

119TH CONGRESS  
2D SESSION

**S.** \_\_\_\_\_

To require the Secretary of Commerce to promulgate regulations to improve  
nucleic acid synthesis security, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

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Mr. COTTON (for himself and Ms. KLOBUCHAR) introduced the following bill;  
which was read twice and referred to the Committee on

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**A BILL**

To require the Secretary of Commerce to promulgate regula-  
tions to improve nucleic acid synthesis security, and for  
other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Biosecurity Moderniza-  
5       tion and Innovation Act of 2026”.

6       **SEC. 2. DEFINITIONS.**

7       In this Act:

8               (1) COVERED PROVIDER.—The term “covered  
9       provider” means a person who—

1 (A) synthesizes and sells synthetic nucleic  
2 acids to persons in the United States; or

3 (B) produces and distributes or sells, in-  
4 cluding resellers, equipment for synthesizing  
5 nucleic acids, including benchtop synthesizers,  
6 to persons in the United States.

7 (2) DIRECTOR.—The term “Director” means  
8 the Director of the Office of Science and Technology  
9 Policy.

10 (3) SECRETARY.—The term “Secretary” means  
11 the Secretary of Commerce.

12 (4) UNDER SECRETARY.—The term “Under  
13 Secretary” means the Under Secretary of Commerce  
14 for Standards and Technology.

15 **SEC. 3. SENSE OF CONGRESS.**

16 It is the Sense of Congress that—

17 (1) the field of biotechnology is accelerating and  
18 the United States is at risk of losing its bio-  
19 technology leadership to foreign adversaries;

20 (2) this acceleration of the field brings the  
21 United States into a period of both great oppor-  
22 tunity and risk;

23 (3) policymaking for biosecurity, biosafety, and  
24 responsible innovation needs to be flexible to keep  
25 pace with advances in the biotechnology and ensure

1 an environment that allows biotechnology research  
2 and industry to flourish;

3 (4) the current landscape of biosecurity and  
4 biosafety authorities is spread among multiple agen-  
5 cies, contributing to slow policymaking, which, cou-  
6 pled with the rapid advancement of biotechnology,  
7 becomes outdated quickly;

8 (5) previous studies conducted by the Govern-  
9 ment Accountability Office, the National Security  
10 Commission for Emerging Biotechnology, and sev-  
11 eral presidential administrations have already identi-  
12 fied gaps in the Federal Government's oversight of  
13 biosecurity and biosafety risks;

14 (6) the United States Government needs to  
15 streamline biosecurity and biosafety authorities to  
16 ensure efficiency and clarity;

17 (7) gene synthesis technology is becoming in-  
18 creasingly sophisticated and accessible, along with  
19 the ability to design novel nucleic acid sequences;

20 (8) both of these factors described in paragraph  
21 (7) may increase the risk of the development and de-  
22 ployment of new pathogens by bad actors; and

23 (9) gene synthesis screening of orders and cus-  
24 tomers is immediately needed to mitigate risk in the  
25 short-term, which will act as a stopgap while the

1 United States Government develops a comprehensive  
2 biosecurity and biosafety strategy that is appropriate  
3 for the dynamic and rapidly advancing field of bio-  
4 technology.

5 **SEC. 4. NUCLEIC ACID SYNTHESIS SECURITY.**

6 (a) REGULATIONS REQUIRED.—Not later than 1 year  
7 after the date of the enactment of this Act, the Secretary  
8 shall, in coordination with the Under Secretary and the  
9 heads of such other agencies as the Secretary considers  
10 appropriate, establish and maintain by regulation the fol-  
11 lowing:

12 (1) A requirement for covered providers to im-  
13 plement screening protocols for all sequences of con-  
14 cern included in the list established and maintained  
15 under paragraph (3). Such protocols shall—

16 (A) include the ability for privacy-pre-  
17 serving submission of information regarding or-  
18 ders for potential sequences of concern to a  
19 mechanism, which may be maintained by the  
20 Secretary or an independent organization des-  
21 ignated by the Secretary, for facilitating effec-  
22 tive split order detection across covered pro-  
23 viders, utilizing the list established and main-  
24 tained under paragraph (3); and

1 (B) prioritize the mitigation of misuse of  
2 sequences capable of creating pathogens with  
3 pandemic potential.

4 (2) A requirement for covered providers to im-  
5 plement screening protocols to verify the identity  
6 and legitimacy of customers.

7 (3) A list of sequences of concern, which shall  
8 be determined by the Secretary in consultation with  
9 such heads of Federal departments and agencies, in-  
10 dustry experts, academics, and researchers as the  
11 Secretary considers appropriate.

12 (4) A system for reviewing and updating on a  
13 regular basis the list of sequences of concern estab-  
14 lished and maintained under paragraph (3) that—

15 (A) uses a docket to allow for privacy-pre-  
16 serving submissions from the public on rec-  
17 ommendations for the list of sequences of con-  
18 cern;

19 (B) includes an expedited procedure to  
20 rapidly add sequences of concern to the list on  
21 a provisional basis, which may include, as far as  
22 technically feasible, automatic procedures such  
23 as algorithmic literature scanning, industry self-  
24 reporting, or inter-agency submissions; and

1 (C) incorporates strong data security and  
2 confidentiality standards.

3 (5) A conformity assessment system to verify  
4 that covered providers are adhering to the require-  
5 ments established and maintained under paragraphs  
6 (1) and (2), which will include—

7 (A) an auditing process to ensure orders  
8 and customers have been scrutinized appro-  
9 priately, including procedures to conduct adver-  
10 sarial testing (sometimes referred to as “red-  
11 teaming”) at random intervals to ensure com-  
12 pliance; and

13 (B) a process to revoke conformity status  
14 of covered providers that fail to maintain com-  
15 pliance with the requirements established and  
16 maintained under paragraphs (1) and (2), in-  
17 cluding the establishment of a grace period for  
18 covered providers who have failed auditing or  
19 adversarial testing under subparagraph (B) to  
20 demonstrate compliance or mitigation steps.

21 (6) Safeguards to ensure regulations promul-  
22 gated under this subsection avoid unnecessary bur-  
23 den on innovation and industry by—

24 (A) allowing covered providers to offer an  
25 expedited review process for institutional cus-

1           tomers, including accredited institutions of  
2           higher education, with demonstrated records of  
3           legitimacy;

4                 (B) providing exemptions from customer  
5           screening requirements for sequences or prod-  
6           ucts that are clearly non-hazardous and pose no  
7           credible threat to public health and safety based  
8           on scientific literature and industry best prac-  
9           tices for biosecurity screening; and

10                (C) conducting regular consultations with  
11           relevant experts to determine exempted se-  
12           quences and minimize regulatory burden while  
13           maintaining security effectiveness.

14                (7) A requirement that any person who receives  
15           Federal funds can only purchase nucleic acid syn-  
16           thesis products from a covered provider in compli-  
17           ance with the requirements in paragraphs (1) and  
18           (2).

19                (8) A program to provide technical assistance  
20           upon request of a covered provider, including assist-  
21           ance with orders whose screening results are ambig-  
22           uous, subject to determination by the Secretary, in  
23           consultation with the heads of such other Federal  
24           departments and agencies as the Secretary considers  
25           appropriate.

1 (b) NATIONAL INSTITUTE OF STANDARDS AND  
2 TECHNOLOGY REQUIREMENTS.—The Under Secretary  
3 shall develop best practices, technical standards, and other  
4 tools needed to support the administration of subsection  
5 (a), including the following:

6 (1) Testing and evaluation of customer and  
7 order screening protocols to improve accuracy, effi-  
8 cacy, and reliability, and to support the conformity  
9 assessment system under of subsection (a)(5).

10 (2) Evaluation of the sequences recommended  
11 for the list established and updated under para-  
12 graphs (3) and (4) of subsection (a), including by  
13 developing best practices and guidelines for deter-  
14 mining if a novel sequence is a sequence of concern.

15 (3) Research and prototype sequence-to-func-  
16 tion models to supplement the system established  
17 and maintained under subsection (a)(4).

18 (c) UPDATES.—As frequently as the Secretary con-  
19 siderers appropriate to account for technological advances,  
20 but not less frequently than once every 2 years, the Sec-  
21 retary shall review and update the regulations promul-  
22 gated under subsection (a).

23 (d) PROTECTION OF CUSTOMER INFORMATION.—  
24 Any information about a customer included in a submis-  
25 sion under paragraph (1)(A) or (4)(A) of subsection (a)



1 shall, if applicable, be exempt from records access under  
2 section 552(b)(4) of title 5, United States Code.

3 (e) RELATIONSHIP WITH OTHER FEDERAL GUIDE-  
4 LINES AND RECOMMENDATIONS.—The regulations estab-  
5 lished and maintained under paragraphs (1) and (2) of  
6 subsection (a) shall supplant any Federal guidelines or  
7 recommendations relating to nucleic acid synthesis screen-  
8 ing that—

9 (1) were in effect before the date of the enact-  
10 ment of this Act; and

11 (2) are voluntary.

12 (f) CIVIL ENFORCEMENT.—

13 (1) CIVIL ACTION.—The Attorney General may  
14 bring a civil action in a court of competent jurisdic-  
15 tion against any person who violates a requirement  
16 promulgated under paragraph (1) or (2) of sub-  
17 section (a), including through providing false or mis-  
18 leading information or engaging in other deceptive  
19 practices, or does not demonstrate compliance within  
20 the grace period set forth by subsection (a)(5)(C).

21 (2) POWERS OF THE COURT.—In an action  
22 brought under paragraph (1), the court may—

23 (A) enjoin a violation described in para-  
24 graph (1); or

25 (B) award damages under paragraph (3).

1           (3) AWARD OF DAMAGES.—A person who vio-  
2           lates a requirement as described in paragraph (1) is  
3           liable for statutory damages—

4                   (A) in the case of an individual, in the sum  
5                   of not more than \$500,000, adjusted from time  
6                   to time under paragraph (4); and

7                   (B) in the case of a person who is not an  
8                   individual, in the sum of not more than  
9                   \$750,000, adjusted from time to time under  
10                  paragraph (4).

11           (4) ADJUSTMENTS FOR INFLATION.—Effective  
12           on October 1 of each year (beginning in the first fis-  
13           cal year after the date of the enactment of this Act),  
14           the dollar amounts in effect under paragraph (3)  
15           shall be increased by a percentage equal to the per-  
16           centage by which the Consumer Price Index for all  
17           urban consumers (U.S. city average) increased dur-  
18           ing the 12-month period ending with the last month  
19           for which Consumer Price Index data is available. In  
20           the event that such Consumer Price Index does not  
21           increase during such period, the dollar amount in ef-  
22           fect under such paragraph during the previous fiscal  
23           year shall be maintained.

24           (g) REPORTS TO CONGRESS.—Not less frequently  
25           than once each year, the Secretary shall submit to Con-

1 gress a report on the administration of this section. Each  
2 such report shall include an overview of how many covered  
3 providers have been verified by the conformity assessment  
4 system established and maintained under subsection  
5 (a)(5).

6 **SEC. 5. ESTABLISHMENT OF BIOTECHNOLOGY GOVERN-**  
7 **ANCE SANDBOX.**

8 (a) IN GENERAL.—Not later than 1 year after the  
9 date of the enactment of this Act, the Under Secretary  
10 shall, in collaboration with the heads of such Federal  
11 agencies as the Under Secretary considers relevant and  
12 with such persons in the private sector, academia, and civil  
13 society as the Under Secretary considers appropriate, es-  
14 tablish a biotechnology governance sandbox environment.

15 (b) RESPONSIBILITIES.—Through the governance  
16 sandbox developed under subsection (a), the Under Sec-  
17 retary shall—

18 (1) provide secure testing of innovations or  
19 tools developed to advance the science of biosecurity,  
20 biosafety, and responsible biotechnology innovation;

21 (2) foster participation of nongovernmental ex-  
22 perts in the development and testing of appropriate  
23 levels and methods of governance, to achieve the  
24 goals of—

1 (A) ensuring the continued global competi-  
2 tiveness of biotechnology innovations in the  
3 United States;

4 (B) bolstering the national security posture  
5 of the United States; and

6 (C) strengthening the ability of the United  
7 States to robustly analyze emerging threats, an-  
8 ticipate concerns, and govern proactively in the  
9 biotechnology space;

10 (3) carry out biological measurement research  
11 to support the development and improvement of  
12 technical standards for biosecurity, biosafety, and re-  
13 sponsible biotechnology innovation; and

14 (4) report annually to the Secretary of Com-  
15 merce on the administration of paragraph (2) and  
16 whether any promising governance strategies have  
17 resulted from the development and testing.

18 (c) ACCESS TO ENVIRONMENTS.—The Under Sec-  
19 retary may contract with the private sector or coordinate  
20 with other Federal agencies to access environments nec-  
21 essary to provide testing under subsection (b)(1).

1 **SEC. 6. STREAMLINING BIOSECURITY AND BIOSAFETY AU-**  
2 **THORITIES ACROSS THE FEDERAL GOVERN-**  
3 **MENT.**

4 (a) ASSESSMENT AND PLAN REQUIRED.—Not later  
5 than 90 days after the date of the enactment of this Act,  
6 the Director shall, in collaboration with the heads of such  
7 Federal agencies as the Director considers relevant—

8 (1) assess the current state of biosecurity and  
9 biosafety oversight by the Federal Government; and

10 (2) develop, based on the findings of the Direc-  
11 tor with respect to the assessment conducted under  
12 paragraph (1), an implementation plan to make  
13 oversight of biosecurity and biosafety by the Federal  
14 Government more effective and efficient.

15 (b) ELEMENTS OF ASSESSMENT.—The assessment  
16 required by subsection (a)(1) shall include the following:

17 (1) A full accounting of Federal biosecurity and  
18 biosafety authorities and programs, including which  
19 agencies hold these authorities, whether these au-  
20 thorities are exercised effectively, and where there  
21 are overlaps or redundancies, real or perceived, in  
22 regulatory and enforcement authorities.

23 (2) Engagement with industry stakeholders and  
24 academia to understand where there are challenges  
25 with compliance, communication, and information  
26 sharing.

1           (3) Identification of gaps in funding or other  
2     Government support for the development of re-  
3     search, innovation, and tools that advance the  
4     science of applied biosecurity, biosafety, and respon-  
5     sible biotechnology innovation.

6           (4) Identification of gaps in current Federal  
7     biosecurity and biosafety authorities and whether  
8     these gaps are hindering effective and efficient gov-  
9     ernance and assessment of emerging risks and op-  
10    portunities in biotechnology.

11          (5) An evaluation of how consolidation of bio-  
12     security and biosafety guidelines, authorities, and  
13     regulations across Federal agencies, including the  
14     regulations established and maintained under section  
15     4(a), should be implemented to make oversight more  
16     effective and efficient and to address the gaps in  
17     such guidelines, authorities, and regulations, includ-  
18     ing those identified under paragraphs (3) and (4).

19     (c) REPORT TO CONGRESS.—

20          (1) IN GENERAL.—Not later than 90 days after  
21     the date on which the Director completes the assess-  
22     ment required by paragraph (1) of subsection (a)  
23     and the implementation plan required by paragraph  
24     (2) of such subsection, the Director shall submit to  
25     Congress—

1 (A) a report on the findings of the Direc-  
2 tor with respect to the assessment; and

3 (B) a copy of the implementation plan.

4 (2) CONTENTS.—The report submitted pursu-  
5 ant to paragraph (1)(A) shall include the following:

6 (A) The findings of the Director with re-  
7 spect to the assessment conducted pursuant to  
8 subsection (a)(1).

9 (B) Recommendations for legislative or ad-  
10 ministrative action to support the implementa-  
11 tion plan developed under subsection (a)(2), ac-  
12 cording to—

13 (i) what, if any, new biosecurity and  
14 biosafety authorities are needed; and

15 (ii) where the Federal Government  
16 can consolidate biosecurity and biosafety  
17 authorities, including which, if any, should  
18 be reside under a common government en-  
19 tity, and whether this necessitates estab-  
20 lishing a new government entity.

21 (d) IMPLEMENTATION.—

22 (1) IN GENERAL.—Not later than 90 days after  
23 the date on which the Director completes the imple-  
24 mentation plan required by subsection (a)(2), the  
25 Director shall commence implementing the plan

1 through administrative action in accordance with ap-  
2 plicable provisions of law.

3 (2) GOVERNANCE STRATEGIES.—In carrying  
4 out the implementation plan developed under sub-  
5 section (a)(2), the Director shall consider which, if  
6 any, of the governance strategies reported under sec-  
7 tion 5(b)(4) should be included in the plan.