 (Malaysia)
NDRC	National Development and Reform Commission (China)
NTI	Nuclear Threat Initiative
OECD	Organization for Economic Co-operation and Development
OFAC	Office of Foreign Assets Control (United States Department of the Treasury)
OSTP	Office of Science and Technology Policy (United States)
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
QMS	Quality Management System
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals (European Union)
RIE	Research, Innovation and Enterprise Plan (Singapore)
RPD	Restricted Pathogen Database
SATL	Select Agent and Toxin List (United States)
SBRC	Sequence Biosecurity Risk Consortium
SCOMET	Special Chemicals, Organisms, Materials, Equipment and Technologies (India)
SOC	Sequence of Concern
SNA	Synthetic Nucleic Acid
SPAR	IHR States Parties Self-Assessment Annual Report
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures (World Trade Organization)
SSBA	Security Sensitive Biological Agents (Australia)
TBT Agreement	Agreement on Technical Barriers to Trade (World Trade Organization)
U.K.	United Kingdom
UN	United Nations
UNSCR 1540	United Nations Security Council Resolution 1540
U.S.	United States
USDA	United States Department of Agriculture
WHO	World Health Organization
WMD	Weapons of Mass Destruction
WTO	World Trade Organization

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