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Federal Framework for Screening the Synthesis of Nucleic Acids

On May 5th, 2025 a new White House executive order was released, IMPROVING THE SAFETY AND SECURITY OF BIOLOGICAL RESEARCH, related the previous Framework for Nucleic Acid Synthesis Screening executive order.

> " Within 90 days of the date of this order, the Director of OSTP, in coordination with the APNSA and the heads of relevant agencies, shall revise or replace the 2024 "Framework for Nucleic Acid Synthesis Screening" (Framework) to ensure it takes a commonsense approach and effectively encourages providers of synthetic nucleic acid sequences to implement comprehensive, scalable, and verifiable synthetic nucleic acid procurement screening mechanisms to minimize the risk of misuse."

Commented [RM1]: New

The White House Office of Science and Technology Policy (OSTP) released the Framework for Nucleic Acid Synthesis Screening on April 29, 2024 and is effective on April 29, 2025. This Framework establishes requirements – as a condition of receiving U.S. governmental life sciences research funding – that synthetic nucleic acids, and benchtop devices capable of synthesizing them, are only procured from providers and manufacturers that comply with the requirements of the Framework.

> Synthetic Nucleic Acids are defined as chemically or enzymatically manufactured polymers of nucleotides, which encode genetic information. These are distinct from naturally occurring nucleic acids, which can be isolated directly from an organism. The ability to make nucleic acids, based on a genetic sequence, allows a researcher to request custom nucleic acid sequences from a provider who will synthesize the order and ship it to the researcher, or to directly synthesize these genetic elements in their own laboratory using benchtop nucleic acid synthesis equipment.

These screening requirements build on the recommendations in the 2023 HHS Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids. Both documents are focused on preventing access to synthetic genetic materials containing Sequences of Concern (SOC)s by individuals without a legitimate need for them. Synthetic sequences could allow the de novo production of dangerous biological materials without the need to obtain them from natural sources or through networks of legitimate researchers and could

also allow those with malintent to introduce new pathogenic or toxic traits to otherwise benign microorganisms

> SOCs are defined as a nucleotide or amino acid sequence that is a Best Match to a sequence of federally regulated agents (Biological Select Agents and Toxins) or the Commerce Control List, except when the sequence is also found in an unregulated organism or toxin. This includes sequences known to contribute to pathogenicity or toxicity. As of and after October 13, 2026, this definition will include sequences known to contribute to pathogenicity or toxicity, even when not derived from or encoding regulated biological agents

Life science researchers should consult with their funding agencies to determine which providers and manufacturers have made attestations available regarding their compliance with the Framework. It is strongly recommended that purchases for SNA are through a company within the International Gene Synthesis Consortium and to avoid companies listed in the BIOSECURE Act. Importantly all vendors should be approved via Rutgers Third Party Vendor Risk Assessment.

Beginning April 26, 2025, all providers and manufacturers of synthetic nucleic acids must adhere to the following:

- Write a statement attesting to the adherence to the new policy, posted publicly
- Screen POs to identify SOCs
- Screen customers to verify legitimacy
- Report potentially illegitimate POs
- Retain records of POs for a minimum of three years
- Take steps to ensure cybersecurity and informational security

The framework applies to all synthetic nucleic acids (RNA and DNA) and whole organism genomes. At a minimum, DNA or RNA of 200 nucleotides or longer should be screened. Beginning October 13, 2026, the screening window will be decreased to 50 nucleotides.

It is the responsibility of the PI and synthetic nucleic acid equipment holders to adhere to the Framework for Nucleic Acid Synthesis Screening. If you have questions on how these new research requirements impact your research and/or if you are synthesizing nucleic acid sequences at Rutgers, please contact REHS to identify steps to take to remain compliant.

Contact REHS: E-mail: biosafety@rutgers.edu.