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Strategic Report

Biosecurity Strategy I: The Necessity of Introducing a Korean 『Nucleic Acid Synthesis Screening』 System

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- I . Problem Statement
 - II . Expansion of International Discussions on Synthetic Biology
 - III . Introduction and Trends in International Discussions on Nucleic Acid Synthesis Screening
 - IV . Policy Recommendations

Biosecurity Strategy I: The Necessity of Introducing a Korean 『Nucleic Acid Synthesis Screening』 System

I. Problem Statement

II. Expansion of International Discussions on Synthetic Biology

1. The Rapid Advancement of Cutting-Edge Biotechnology and Increasing Security Threats in the International Community
2. Issues Raised by Nucleic Acid Synthesis Technology

III. Introduction and Trends in International Discussions on Nucleic Acid Synthesis Screening

1. Definition and Necessity of the Nucleic Acid Synthesis Screening System
2. Global Efforts to Implement Nucleic Acid Synthesis Screening Systems: Comparison and Analysis

IV. Policy Recommendations

1. The Need for Developing Korean-Specific Nucleic Acid Synthesis Screening Guidelines
2. Policy Recommendations for Establishing a Korean Nucleic Acid Synthesis Screening System

I Problem Statement

▪ Emergence of New Security Threats Due to the Rapid Advancement of Synthetic Biology

- The combination of AI and synthetic biology has accelerated the development of DNA/RNA synthesis and gene editing technologies, bringing innovation and great expectations for advancements in the life sciences.
- However, concerns are rising within the international community regarding the dual-use nature of advanced biotechnology, with the potential misuse of synthetic biology technologies by terrorists to artificially create deadly pathogens.
- Consequently, voices advocating the regulation and standardization of nucleic acid synthesis technologies, which are at the core of synthetic biology, are spreading among major developed countries, international NGOs, and private organizations.¹

▪ Several developed countries and international organizations are implementing nucleic acid synthesis screening while proactively advancing global biosecurity frameworks and standardization efforts

- The United States² and United Kingdom³ have published national guidelines for nucleic acid synthesis screening as part of their biosecurity strategies, marking their strategic moves to take the lead in global regulation and standardization efforts in synthetic biology.
- Global NGOs, such as the International Biosecurity and Biosafety Initiative for Science (IBBIS), have rapidly initiated efforts to establish new international norms and standards for synthetic biology to enhance global biosecurity.

1 Nicole E. Wheelers et al. (2023). "Developing a Common Global Baseline for Nucleic Acid Synthesis Screening," Applied Biosafety, vol.29, no.2

2 The US Department of Health & Human Services (2023). "Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids," published on Oct 2023.

3 The UK Department for Science, Innovation & Technology (2024) "UK screening guidance on synthetic nucleic acid for users and providers," published on Oct 8, 2024.

- Singapore is actively working to lead regional efforts in nucleic acid synthesis guidance through the Asia Centre for Health Security (ACHS), with a focus on developing a pan-Asian regulatory framework for biosecurity.
- **South Korea's limited attention to nucleic acid synthesis screening raises concerns about both the decline of its industrial competitiveness and potential national security vulnerabilities**
 - The Nucleic Acid Synthesis Screening system was designed to ensure that high-risk nucleic acids were legally transacted only between qualified suppliers (companies) and consumers (researchers), thereby minimizing the risk of misuse.
 - South Korea has implemented strict regulations on the dual use of biotechnology through national laws such as the BWC Act⁴ or the LMO Act⁵
 - However, these laws primarily focus on the regulation of complete biological entities (e.g., viruses, bacteria, fungi, or genetically modified organisms) rather than addressing the design, manipulation, and distribution of nucleic acids (DNA/RNA), which serve as the building blocks of these organisms.
 - South Korea's lack of oversight of nucleic acid synthesis poses a significant risk, particularly in international regulatory and standardization efforts. Falling behind in these developments could undermine the credibility of domestic companies and researchers in global markets, potentially leading to South Korea's exclusion from the global bioeconomy and biotechnological supply chains.
 - * Some South Korean companies have voluntarily joined international self-regulatory consortia established by global organizations to comply with evolving biosecurity standards, allowing them to continue operating in international markets.
- **This study examines global trends to assess the need for a Korean-specific Nucleic Acid Synthesis Screening system to enhance biosecurity, industrial competitiveness, and national security.**

4 Republic of Korea, 「Act on the Prohibition of Chemical and Biological Weapons and the Regulation of Certain Chemicals and Biological Agents, Law No. 20319),

5 Republic of Korea, 「Act on Transboundary Movements of Living Modified Organisms」, Law No. 158685),

II Expansion of International Discussions on Synthetic Biology

1. The Rapid Advancement of Biotechnology and Increasing Security Threats in the International Community

- The accelerating pace of advancements in synthetic biology
 - Synthetic Biology is an emerging interdisciplinary field that advances the life sciences through an engineering-based approach. It enables: 1) the design and construction of novel biological components and systems that do not exist in nature; and 2) the redesign and reconstruction of existing biological systems to enhance their functionality or create new applications.
 - Nucleic acids (DNA/RNA) are fundamental biopolymers essential for all living organisms. Nucleic acid sequences determine an organism's physiological functions and biological processes, making them crucial elements in synthetic biology research and applications.
 - Synthetic biology applies engineering principles such as 'modularization', 'standardization', and 'componentization', which are concepts commonly used in electrical, electronic, and computer engineering. This approach facilitates genetic editing and enables production of high-performance biological substances.

What is Nucleic Acid?

Nucleic acid is a biopolymer found in biological cells and plays an essential role in the existence of life. It is responsible for storing and expressing genetic information, protein synthesis, and cellular regulation, making it often referred to as the "blueprint of life."

Structure of Nucleic Acid

Nucleic acids are polymers composed of nucleotides, which are the basic building blocks consisting of 1) Base (nitrogenous base), 2) Sugar (pentose sugar), and 3) Phosphate group. Nucleotides are linked together in a polymer chain, where the phosphate group of one nucleotide bonds with the sugar of another nucleotide, forming a long-chain structure that constitutes DNA and RNA.

What are DNA and RNA?

- * DNA (Deoxyribonucleic Acid): A nucleic acid that serves as the primary genetic material in most living organisms. It has a double-helix structure and is responsible for storing hereditary information.
- * RNA (Ribonucleic Acid): A nucleic acid responsible for transmitting genetic information and facilitating protein synthesis. Unlike DNA, RNA is generally single-stranded and plays a key role in gene expression

- New Opportunities and Challenges Arising from Advances in Gene Manipulation and Editing Techniques
 - Developed in 2012, CRISPR (“gene scissors”) revolutionized gene editing by enabling precise DNA cuts for deletion, replacement, or insertion, transforming genetic modification
 - * However, with current technology, the ability to cut specific sections of DNA or RNA (i.e., nucleic acids) and seamlessly join them to create entirely new biological materials
 - Transformative gene editing technology has introduced new opportunities for society; however, it has also raised critical challenges that require further discussion, including safety, ethics, and regulatory frameworks.⁶

Opportunities:

- ① Development of New Diagnostic Products and Targeted Therapies
 - Creation of advanced diagnostic kits, such as rapid COVID-19 testing methods
 - Development of treatments for rare and intractable diseases (e.g., anemia, cancer)
- ② Development of High-Value Crops
 - Enhancing nutritional value and improving resistance to pests and diseases through specific genetic modifications
 - Eliminating disease-related genes to develop disease-resistant crops
- ③ Development of Industrial New Materials
 - Innovation in biofuels and new biomaterials
 - Engineering microorganisms to mitigate natural disasters

⁶ Korea Research Institute of Bioscience and Biotechnology (2021) “크리스퍼(CRISPR) 유전자편집” (in Eng: “CRISPR and Gene-editing”) BioINregulation, 2021-11; also see, the U.S. Government Accountability Office (2020). “Science&Tech Spotlight: CRISPR Gene Editing,” GAO-20-478SP, released Apr 07, 2020.

Challenges:

- ① Safety Concerns
 - Unintended genetic modifications may lead to the emergence of new diseases.
- ② Ethical Concerns
 - Potential misuse of gene-editing technology beyond therapeutic purposes for human enhancement (e.g., muscle augmentation, improved learning and memory).
 - Ethical debates surrounding genetic modification of germ cells and embryos.
- ③ Regulatory Challenges
 - The lack of global standards prevents countries from establishing clear regulatory frameworks. (e.g. Uncertainty over whether gene-edited crops should be classified the same as traditional GMO crops)

■ The Emergence of a New Paradigm in Synthetic Biology Driven by AI Advancements

- In 2023, South Korea also identified six core technologies in synthetic biology⁷, and these next-generation technologies in advanced biotechnology are being highlighted as key future industries and new growth engines for South Korea’s economy.

① Bio-Molecular Design	Design of nucleic acids (DNA, RNA) and proteins
② Circuit Design	Engineering of genetic circuits and metabolic pathways
③ DNA/RNA Synthesis and Control	Synthesis, assembly, editing, and sequencing of nucleic acids from an engineering perspective
④ Bio-System Fabrication	Production of proteins through cell-free systems or artificial cells
⑤ Digital-Based Automation and High-Speed Processing	Biofoundry
⑥ Scale-Up	Implementation of large-scale production using advanced ICT technologies, such as digital twins

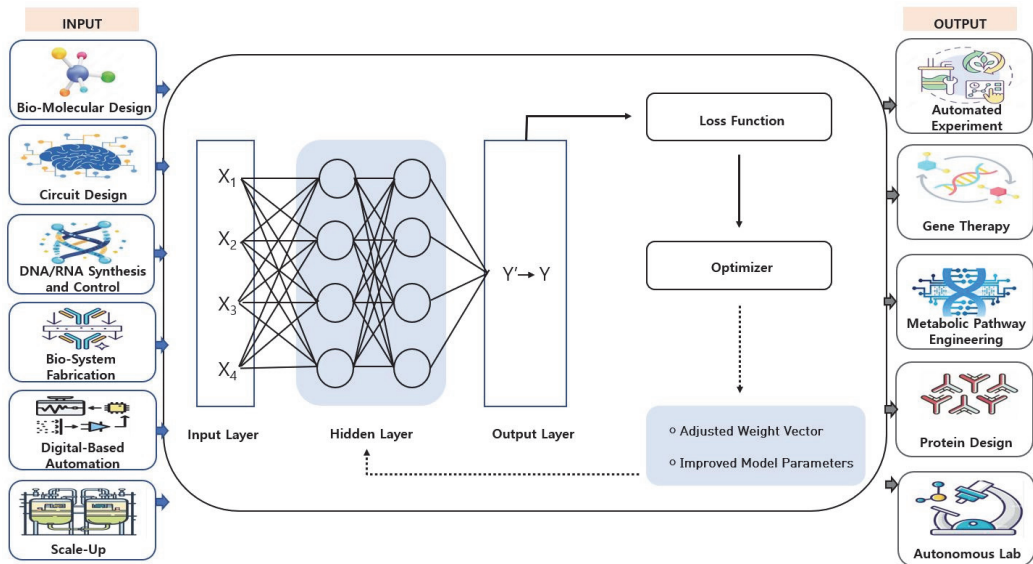
7 과학기술정보통신부, 「합성생물학 핵심기술개발 및 확산전략」 보도자료; in Eng: Ministry of Science and ICT, Republic of Korea (2023). “Development and Dissemination Strategy of Core Technologies in Synthetic Biology” Press Release (2023. 10. 30.)

- Artificial Intelligence (AI), along with machine learning and deep learning technologies, is driving innovation in nucleic acid synthesis by leveraging advancements in high-performance GPUs and big data industries.
- These developments have enabled the accumulation and analysis of vast amounts of data, thereby accelerating progress in this field.
- The integration of advanced synthetic biology technologies with artificial intelligence (AI) is expected to establish a new interdisciplinary domain and drive innovative advancements in the field of biotechnology.⁸

① Automated Experiment Design	<ul style="list-style-type: none"> ◦ Optimization of experimental design ◦ High-confidence result prediction ◦ Data-driven decision-making
② Gene Therapy	<ul style="list-style-type: none"> ◦ Improved efficiency and precision ◦ Targeting of specific genes ◦ Predictive analysis capabilities
③ Metabolic Pathway Engineering	<ul style="list-style-type: none"> ◦ Identification and enhancement of pathways ◦ Production of specific compounds ◦ Development of biofuels, pharmaceuticals, and chemicals
④ Protein Design	<ul style="list-style-type: none"> ◦ Prediction of protein structure and function ◦ Creation of innovative proteins ◦ Development of therapeutics, enzymes, and biomaterials
⑤ Autonomous Laboratories	<ul style="list-style-type: none"> ◦ Fully automated experiments ◦ AI-driven decision-making ◦ Innovation in research processes

- Based on the above information, <Figure 1> illustrates the process by which advanced synthetic biology technologies leverage AI’s learning capabilities and big data analysis, establishing a new paradigm and driving innovation in the field of advanced biotechnology.

8 Amaan Arif, Prekashi Garg, and Prachi Srivastava (2024) Unlocking the Transformative Power of Synthetic Biology, *Archives of Biotechnology and Biomedicine*, 2024(8).



〈Figure 1〉 Expansion of Advanced Biotechnology Through Artificial Intelligence⁹

- Particularly As depicted in Fig. 1, the hidden layer of AI learning highlights the necessity for heightened attention and caution in synthetic biology regarding the black-box nature of AI and the potential occurrence of unintended outcomes owing to hallucination effects.
- These factors emphasize the need for robust validation, transparency, and regulatory oversight in AI-driven synthetic biology applications.

2. Challenges and Emerging Issues in Nucleic Acid Synthesis Technology

- Potential for Bioweapon Development and Dual-Use Risks
 - Countries may leverage AI and synthetic biology technologies to artificially create highly pathogenic viruses or deadly biological agents to develop weapons of mass destruction (WMD) as part of their national security strategies.

⁹ referenced by: Attia Iram, Yueming Dong, Condruta Ignea (2024) “Synthetic biology advances towards a bio-based society in the era of artificial intelligence,” *Plant Biotechnology*, vol. 87. 103143.; also, see Amaan Arif, Prekashi Garg, and Prachi Srivastava (2024) *Ibid*.

- If individual scientists or private companies synthesize nucleic acids and attempt genetic manipulation without regulatory oversight, this could lead to unintended biological risks or malicious use, such as bioterrorism.
 - Notable Cases: Poliovirus synthesis in a laboratory (2002)¹⁰, reconstruction of the 1918 Spanish Influenza Virus (2005)¹¹, chemical synthesis of a bacterial genome (2010)¹², synthesis of an artificial minimal bacterial genome (2016)¹³, and de novo synthesis of horsepox virus (2017)¹⁴
- Ethical Issues in Gene Manipulation and Editing Technologies
 - Ethical concerns over the editing of specific genetic traits (e.g., intelligence, physical abilities, and appearance) to create customized humans are increasing as such possibilities become more realistic.
 - The integration of advanced nucleic acid synthesis technology with CRISPR gene editing has intensified ethical debates over germline editing, particularly regarding the genetic modification of human embryos.¹⁵
- Safety Concerns in AI-Based Genome Manipulation
 - If AI-designed genetic sequences cause unexpected mutations or toxicity, the treatments or vaccines developed using these sequences may cause serious side effects.

¹⁰ Jeronimo Cello, Anniko V. Paul, and Ekard Wimmer (2002). "Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Templat," *Science*, Vol.297, No.5583

¹¹ Terrence M. Tumpey et al. (2005). "Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus," *Science* Vol.310, No.5745

¹² Daniel G. Gibson et al. (2010). "Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome," *Science*, Vol.329, No.5987

¹³ Clyde A. Hutchison (2016). "Design and synthesis of a minimal bacterial genome," *Science*, Vol.351, No.6280.

¹⁴ Gregory D. Koblentz (2017). "The De Novo Synthesis of Horsepox Virus: Implications for Biosecurity and Recommendations for Preventing the Reemergence of Smallpox," *Health Security* Vol 15, No.6, pp.620-628.

¹⁵ Jung, Tae-Chang (2020). "Bioethics and Personal Autonomy in Genetic Enhancement: Issues of Germline Gene Editing Using CRISPR-Cas9 Technology," *Interdisciplinary Humanities*, Vol.13, No.1, Issue 27, pp.29-61

- During AI-driven nucleic acid editing, there is a risk of off-target effects, where unintended genetic modifications occur instead of in the intended target genes, leading to unpredictable consequences.
 - Black-box algorithms obscure the decision-making process of AI, making it difficult to trace the principles and criteria used in genome design, and complicating accountability and regulatory oversight.
 - If artificially synthesized organisms are released into natural ecosystems, they may disrupt ecological balance or cause unforeseen biological changes, posing significant environmental risks.
- Lack of Data Privacy Protection and Risk Assessment Protocols
- Currently, there is a lack of internationally unified risk assessment protocols for gene editing and nucleic acid synthesis technologies and standardized, reliable guidelines remain underdeveloped.
 - As gene-editing technologies advance rapidly, securing stable nucleotide sequence data remains challenging. Bioindustry stakeholders, particularly biotechnology companies, are often reluctant to share genetic data due to intellectual property concerns.
 - * Nucleotide sequence stability refers to the ability of biomolecules to resist degradation while maintaining functionality within the body or under laboratory conditions, which is a critical factor in synthetic biology, gene therapy, and vaccine development (e.g., the introduction of pseudouridine in Pfizer-BioNTech mRNA technology).
 - With AI-driven nucleic acid synthesis and gene editing becoming increasingly digitized, concerns have grown over the potential misuse of stored genetic information and the risk of government surveillance and control.
 - * Gene-based racial discrimination and targeted surveillance of high-risk individuals are possible at the state level. Additionally, insurance companies may use genomic data to discriminate applicants based on genetic predispositions.¹⁶

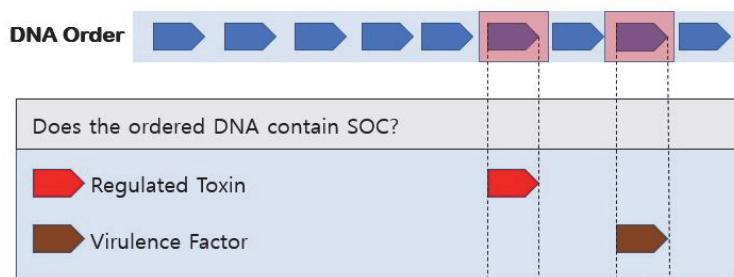
16 Kim, HyunJung (2024). "The U.S. Biosecure Act and National Security in the Digital Bio Era," Issue Brief, No. 516, Institute for National Security Strategy (February 22, 2024).

III International Trends in Nucleic Acid Synthesis Screening

1. Definition and Necessity of the Nucleic Acid Synthesis Screening System

- Definition of Nucleic Acid Synthesis Screening

- Evaluating synthetic DNA or RNA sequences to ensure that potentially hazardous genetic materials are not misused.
- High-risk sequences that may pose pathogenic, toxic, or biosecurity threats are classified as “Sequences of Concern(SOC).”



〈Figure 2〉 the concept of nucleic synthesis screening¹⁷

- Efforts are underway to establish an international import/export control system that screens DNA and RNA sequences in the global market. This system detects the presence of Sequences of Concern (SOC) and prevents the distribution of genetic material to unauthorized users.
- The Nucleic Acid Synthesis Screening system is modeled after international arms control and non-proliferation regimes, such as the Missile Technology Control Regime (MTCR) and Australian Group (AG).

→ Nucleic Acid Synthesis Screening is being established as an international arms control and non-proliferation regime based on strategic trade control mechanisms for imports and exports.

17 Nicole E. Wheelers et al. (2023). *Ibid.* Figure 1

■ Necessity of Nucleic Acid Synthesis Screening

- **Prevention of Misuse:** Restricts access to Sequences of Concern (SOC) to authorized users to prevent unregulated and uncontrolled nucleic acid synthesis.

- Blocks malicious actors (e.g., terrorists) from exploiting SOC to develop bioweapons or high-risk novel pathogens for terrorist purposes.
- Prevents unregulated nucleic acid synthesis by non-expert individuals outside institutional oversight, reducing the risk of emerging high-risk pathogens being developed or released.

- **Adapting to Technological Advancements:** Advances in synthetic biology have made genetic material synthesis easier and cheaper, creating gaps in existing regulations that could be exploited.

- Example: Benchtop DNA synthesizers, small enough to fit on a laboratory desk, can synthesize DNA strands. However, current technology limits synthesis to sequences under 120 base pairs (bp).¹⁸
- Future advances in enzyme-based DNA synthesis, hardware automation, and AI-powered computational tools could revolutionize the use of benchtop DNA synthesizers, making regulation even more critical.¹⁹

- **Strengthening Public Health and Global Trust:** Ensures responsible oversight and governance in biotechnology, maintaining public trust in the industry.

- Enhancing national public health capabilities and public confidence in the biotechnology sector.
- Nucleic Acid Synthesis Screening is likely to become a key issue in international strategic trade control agreements and treaties, including the BWC and the Australia Group.

18 Conversely, large-scale U.S.-based gene synthesis companies can use industrial-scale equipment to synthesize 400 bp sequences in batches of 100,000 at once, with expectations of reaching 500 bp in the near future

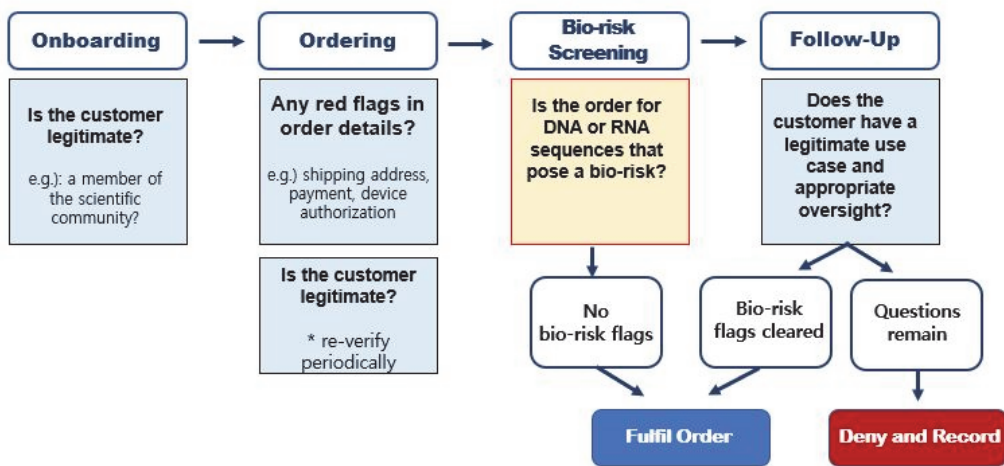
19 Max Langenkamp, “Securing Benchtop DNA Synthesizers: As the field of benchtop DNA synthesis evolves, it will require ongoing monitoring,” *Biotechnology*, Institute for Progress (IFP), Dec.10th, 2024, available at ifp.org/securing-benchtop-dna-synthesizers/

2. Global Efforts to Implement Nucleic Acid Synthesis Screening Systems: Comparison and Analysis

- International Consensus and Initiatives on the Necessity of Nucleic Acid Synthesis Screening
 - Over 30 DNA suppliers have joined the International Gene Synthesis Consortium (IGSC), voluntarily committing to biosecurity-related screening systems and pledging to implement them internally.

Referencing international export control regime such as the Australia Group (AG), and legal framework such as the U.S. Department of Commerce’s Export Administration Regulations (EAR), and the U.S. Department of State’s International Traffic in Arms Regulations (ITAR).²⁰

- The International Biosecurity and Biosafety Initiative for Science (IBBIS), a global NGO, has developed and provides free access to “Common Mechanism,” an open-source software for nucleic acid synthesis screening



〈Figure 3〉 Basic Protocol of IBBIS’s “Common Mechanism”²¹

²⁰ Sophie Rose and Cassidy Nelson (2023). “Synthetic Nucleic Acid Screening: Overcoming challenges with implementation,” The Center for Long-Term Resilience, Nov 2023.

²¹ IBBIS. “Common Mechanism: A free, open-source, globally-available tool for synthesis screening,” available at ibbis.bio/our-work/common-mechanism (last accessed on Feb 10, 2025)

* Currently available screening platforms include ‘ThreatSeq,’ ‘FAST-NA,’ ‘SeqScreen,’ and ‘Aclid.’ ‘Meanwhile,’ ‘Common Mechanism’ and ‘SecureDNA’ are in beta testing.²²

- Comparative Analysis of the Commonalities and Differences in U.S. and U.K. policies
 - In October 2023, the U.S. Department of Health and Human Services (HHS) released the “Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids.”
 - * A recent Executive Order mandates that U.S. government-funded institutions must purchase nucleic acid sequences only from suppliers that conduct customer and sequence screening²³
 - In October 2024, the United Kingdom introduced its own “UK Screening Guidance on Synthetic Nucleic Acids for Users and Providers.”
 - Currently, the U.S. and U.K. are the only countries to have officially released screening guidelines for nucleic acid synthesis. Although their policies share common principles, they exhibit distinct differences in terms of approach and implementation.

- Commonalities in U.S. and U.K.

① Emphasis on Screening for Sequences of Concern (SOC)

- Identifies SOC to prevent misuse in synthetic production and mitigate biosecurity risks.
- Recognizes SOC as dual-use materials and aligns screening guidelines with export control regulations.

② User Identity Verification and Record-Keeping

- Requires verification of the legitimacy of customers and end-users ordering SOC or related equipment.
- Recommends that suppliers, users, and manufacturers maintain detailed records of customer information, sequence data, and transaction history for traceability.

²² Sophie Rose et al. (2023). “Practical Questions for Securing Nucleic Acid Synthesis,” *Applied Biosafety*, vol.29, no.3

²³ The White House. (2023) (Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence)

③ Balancing Responsibility and Innovation

- Promotes the responsible use of synthetic biology while ensuring that regulations do not hinder legitimate research and commercial activities.
 - Aims to establish a balanced governance framework that supports both security and scientific progress.
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■ Differences Between U.S. and U.K

① Differences in Legal Frameworks

- U.S.: Established as an export control system for homeland security based on the Federal Select Agent Program (FSAP) and the Commerce Control List (CCL)
- U.K.: References various legal frameworks across multiple domains, including the Genetically Modified Organisms (GMO) Regulations, the Control of Substances Hazardous to Health (COSHH) Regulations, and the Anti-Terrorism, Crime and Security Act (ATCSA)

② Screening Methods

- U.S.: Uses the Best Match screening method to precisely identify pathogenic gene sequences and SOC listed under the CCL
 - Aims to align with international agreements, such as the Biological Weapons Convention (BWC), and promote broad participation from academia and industry worldwide by supporting the establishment of ISO 20688-2:2024²⁴
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²⁴ ISO 20688-2:2024 provides guidelines for the manufacturing and quality management of synthetic gene fragments, genes, and genome products, ensuring high product quality, fair trade, and standardized global practices.

IV Policy Recommendations

1. The Need for Developing Korean-Specific Nucleic Acid Synthesis Screening Guidelines

- Strengthening Biosecurity Capabilities → Prevention of bioweapon development and bioterrorism
- Maintaining Global Competitiveness in Advanced Biotechnology → Enhancing global research collaboration and promoting the bioeconomy
- Establishing an Ethical Research Environment → Ensuring the responsible use of nucleic acid synthesis and genetic engineering
- Enhancing Research Credibility → Preventing illegal research and the misuse of nucleic acid synthesis

- Preventing Biosecurity Threats and Strengthening National Security
 - According to a report published last year by the U.S. Department of State, North Korea has advanced beyond its previous 13 known biological warfare agents and is now acquiring gene-editing capabilities using CRISPR technology.²⁵
 - South Korea is not only exposed to threats from North Korea but also to global terrorism, making it imperative to actively participate in international counterterrorism efforts.
 - The South Korean government has designated advanced biotechnology as a national strategic industry, investing substantial budgets and pushing for regulatory reform. However, overemphasizing technological developments without adequate oversight can lead to unforeseen biosecurity incidents.

25 Kim, HyunJung & Byun, Sang-Jung (2024). "North Korea's CRISPR Capabilities and National Security as Indicated in This Year's U.S. State Department Report," Issue Brief No. 537, Institute for National Security Strategy

- Securing Global Competitiveness in Advanced Biotechnology and Life Sciences Industry
 - The South Korean government launched the National Bio-Committee, the highest-level interagency governance body for the biotechnology sector.
 - To position South Korea among the world's top five bio-powerhouses, the government established a 1-trillion KRW fund to revitalize its bio-cluster ecosystem.²⁶
 - To maintain competitiveness in the advanced global biotechnology market and gain strategic advantages in collaboration with international partners, South Korean companies must proactively and dynamically respond to changes in international regulations and standards.
 - Failure to take the initiative in nucleic acid synthesis regulation could result in South Korea's exclusion from the global biosecurity regulatory framework and synthetic biology standardization efforts, which are expected to be led by advanced biotechnological nations.
 - Leading biotechnology nations and competitors may restrict transactions with South Korean companies due to concerns over global biosecurity and trust, potentially excluding South Korea from the global biotechnology supply chain.

- Addressing Ethical Issues in Gene Synthesis and Editing Technologies
 - As global debates on human embryo gene editing intensify, there is the potential risk of unethical genetic manipulation research occurring domestically.²⁷
 - South Korea currently enforces BWC Law²⁸ and the LMO Law²⁹, however, as synthetic biology advances, new regulations are needed to assess and control the impact of unregulated nucleic acid synthesis and genetically modified organisms (GMOs) on the environment.

26 Republic of Korea Policy Briefing (2025.01.24), "Pre-Briefing on the Launch of the National Bio Committee."

27 Kim Yoon-Sun (2024). "A Study on the Regulation of Human Gene Editing," [Summary Report], Judicial Policy Research Institute.

28 「Act on the Prohibition of Chemical and Biological Weapons and the Regulation of Certain Chemicals and Biological Agents」, *Ibid.*, Law No. 20319

29 「Act on the Transboundary Movements of Living Modified Organisms」, *Ibid.*, Law No. 158685.

- Ensuring Research Transparency and Credibility in the Advanced Biotechnology Industry
 - There is a risk of illegal genetic research being conducted by private companies and research institutes, particularly in areas such as personalized gene therapy (Designer DNA) and prohibited biological research.
 - A Nucleic Acid Synthesis Screening System should be implemented to monitor and ensure transparency in gene synthesis research activities, enabling the systematic oversight of corporate and research institution practices.

2. Policy Recommendations for Establishing a Korean Nucleic Acid Synthesis Screening System

- Direction for a Korean-Specific Nucleic Acid Synthesis Screening System

Category	Key Measures
① Review of DNA/RNA Sequence Orders	Nucleic acid synthesis companies examine whether the ordered DNA/RNA sequences match pathogenic genes.
② Verification of Researchers and Institutions	Verify the identity, affiliation, and research purpose of synthesis requesters, maintaining records.
③ Establishment of a Pathogenic Gene Database	Develop a national-level high-risk gene database and implement AI-based screening.
④ Biohacking Prevention Measures	Enforce legal regulations to prevent the misuse of nucleic acid synthesis technology in unethical research.
⑤ International Regulation and Cooperation	Collaborate with the U.S., U.K., and international organizations to promote nucleic acid synthesis screening regulations and standardization.

- The proposed (tentative) “National Nucleic Acid Synthesis Screening Guidelines” should align with the common policy directions observed in U.S. and U.K. screening systems as well as international NGO screening models. This contributes to the establishment of global norms and biosecurity values.
- Additionally, an in-depth analysis of the U.S. and U.K. cases and the key lessons learned is essential. South Korea must actively participate in global standardization discussions with international NGOs to address regulatory gaps and enhance its screening framework.

- Three Key Considerations for Establishing a Korean Nucleic Acid Synthesis Screening System
 - ① Defining and Standardizing the sequences of concern (SOC)
 - Regulatory authorities must establish clear definitions of SOC based on the existing National Security Strategy, determining the base sequences that pose high risks when synthesized or recombined. This will guide government regulations and control of SOC.
 - Overly restrictive regulations on SOC usage in public-interest research, such as in vaccine and therapeutic development, should be avoided.
 - A method for integrating screening mechanisms into benchtop nucleic acid synthesizers from different manufacturers must be developed:
 - * **(1) Closed System:** Only benchtop devices with pre-installed programs preventing SOC synthesis without approval can be sold, requiring the use of proprietary reagents.
 - (2) Open System:** Internet-connected benchtop synthesizers must receive real-time approval from a government agency or control center database before operation.
 - ② Economic Challenges and Potential Infringement on Private Sector Autonomy
 - Implementing a nucleic acid synthesis screening system requires significant financial resources, necessitating financial support measures for small- and mid-sized biotech ventures.³⁰
 - While ensuring public safety and trust through nucleic acid synthesis screening, regulatory frameworks must also include safeguards to prevent excessive restrictions on creative research and technological advancements in academia and industry.
 - ③ Data Privacy and Security
 - Strong protective measures must be established to prevent the leakage of intellectual property and customer information during the screening process.
 - Security must be enhanced for SOC databases and screening algorithms to prevent unauthorized access, data falsification, and database manipulation by malicious actors, thus ensuring database integrity.³¹

30 Forrest W. Crawford et al. (2024). "Securing Commercial Nucleic Acid Synthesis," Research Report, *RAND Corporation*, published on Jul 1st, 2024.

31 Carsten Baum et al. (2024). "A system capable of verifiably and privately screening global DNA synthesis," *Cryptography and Security* in Arxiv, Cornell Univ. submitted on March 20, 2024.

- Manufacturers are required to preinstall secure synthesis screening programs in benchtop DNA synthesizers used in practical applications to prevent tampering or unauthorized modifications.

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Abstract

Biosecurity Strategy I: The Necessity of Introducing a Korean 『Nucleic Acid Synthesis Screening』 System

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The rapid advancement of life sciences, particularly synthetic biology and gene-editing technologies, has driven significant progress in drug development, vaccine production, and gene therapy. However, these innovations also pose biosecurity risks, including the misuse of synthetic biology for creating engineered pathogens, vaccine-resistant viruses, and genetic bioweapons. Global regulatory efforts, led by the United States of America (U.S.), the United Kingdom, and major NGOs, are promoting "Nucleic Acid Synthesis Screening" systems to monitor and control synthetic genetic material.

As South Korea positions itself as a global biotechnology leader, proactive engagement in emerging international biosecurity regulations is essential. The nucleic acid synthesis screening framework is expected to become a global standard, and failure to comply may hinder South Korea's credibility and competitiveness in the international bioindustry. Moreover, South Korea's geopolitical vulnerabilities, particularly concerns over North Korea's potential development of biological weapons, underscore the necessity of strengthening national biosecurity.

Implementing a nucleic acid synthesis screening system would enhance South Korea's standing in global biotechnology markets, reinforcing trust and enabling high-level international collaborations. However, regulation must balance security with innovation, ensuring that scientific progress is not hindered. —engaging government agencies, academia, and industry—will be essential in designing an effective regulatory framework. By integrating biosecurity measures with its broader bioeconomic strategies, South Korea can establish itself as a responsible global leader in biotechnology governance while safeguarding national security.

Keywords: Nucleic acid synthesis, Synthetic biology, Gene-editing, Biosecurity

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