

Suspend the Rules and Pass the Bill, H.R. 8333, With an Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

118TH CONGRESS
2^D SESSION

H. R. 8333

To prohibit contracting with certain biotechnology providers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 10, 2024

Mr. WENSTRUP (for himself, Mr. KRISHNAMOORTHY, Mr. MOOLENAAR, Ms. ESHOO, Mr. DUNN of Florida, Mr. MOULTON, Ms. STEFANIK, and Mr. DAVIS of North Carolina) introduced the following bill; which was referred to the Committee on Oversight and Accountability, and in addition to the Permanent Select Committee on Intelligence, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To prohibit contracting with certain biotechnology providers, 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 “BIOSECURE Act”.

1 **SEC. 2. PROHIBITION ON CONTRACTING WITH CERTAIN**
2 **BIOTECHNOLOGY PROVIDERS.**

3 (a) IN GENERAL.—The head of an executive agency
4 may not—

5 (1) procure or obtain any biotechnology equip-
6 ment or service produced or provided by a bio-
7 technology company of concern; or

8 (2) enter into a contract or extend or renew a
9 contract with any entity that—

10 (A) uses biotechnology equipment or serv-
11 ices produced or provided by a biotechnology
12 company of concern and acquired after the ap-
13 plicable effective date in subsection (c) in per-
14 formance of the contract with the executive
15 agency; or

16 (B) enters into any contract the perform-
17 ance of which such entity knows or has reason
18 to believe will require, in performance of the
19 contract with the executive agency, the use of
20 biotechnology equipment or services produced or
21 provided by a biotechnology company of concern
22 and acquired after the applicable effective date
23 in subsection (c).

24 (b) PROHIBITION ON LOAN AND GRANT FUNDS.—
25 The head of an executive agency may not obligate or ex-

1 pend loan or grant funds to, and a loan or grant recipient
2 may not use loan or grant funds to—

3 (1) procure, obtain, or use any biotechnology
4 equipment or services produced or provided by a bio-
5 technology company of concern; or

6 (2) enter into a contract or extend or renew a
7 contract with an entity described in subsection
8 (a)(2).

9 (c) EFFECTIVE DATES.—

10 (1) CERTAIN ENTITIES.—With respect to the
11 biotechnology companies of concern covered by sub-
12 section (f)(2)(A), the prohibitions under subsections
13 (a) and (b) shall take effect 60 days after the
14 issuance of the regulation in subsection (h).

15 (2) OTHER ENTITIES.—With respect to the bio-
16 technology companies of concern covered by sub-
17 section (f)(2)(B), the prohibitions under subsections
18 (a) and (b) shall take effect 180 days after the
19 issuance of the regulation in subsection (h).

20 (3) RULES OF CONSTRUCTION.—

21 (A) CERTAIN ENTITIES.—Prior to January
22 1, 2032, with respect to biotechnology compa-
23 nies of concern covered by subsections
24 (f)(2)(A), subsections (a)(2) and (b)(2) shall
25 not apply to biotechnology equipment or serv-

1 ices produced or provided under a contract or
2 agreement, including previously negotiated con-
3 tract options, entered into before the effective
4 date under paragraph (1).

5 (B) OTHER ENTITIES.—Prior to the date
6 that is five years after the issuance of the regu-
7 lation in subsection (h) that identifies a bio-
8 technology company of concern covered by sub-
9 sections (f)(2)(B), subsections (a)(2) and (b)(2)
10 shall not apply to biotechnology equipment or
11 services produced or provided under a contract
12 or agreement, including previously negotiated
13 contract options, entered into before the effec-
14 tive date under paragraph (2).

15 (C) SAFE HARBOR.—The term “bio-
16 technology equipment or services produced or
17 provided by a biotechnology company of con-
18 cern” shall not be construed to refer to any bio-
19 technology equipment or services that were for-
20 merly, but are no longer, produced or provided
21 by biotechnology companies of concern.

22 (d) WAIVER AUTHORITIES.—

23 (1) SPECIFIC BIOTECHNOLOGY EXCEPTION.—

24 (A) WAIVER.—The head of the applicable
25 executive agency may waive the prohibition

1 under subsections (a) and (b) on a case-by-case
2 basis—

3 (i) with the approval of the Director
4 of the Office of Management and Budget,
5 in coordination with the Secretary of De-
6 fense; and

7 (ii) if such head submits a notification
8 and justification to the appropriate con-
9 gressional committees not later than 30
10 days after granting such waiver.

11 (B) DURATION.—

12 (i) IN GENERAL.—Except as provided
13 in clause (ii), a waiver granted under sub-
14 paragraph (A) shall last for a period of not
15 more than 365 days.

16 (ii) EXTENSION.—The head of the ap-
17 plicable executive agency, with the ap-
18 proval of the Director of the Office of
19 Management and Budget, and in coordina-
20 tion with the Secretary of Defense, may
21 extend a waiver granted under subpara-
22 graph (A) one time, for a period up to 180
23 days after the date on which the waiver
24 would otherwise expire, if such an exten-
25 sion is in the national security interests of

1 the United States and if such head sub-
2 mits a notification and justification to the
3 appropriate congressional committees not
4 later than 10 days after granting such
5 waiver extension.

6 (2) OVERSEAS HEALTH CARE SERVICES.—The
7 head of an executive agency may waive the prohibi-
8 tions under subsections (a) and (b) with respect to
9 a contract, subcontract, or transaction for the acqui-
10 sition or provision of health care services overseas on
11 a case-by-case basis—

12 (A) if the head of such executive agency
13 determines that the waiver is—

14 (i) necessary to support the mission or
15 activities of the employees of such execu-
16 tive agency described in subsection
17 (e)(2)(A); and

18 (ii) in the interest of the United
19 States;

20 (B) with the approval of the Director of
21 the Office of Management and Budget, in con-
22 sultation with the Secretary of Defense; and

23 (C) if such head submits a notification and
24 justification to the appropriate congressional

1 committees not later than 30 days after grant-
2 ing such waiver.

3 (e) EXCEPTIONS.—The prohibitions under sub-
4 sections (a) and (b) shall not apply to—

5 (1) any activity subject to the reporting require-
6 ments under title V of the National Security Act of
7 1947 (50 U.S.C. 3091 et seq.) or any authorized in-
8 telligence activities of the United States;

9 (2) the acquisition or provision of health care
10 services overseas for—

11 (A) employees of the United States, includ-
12 ing members of the uniformed services (as de-
13 fined in section 101(a) of title 10, United
14 States Code), whose official duty stations are
15 located overseas or are on permissive temporary
16 duty travel overseas; or

17 (B) employees of contractors or sub-
18 contractors of the United States—

19 (i) who are performing under a con-
20 tract that directly supports the missions or
21 activities of individuals described in sub-
22 paragraph (A); and

23 (ii) whose primary duty stations are
24 located overseas or are on permissive tem-
25 porary duty travel overseas; or

1 (3) the acquisition, use, or distribution of
2 human multiomic data, lawfully compiled, that is
3 commercially or publicly available.

4 (f) EVALUATION OF CERTAIN BIOTECHNOLOGY EN-
5 TITIES.—

6 (1) ENTITY CONSIDERATION.—Not later than
7 365 days after the date of the enactment of this Act,
8 the Director of the Office of Management and Budg-
9 et shall publish a list of the entities that constitute
10 biotechnology companies of concern based on a list
11 of suggested entities that shall be provided by the
12 Secretary of Defense in coordination with the Attor-
13 ney General, the Secretary of Health and Human
14 Services, the Secretary of Commerce, the Director of
15 National Intelligence, the Secretary of Homeland Se-
16 curity, the Secretary of State, and the National
17 Cyber Director.

18 (2) BIOTECHNOLOGY COMPANIES OF CONCERN
19 DEFINED.—The term “biotechnology company of
20 concern” means—

21 (A) BGI, MGI, Complete Genomics, WuXi
22 AppTec, and WuXi Biologics;

23 (B) any entity that is determined by the
24 process established in paragraph (1) to meet
25 the following criteria—

1 (i) is subject to the administrative
2 governance structure, direction, control, or
3 operates on behalf of the government of a
4 foreign adversary;

5 (ii) is to any extent involved in the
6 manufacturing, distribution, provision, or
7 procurement of a biotechnology equipment
8 or service; and

9 (iii) poses a risk to the national secu-
10 rity of the United States based on—

11 (I) engaging in joint research
12 with, being supported by, or being af-
13 filiated with a foreign adversary's
14 military, internal security forces, or
15 intelligence agencies;

16 (II) providing multiomic data ob-
17 tained via biotechnology equipment or
18 services to the government of a for-
19 eign adversary; or

20 (III) obtaining human multiomic
21 data via the biotechnology equipment
22 or services without express and in-
23 formed consent; and

24 (C) any subsidiary, parent, affiliate, or
25 successor of entities listed in subparagraphs (A)

1 and (B), provided they meet the criteria in sub-
2 paragraph (B)(i).

3 (3) GUIDANCE.—Not later than 120 days after
4 the date of the enactment of this Act for the bio-
5 technology companies of concern named in para-
6 graph (2)(A), and not later than 180 days after the
7 development of the list pursuant to paragraph (1)
8 and any update to the list pursuant to paragraph
9 (4), the Director of the Office of Management and
10 Budget, in coordination with the Secretary of De-
11 fense, the Attorney General, the Secretary of Health
12 and Human Services, the Secretary of Commerce,
13 the Director of National Intelligence, the Secretary
14 of Homeland Security, the Secretary of State, and
15 the National Cyber Director, shall establish guidance
16 as necessary to implement the requirements of this
17 section.

18 (4) UPDATES.—The Director of the Office of
19 Management and Budget, in coordination with or
20 based on a recommendation provided by the Sec-
21 retary of Defense, the Attorney General, the Sec-
22 retary of Health and Human Services, the Secretary
23 of Commerce, the Director of National Intelligence,
24 the Secretary of Homeland Security, the Secretary
25 of State, and the National Cyber Director, shall pe-

1 riodically, though not less than annually, review and,
2 as appropriate, modify the list of biotechnology com-
3 panies of concern, and notify the appropriate con-
4 gressional committees of any such modifications.

5 (5) NOTICE OF A DESIGNATION AND REVIEW.—

6 (A) IN GENERAL.—A notice of a designa-
7 tion as a biotechnology company of concern
8 under paragraph (2)(B) shall be issued to any
9 biotechnology company of concern named in the
10 designation—

11 (i) advising that a designation has
12 been made;

13 (ii) identifying the criteria relied upon
14 under such subparagraph and, to the ex-
15 tent consistent with national security and
16 law enforcement interests, the information
17 that formed the basis for the designation;

18 (iii) advising that, within 90 days
19 after receipt of notice, the biotechnology
20 company of concern may submit informa-
21 tion and argument in opposition to the
22 designation;

23 (iv) describing the procedures gov-
24 erning the review and possible issuance of

1 a designation pursuant to paragraph (1);
2 and

3 (v) where practicable, identifying miti-
4 gation steps that could be taken by the
5 biotechnology company of concern that
6 may result in the rescission of the designa-
7 tion.

8 (B) CONGRESSIONAL NOTIFICATION RE-
9 QUIREMENTS.—

10 (i) NOTICE OF DESIGNATION.—The
11 Director of the Office of Management and
12 Budget shall submit the notice required
13 under subparagraph (A) to the Committee
14 on Homeland Security and Governmental
15 Affairs of the Senate and the Committee
16 on Oversight and Accountability of the
17 House of Representatives.

18 (ii) INFORMATION AND ARGUMENT IN
19 OPPOSITION TO DESIGNATIONS.—Not later
20 than 7 days after receiving any informa-
21 tion and argument in opposition to a des-
22 ignation pursuant to subparagraph (A)(iii),
23 the Director of the Office of Management
24 and Budget shall submit such information
25 to the Committee on Homeland Security

1 and Governmental Affairs of the Senate
2 and the Committee on Oversight and Ac-
3 countability of the House of Representa-
4 tives.

5 (C) EXCEPTIONS.—The provisions under
6 subparagraphs (A) and (B) shall not apply to
7 an entity listed under paragraph (2)(A).

8 (6) NO IMMEDIATE PUBLIC RELEASE.—Any
9 designation made under paragraph (1) or paragraph
10 (4) shall not be made publicly available until the Di-
11 rector of the Office of Management and Budget, in
12 coordination with appropriate agencies, reviews all
13 information submitted under paragraph (5)(A)(iii)
14 and issues a final determination that a company
15 shall remain listed as a biotechnology company of
16 concern.

17 (g) EVALUATION OF NATIONAL SECURITY RISKS
18 POSED BY FOREIGN ADVERSARY ACQUISITION OF AMER-
19 ICAN MULTIOMIC DATA.—

20 (1) ASSESSMENT.—Not later than 270 days
21 after the enactment of this Act, the Director of Na-
22 tional Intelligence, in consultation with the Secretary
23 of Defense, the Attorney General of the United
24 States, the Secretary of Health and Human Serv-
25 ices, the Secretary of Commerce, the Secretary of

1 Homeland Security, the Secretary of State, and the
2 National Cyber Director, shall complete an assess-
3 ment of risks to national security posed by human
4 multiomic data from United States citizens that is
5 collected or stored by a foreign adversary from the
6 provision of biotechnology equipment or services.

7 (2) REPORT REQUIREMENT.—Not later than 30
8 days after the completion of the assessment devel-
9 oped under paragraph (1), the Director of National
10 Intelligence shall submit a report with such assess-
11 ment to the appropriate congressional committees.

12 (3) FORM.—The report required under para-
13 graph (2) shall be in unclassified form accompanied
14 by a classified annex.

15 (h) REGULATIONS.—Not later than one year after
16 the date of establishment of guidance required under sub-
17 section (f)(3), and as necessary for subsequent updates,
18 the Federal Acquisition Regulatory Council shall revise
19 the Federal Acquisition Regulation as necessary to imple-
20 ment the requirements of this section.

21 (i) REPORTING ON INTELLIGENCE ON NEFARIOUS
22 ACTIVITIES OF BIOTECHNOLOGY COMPANIES WITH
23 HUMAN MULTIOMIC DATA.—Not later than 180 days
24 after the date of the enactment of this Act, and annually
25 thereafter, the Director of National Intelligence, in con-

1 sultation with the heads of executive agencies, shall submit
2 to the appropriate congressional committees a report on
3 any intelligence in possession of such agencies related to
4 nefarious activities conducted by biotechnology companies
5 with human multiomic data. The report shall include in-
6 formation pertaining to potential threats to national secu-
7 rity or public safety from the selling, reselling, licensing,
8 trading, transferring, sharing, or otherwise providing or
9 making available to any foreign country of any forms of
10 multiomic data of a United States citizen.

11 (j) NO ADDITIONAL FUNDS.—No additional funds
12 are authorized to be appropriated for the purpose of car-
13 rying out this section.

14 (k) DEFINITIONS.—In this section:

15 (1) APPROPRIATE CONGRESSIONAL COMMIT-
16 TEES.—The term “appropriate congressional com-
17 mittees” means—

18 (A) the Committee on Armed Services, the
19 Select Committee on Intelligence, and the Com-
20 mittee on Homeland Security and Govern-
21 mental Affairs of the Senate; and

22 (B) the Committee on Armed Services, the
23 Permanent Select Committee on Intelligence,
24 the Committee on Foreign Affairs, the Com-
25 mittee on Oversight and Accountability, the

1 Committee on Energy and Commerce, and the
2 Select Committee on Strategic Competition be-
3 tween the United States and the Chinese Com-
4 munist Party of the House of Representatives.

5 (2) BIOTECHNOLOGY EQUIPMENT OR SERV-
6 ICE.—The term “biotechnology equipment or serv-
7 ice” means—

8 (A) equipment, including genetic sequenc-
9 ers, combined mass spectrometry technologies,
10 polymerase chain reaction machines, or any
11 other instrument, apparatus, machine, or de-
12 vice, including components and accessories
13 thereof, that is designed for use in the research,
14 development, production, or analysis of biologi-
15 cal materials as well as any software, firmware,
16 or other digital components that are specifically
17 designed for use in, and necessary for the oper-
18 ation of, such equipment;

19 (B) any service for the research, develop-
20 ment, production, analysis, detection, or provi-
21 sion of information, including data storage and
22 transmission related to biological materials, in-
23 cluding—

24 (i) advising, consulting, or support
25 services with respect to the use or imple-

1 mentation of a instrument, apparatus, ma-
2 chine, or device described in subparagraph
3 (A); and

4 (ii) disease detection, genealogical in-
5 formation, and related services; and

6 (C) any other service, instrument, appa-
7 ratus, machine, component, accessory, device,
8 software, or firmware that is designed for use
9 in the research, development, production, or
10 analysis of biological materials that the Direc-
11 tor of the Office of Management and Budget, in
12 consultation with the heads of Executive agen-
13 cies, as determined appropriate by the Director
14 of the Office of Management and Budget, de-
15 termines appropriate in the interest of national
16 security.

17 (3) CONTRACT.—Except as the term is used
18 under subsection (b)(2) and subsection (c)(3), the
19 term “contract” means any contract subject to the
20 Federal Acquisition Regulation issued under section
21 1303(a)(1) of title 41, United States Code.

22 (4) CONTROL.—The term “control” has the
23 meaning given to that term in section 800.208 of
24 title 31, Code of Federal Regulations, or any suc-
25 cessor regulations.

1 (5) EXECUTIVE AGENCY.—The term “executive
2 agency” has the meaning given the term “Executive
3 agency” in section 105 of title 5, United States
4 Code.

5 (6) FOREIGN ADVERSARY.—The term “foreign
6 adversary” has the meaning given the term “covered
7 nation” in section 4872(d) of title 10, United States
8 Code.

9 (7) MULTIOMIC.—The term “multiomic” means
10 data types that include genomics, epigenomics,
11 transcriptomics, proteomics, and metabolomics.

12 (8) OVERSEAS.—The term “overseas” means
13 any area outside of the United States, the Common-
14 wealth of Puerto Rico, or a territory or possession
15 of the United States.