

119TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

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

A BILL

To require the Secretary of Commerce to promulgate regulations 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—

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7 becomes outdated quickly;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

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

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

(C) incorporates strong data security and confidentiality standards.

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 siders 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).

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

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

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 mercial 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.

19 (c) REPORT TO CONGRESS.—

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.