

119TH CONGRESS
2D SESSION

H. R. 10197

To improve the security of nucleic acid synthesis in interstate and foreign commerce, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 31, 2026

Mr. PFLUGER (for himself and Ms. HOULAHAN) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To improve the security of nucleic acid synthesis in interstate and foreign commerce, 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”.

6 **SEC. 2. REQUIREMENTS FOR COVERED ENTITIES WITH RE-**
7 **SPECT TO HIGH-RISK SEQUENCES.**

8 (a) IN GENERAL.—A covered entity shall establish a
9 program of reasonable administrative and technical proto-
10 cols to carry out, with respect to any nucleic acid sequence

1 made available in interstate or foreign commerce by such
2 covered entity, the following requirements:

3 (1) Verify the identity of any buyer or prospec-
4 tive buyer of such a nucleic acid sequence, including
5 with respect to any such nucleic acid sequence gen-
6 erated by a benchtop nucleic acid synthesizer.

7 (2) Establish the purpose for which any such
8 buyer or prospective buyer seeks to obtain any such
9 nucleic acid sequence.

10 (3) Identify whether such a nucleic acid se-
11 quence, including any such nucleic acid sequence
12 generated by a benchtop nucleic acid synthesizer, is
13 a covered sequence as determined by the Secretary
14 under paragraph (1)(A) of subsection (e), and on
15 the list established and made available under para-
16 graph (1)(C) of such subsection.

17 (4) Establish risk-based criteria for refusing the
18 sale of a covered sequence to a buyer, prospective
19 buyer, or any combination thereof, and document
20 each instance of refusal by the covered entity in ac-
21 cordance with such criteria.

22 (5) Provide timely notification to the Secretary
23 if the covered entity has a reasonable belief that
24 such a buyer or prospective buyer is likely to use a
25 covered sequence in a manner that poses a high risk

1 to the national security of the United States or to
2 the security and safety of persons in the United
3 States.

4 (6) Ensure regular independent assessment of
5 compliance by the covered entity with paragraphs
6 (1) through (5) and paragraph (7), including
7 through adversarial testing, third-party certifi-
8 cations, independent internal or external audits, di-
9 rect examination by the Secretary, or any combina-
10 tion thereof.

11 (7) Maintain records sufficient to demonstrate
12 to the Secretary compliance with the requirements
13 described in paragraphs (1) through (6) for a period
14 of not less than 5 years, as practicable.

15 (b) GUIDANCE.—

16 (1) IN GENERAL.—Not later than 180 days
17 after the date of the enactment of this Act, the Sec-
18 retary, in consultation with relevant heads of other
19 Federal departments, agencies, or offices, as appro-
20 priate, shall issue guidance that identifies the fol-
21 lowing:

22 (A) Approaches, best practices, frame-
23 works, and methods that may be implemented,
24 alone or in combination, by a covered entity to
25 satisfy the requirements under subsection (a).

1 (B) How a covered entity may ensure reg-
2 ular independent assessment of compliance as
3 described in paragraph (6) of such subsection.

4 (C) What constitutes a timely notification
5 under paragraph (5) of such subsection, includ-
6 ing by when and in what manner a covered en-
7 tity is required to provide such a notification to
8 the Secretary.

9 (2) ENFORCEMENT PLAN.—Not later than 1
10 year after the date of the enactment of this Act, the
11 Secretary shall issue guidance relating to the prior-
12 ities of the Secretary for enforcing the requirements
13 under subsection (a).

14 (3) PROCESS.—Any guidance issued by the Sec-
15 retary under paragraphs (1) and (2) shall be devel-
16 oped through a covered process.

17 (4) NO CONFERRING OF RIGHTS OR BINDING
18 EFFECT.—Any guidance issued by the Secretary
19 under paragraphs (1) and (2) may not confer any
20 rights on any person, State, or locality or bind the
21 Secretary or any person recommended in such guid-
22 ance.

23 (c) NOTIFICATION, COORDINATION, AND DIRECT EX-
24 AMINATION.—Not later than 180 days after the date of
25 the enactment of this Act, the Secretary shall establish

1 a means, using a covered process, for the Secretary to
2 carry out the following:

3 (1) Accept a notification provided by a covered
4 entity under paragraph (5) of subsection (a).

5 (2) Facilitate coordination with covered entities
6 and stakeholders to identify a buyer, prospective
7 buyer, or any combination thereof, that has split or-
8 ders across two or more covered entities with the
9 purpose of obtaining or synthesizing a covered se-
10 quence.

11 (3) At the request of a covered entity, provide
12 direct examination to carry out the requirement
13 under paragraph (6) of such subsection.

14 (d) IDENTIFICATION OF APPROACHES, BEST PRAC-
15 TICES, FRAMEWORKS, AND METHODS.—

16 (1) IN GENERAL.—Not later than 1 year after
17 the date of the enactment of this Act, the Secretary
18 shall, in consultation with the relevant heads of
19 other Federal departments, agencies, or offices, as
20 appropriate, regularly consult with stakeholders, in-
21 cluding persons from academia and the private sec-
22 tor, to identify the approaches, best practices, frame-
23 works, and methods under subsection (b)(1)(A), in-
24 cluding related to the following:

1 (A) Improving the accuracy, efficiency, and
2 reliability of any administrative and technical
3 protocols required under subsection (a), includ-
4 ing with respect to the independent assessment
5 requirement under paragraph (6) of such sub-
6 section.

7 (B) How a covered entity may offer an ex-
8 pedited review process to a previous buyer of
9 such covered entity with respect to which the
10 covered entity has carried out the requirements
11 under paragraphs (1) and (2) of subsection (a).

12 (C) How the Secretary and any covered en-
13 tity may identify nucleic acid sequences with a
14 low potential for misuse.

15 (D) How the Secretary and any covered
16 entity may identify nucleic acid sequences, in-
17 cluding novel nucleic acid sequences, that may
18 be used in a manner that would pose a high
19 risk to the national security of the United
20 States or to the security and safety of persons
21 in the United States.

22 (E) Mitigate any risk related to misuse of
23 benchtop nucleic acid synthesizers.

24 (2) REPORT.—Not later than 2 years after the
25 date of the enactment of this Act, and annually

1 thereafter for 6 years, the Secretary shall submit to
2 the Committee on Energy and Commerce of the
3 House of Representatives and the Committee on
4 Commerce, Science, and Transportation of the Sen-
5 ate a report—

6 (A) developed through a covered process;

7 and

8 (B) that includes information related to
9 any approaches, best practices, frameworks, or
10 methods identified under paragraph (1).

11 (e) REPORT AND RECOMMENDATIONS.—

12 (1) IN GENERAL.—Not later than 2 years after
13 the date of the enactment of this Act, and every 2
14 years thereafter for 6 years, the Secretary shall pub-
15 lish on a publicly available website a report that in-
16 cludes the following:

17 (A) An assessment on the following:

18 (i) The economic competitiveness of
19 the United States with respect to bio-
20 technology, including the manufacturing of
21 nucleic acids.

22 (ii) The ability of the Secretary, cov-
23 ered entities, and any other relevant entity
24 to mitigate any national security risk re-

1 lated to covered sequences manufactured
2 and sold in interstate or foreign commerce.

3 (B) Any legislative recommendation related
4 to the following:

5 (i) Advancing such competitiveness.

6 (ii) Mitigating any such national secu-
7 rity risk.

8 (2) PUBLIC CONSULTATION.—In carrying out
9 paragraph (1), the Secretary shall use a covered
10 process.

11 (3) CONGRESSIONAL NOTIFICATION.—Prior to
12 publishing a report under paragraph (1), the Sec-
13 retary shall submit to the Committee on Energy and
14 Commerce of the House of Representatives and the
15 Committee on Commerce, Science, and Transpor-
16 tation of the Senate such report.

17 (f) COVERED SEQUENCE LIST.—

18 (1) IN GENERAL.—Not later than 180 days
19 after the date of the enactment of this Act, and reg-
20 ularly thereafter, the Secretary, in consultation with
21 the relevant heads of other Federal departments,
22 agencies, or offices, as appropriate, shall carry out
23 the following:

24 (A) A determination of whether a nucleic
25 acid sequence is a covered sequence.

1 (B) If the Secretary makes a determina-
2 tion that a nucleic acid sequence is a covered
3 sequence, make available to covered entities a
4 statement that explains the basis for such de-
5 termination, including any basis specified in
6 paragraph (2), as applicable.

7 (C) Establish and make available to cov-
8 ered entities a list that includes any such cov-
9 ered sequence.

10 (D) Establish a procedure to make any
11 such statement and such list available to stake-
12 holders in a manner that does not pose an un-
13 acceptable risk to the national security of the
14 United States or the security and safety of
15 United States persons.

16 (2) BASIS.—A determination under paragraph
17 (1)(A) shall be based on one or more of the fol-
18 lowing:

19 (A) An assessment by the head of any
20 other Federal agency, including a relevant na-
21 tional security agency or public health agency.

22 (B) A submission by a member of the pub-
23 lic or a covered entity under paragraph (3)(A).

24 (C) A determination by the Secretary that
25 a nucleic acid sequence poses an imminent or

1 high likelihood of use in such a manner that it
2 poses an unacceptable risk to the national secu-
3 rity of the United States or the security and
4 safety of United States persons.

5 (3) UPDATES.—

6 (A) IN GENERAL.—The Secretary shall up-
7 date, as the Secretary determines appropriate,
8 any list established and made available to cov-
9 ered entities under subparagraph (C) of para-
10 graph (1), and any statement or list made
11 available to stakeholders pursuant to the proce-
12 dure established under subparagraph (D) of
13 such paragraph, including in response to a
14 novel nucleic acid sequence.

15 (B) SUBMISSION PROCESS.—Not later
16 than 180 days after the date of the enactment
17 of this Act, the Secretary shall, through a cov-
18 ered process, establish a process for the fol-
19 lowing:

20 (i) A member of the public to submit
21 to the Secretary a recommendation related
22 to adding a nucleic acid sequence to, re-
23 moving a covered sequence from, or other-
24 wise modifying any list established and
25 made available to covered entities under

1 subparagraph (C) of paragraph (1), and
2 any statement or list made available to
3 stakeholders pursuant to the procedure es-
4 tablished under subparagraph (D) of such
5 paragraph.

6 (ii) A covered entity to carry out the
7 following:

8 (I) Submit to the Secretary a re-
9 quest for the Secretary to review the
10 inclusion of a covered sequence in any
11 list established and made available to
12 covered entities under subparagraph
13 (C) of paragraph (1), and any state-
14 ment or list made available to stake-
15 holders pursuant to the procedure es-
16 tablished under subparagraph (D) of
17 such paragraph, to remove the cov-
18 ered sequence from, or otherwise mod-
19 ify, such list or statement.

20 (II) Submit evidence to the Sec-
21 retary related to such request.

22 (C) CONFIDENTIALITY.—Any information
23 related to a recommendation, request, or evi-
24 dence submitted pursuant to the process estab-
25 lished under subparagraph (B) shall be treated

1 as a trade secret and commercial or financial
2 information, and shall be exempt from disclo-
3 sure, under section 552(b)(4) of title 5, United
4 States Code.

5 (D) OPTION TO REQUEST NONDISCLO-
6 SURE.—In carrying out subparagraph (B), the
7 Secretary shall offer any member of the public
8 or covered entity that utilizes the process estab-
9 lished under such subparagraph the ability to
10 request that any information related to a rec-
11 ommendation, request, or evidence submitted
12 pursuant to such process is not published or
13 disclosed in any identifiable form, including any
14 publication or disclosure of any such informa-
15 tion that would allow the identity of the mem-
16 ber of the public or covered entity to be reason-
17 ably inferred.

18 (4) CONGRESSIONAL NOTIFICATION.—With re-
19 spect to any list established and made available to
20 covered entities under subparagraph (C) of para-
21 graph (1), and any statement or list made available
22 to stakeholders pursuant to the procedure estab-
23 lished under subparagraph (D) of such paragraph,
24 the Secretary shall—

1 (A) at least 5 days before establishing and
2 making available such a list under such para-
3 graph, or adding a nucleic acid sequence to, re-
4 moving a covered sequence from, or otherwise
5 modifying such list, submit to the Committee
6 on Energy and Commerce of the House of Rep-
7 resentatives and the Committee on Commerce,
8 Science, and Transportation of the Senate such
9 list; and

10 (B) provide to such committees a briefing
11 related to such list, upon request by such com-
12 mittees.

13 (g) ENFORCEMENT.—

14 (1) AUTHORITY.—The Secretary shall have the
15 authority to carry out any of the following to enforce
16 subsection (a):

17 (A) Require, inspect, and compel the provi-
18 sion of any physical and electronic records and
19 any other information from such covered entity.

20 (B) Administer oaths or affirmations and
21 require any person to appear and testify or to
22 appear and produce any such record or other
23 information by subpoena.

24 (C) Conduct investigations within the
25 United States and outside the United States.

1 (2) CIVIL ACTIONS.—

2 (A) IN GENERAL.—The Secretary may
3 commence a civil action against a covered entity
4 for a violation of subsection (a) in any district
5 court of the United States for appropriate re-
6 lief, including—

7 (i) the penalty described under sub-
8 paragraph (B); or

9 (ii) an injunction.

10 (B) PENALTY.—The penalty for a violation
11 of subsection (a) may not exceed \$750,000 per
12 violation (as adjusted on January 1 each year
13 by the percentage increase, if applicable, in the
14 consumer price index for all urban consumers
15 published by the Bureau of Labor Statistics
16 with respect to the 12-month period preceding
17 the date of such adjustment).

18 (C) RIGHT TO CURE.—

19 (i) IN GENERAL.—The Secretary may
20 initiate a civil action under subparagraph
21 (A) only if—

22 (I) the Secretary has provided to
23 the relevant covered entity a written
24 notice that describes the alleged viola-
25 tion and identifies the provision under

1 subsection (a) related to such alleged
2 violation; and

3 (II) at least 30 days have passed
4 since the date on which such written
5 notice was so provided.

6 (ii) EFFECT OF CURE.—If a covered
7 entity that receives a written notice under
8 clause (i)(I) cures the alleged violation de-
9 scribed in such notice not later than 30
10 days after the date on which such covered
11 entity was provided such notice, the Sec-
12 retary shall consider the requirements
13 under subsection (a) as satisfied with re-
14 spect to such covered entity.

15 (iii) FAILURE TO CURE.—After car-
16 rying out clause (i), the Secretary may ini-
17 tiate an action under subparagraph (A)—

18 (I) if the relevant covered entity
19 fails to cure the alleged violation de-
20 scribed in the written notice provided
21 pursuant to clause (i)(I); or

22 (II) if, after the curing the al-
23 leged violation as specified in clause
24 (ii), the covered entity violates the rel-

1 evant provision under subsection (a)
2 again.

3 (3) RELATION TO GUIDANCE.—The Secretary
4 may not commence a civil action under paragraph
5 (2) solely on the basis that a covered entity has car-
6 ried out the requirements under subsection (a) in a
7 manner that is inconsistent with any guidance issued
8 under subsection (b)(1).

9 (h) RELATIONSHIP WITH OTHER FEDERAL GUIDE-
10 LINES AND RECOMMENDATIONS.—The requirements in
11 subsection (a) shall supersede any Federal guideline or
12 recommendation related to the screening of nucleic acid
13 sequences made available in interstate or foreign com-
14 merce if such guideline or recommendation is voluntary
15 and in effect before the date of the enactment of this Act.

16 (i) PREEMPTION.—

17 (1) IN GENERAL.—No State or political subdivi-
18 sion of a State may prescribe, maintain, or enforce
19 any law, rule, regulation, requirement, standard, or
20 other provision having the force and effect of law to
21 the extent such law, rule, regulation, requirement,
22 standard, or other provision is covered by a require-
23 ment under subsection (a).

24 (2) EXCEPTION.—Notwithstanding paragraph
25 (1), nothing in this Act may be construed to pre-

1 empt any law, rule, requirement, or regulation of a
2 State, or political subdivision of a State, with respect
3 to any of the following:

4 (A) Contract, tort, or product liability.

5 (B) Consumer protection, data privacy, or
6 data security.

7 (C) Any such generally applicable law,
8 rule, requirement, or regulation of a State, or
9 a political subdivision of a State, as it relates
10 to public health.

11 (D) The procurement or use of nucleic
12 acids or nucleic acid sequences by a State or a
13 political subdivision of a State.

14 (j) RULE OF CONSTRUCTION.—Nothing in this Act
15 may be construed to prohibit a covered entity from synthe-
16 sizing a nucleic acid sequence or prohibit a covered entity
17 from producing equipment for synthesizing a nucleic acid,
18 including a benchtop nucleic acid synthesizer.

19 (k) EFFECTIVE DATE.—The requirement under sub-
20 section (a) shall take effect on the date that is 1 year after
21 the date of the enactment of this Act.

22 (l) DEFINITIONS.—In this section:

23 (1) BENCHTOP NUCLEIC ACID SYNTHESIZER.—
24 The term “benchtop nucleic acid synthesizer” means

1 a product, device, or integrated system in interstate
2 or foreign commerce that is—

3 (A) capable of generating de novo a nucleic
4 acid sequence—

5 (i) at the direction of an end user of
6 such product, device, or system; or

7 (ii) without requiring an end user of
8 such product, device, or system to submit
9 to another covered entity an order to per-
10 form the generation of such nucleic acid
11 sequence; and

12 (B) intended for distribution to, or use by,
13 end users other than the developer of the prod-
14 uct, device, or system, regardless of the physical
15 dimensions of such product, device, or system.

16 (2) COVERED ENTITY.—

17 (A) IN GENERAL.—The term “covered en-
18 tity” means a person operating in interstate or
19 foreign commerce who—

20 (i) synthesizes and sells nucleic acids
21 to a person in the United States or in a
22 foreign country; or

23 (ii) produces, distributes, sells, or re-
24 sells equipment for synthesizing nucleic
25 acids, including a benchtop nucleic acid

1 synthesizer, to persons in the United
2 States or in a foreign country.

3 (B) EXCEPTION.—Subparagraph (A) does
4 not apply to the extent a person produces, dis-
5 tributes, sells, or resells synthetic acids within
6 a commercial entity solely for the internal use
7 of such commercial entity.

8 (3) COVERED PROCESS.—The term “covered
9 process” means, with respect to the implementation
10 of a requirement under this section, a process by
11 which the Secretary—

12 (A) publishes in the Federal Register a re-
13 quest for public feedback on the matters de-
14 scribed in such provision;

15 (B) provides the public with an oppor-
16 tunity to comment on the matters described in
17 subparagraph (A) for a period of not less than
18 60 days;

19 (C) ensures that public comments made
20 under subparagraph (B) that are not marked
21 confidential are available for public inspection;
22 and

23 (D) demonstrates consideration of any
24 such public comments with respect to such im-
25 plementation.

1 (4) SECRETARY.—The term “Secretary” means
2 the Secretary of Commerce, acting through the Of-
3 fice of the Secretary.

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