

118TH CONGRESS
2^D SESSION

H. R. 8333

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “BIOSECURE Act”.

3 **SEC. 2. PROHIBITION ON CONTRACTING WITH CERTAIN**
4 **BIOTECHNOLOGY PROVIDERS.**

5 (a) IN GENERAL.—The head of an executive agency
6 may not—

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

10 (2) enter into a contract or extend or renew a
11 contract with any entity that—

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

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

1 (b) PROHIBITION ON LOAN AND GRANT FUNDS.—

2 The head of an executive agency may not obligate or ex-
3 pend loan or grant funds to, and a loan or grant recipient
4 may not use loan or grant funds to—

5 (1) procure, obtain, or use any biotechnology
6 equipment or services 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 an entity described in subsection
10 (a)(2).

11 (c) EFFECTIVE DATES.—

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

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

22 (3) RULES OF CONSTRUCTION.—

23 (A) CERTAIN ENTITIES.—Prior to January
24 1, 2032, with respect to biotechnology compa-
25 nies of concern covered by subsections

1 (f)(2)(A), subsections (a)(2) and (b)(2) shall
2 not apply to biotechnology equipment or serv-
3 ices produced or provided under a contract or
4 agreement, including previously negotiated con-
5 tract options, entered into before the effective
6 date under paragraph (1).

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

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

24 (d) WAIVER AUTHORITIES.—

25 (1) SPECIFIC BIOTECHNOLOGY EXCEPTION.—

1 (A) WAIVER.—The head of the applicable
2 executive agency may waive the prohibition
3 under subsections (a) and (b) on a case-by-case
4 basis—

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

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

13 (B) DURATION.—

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

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

1 would otherwise expire, if such an exten-
2 sion is in the national security interests of
3 the United States and if such head sub-
4 mits a notification and justification to the
5 appropriate congressional committees not
6 later than 10 days after granting such
7 waiver extension.

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

14 (A) if the head of such executive agency
15 determines that the waiver is—

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

20 (ii) in the interest of the United
21 States;

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

1 (C) if such head submits a notification and
2 justification to the appropriate congressional
3 committees not later than 30 days after grant-
4 ing such waiver.

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

7 (1) any activity subject to the reporting require-
8 ments under title V of the National Security Act of
9 1947 (50 U.S.C. 3091 et seq.) or any authorized in-
10 telligence activities of the United States;

11 (2) the acquisition or provision of health care
12 services overseas for—

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

19 (B) employees of contractors or sub-
20 contractors of the United States—

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

1 (ii) whose primary duty stations are
2 located overseas or are on permissive tem-
3 porary duty travel overseas; or

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

7 (f) EVALUATION OF CERTAIN BIOTECHNOLOGY EN-
8 TITIES.—

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

21 (2) BIOTECHNOLOGY COMPANIES OF CONCERN
22 DEFINED.—The term “biotechnology company of
23 concern” means—

24 (A) BGI, MGI, Complete Genomics, WuXi
25 AppTec, and WuXi Biologics;

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

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

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

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

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

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

23 (III) obtaining human multiomic
24 data via the biotechnology equipment

1 or services without express and in-
2 formed consent; and

3 (C) any subsidiary, parent, affiliate, or
4 successor of entities listed in subparagraphs (A)
5 and (B), provided they meet the criteria in sub-
6 paragraph (B)(i).

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

22 (4) UPDATES.—The Director of the Office of
23 Management and Budget, in coordination with or
24 based on a recommendation provided by the Sec-
25 retary of Defense, the Attorney General, the Sec-

1 retary of Health and Human Services, the Secretary
2 of Commerce, the Director of National Intelligence,
3 the Secretary of Homeland Security, the Secretary
4 of State, and the National Cyber Director, shall pe-
5 riodically, though not less than annually, review and,
6 as appropriate, modify the list of biotechnology com-
7 panies of concern, and notify the appropriate con-
8 gressional committees of any such modifications.

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

10 (A) IN GENERAL.—A notice of a designa-
11 tion as a biotechnology company of concern
12 under paragraph (2)(B) shall be issued to any
13 biotechnology company of concern named in the
14 designation—

15 (i) advising that a designation has
16 been made;

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

22 (iii) advising that, within 90 days
23 after receipt of notice, the biotechnology
24 company of concern may submit informa-

1 tion and argument in opposition to the
2 designation;

3 (iv) describing the procedures gov-
4 erning the review and possible issuance of
5 a designation pursuant to paragraph (1);
6 and

7 (v) where practicable, identifying miti-
8 gation steps that could be taken by the
9 biotechnology company of concern that
10 may result in the rescission of the designa-
11 tion.

12 (B) CONGRESSIONAL NOTIFICATION RE-
13 QUIREMENTS.—

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

22 (ii) INFORMATION AND ARGUMENT IN
23 OPPOSITION TO DESIGNATIONS.—Not later
24 than 7 days after receiving any informa-
25 tion and argument in opposition to a des-

1 ignation pursuant to subparagraph (A)(iii),
2 the Director of the Office of Management
3 and Budget shall submit such information
4 to the Committee on Homeland Security
5 and Governmental Affairs of the Senate
6 and the Committee on Oversight and Ac-
7 countability of the House of Representa-
8 tives.

9 (C) EXCEPTIONS.—The provisions under
10 subparagraphs (A) and (B) shall not apply to
11 an entity listed under paragraph (2)(A).

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

21 (g) EVALUATION OF NATIONAL SECURITY RISKS
22 POSED BY FOREIGN ADVERSARY ACQUISITION OF AMER-
23 ICAN MULTIOMIC DATA.—

24 (1) ASSESSMENT.—Not later than 270 days
25 after the enactment of this Act, the Director of Na-

1 tional Intelligence, in consultation with the Secretary
2 of Defense, the Attorney General of the United
3 States, the Secretary of Health and Human Serv-
4 ices, the Secretary of Commerce, the Secretary of
5 Homeland Security, the Secretary of State, and the
6 National Cyber Director, shall complete an assess-
7 ment of risks to national security posed by human
8 multiomic data from United States citizens that is
9 collected or stored by a foreign adversary from the
10 provision of biotechnology equipment or services.

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

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

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

1 (i) REPORTING ON INTELLIGENCE ON NEFARIOUS
2 ACTIVITIES OF BIOTECHNOLOGY COMPANIES WITH
3 HUMAN MULTIOMIC DATA.—Not later than 180 days
4 after the date of the enactment of this Act, and annually
5 thereafter, the Director of National Intelligence, in con-
6 sultation with the heads of executive agencies, shall submit
7 to the appropriate congressional committees a report on
8 any intelligence in possession of such agencies related to
9 nefarious activities conducted by biotechnology companies
10 with human multiomic data. The report shall include in-
11 formation pertaining to potential threats to national secu-
12 rity or public safety from the selling, reselling, licensing,
13 trading, transferring, sharing, or otherwise providing or
14 making available to any foreign country of any forms of
15 multiomic data of a United States citizen.

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

19 (k) DEFINITIONS.—In this section:

20 (1) APPROPRIATE CONGRESSIONAL COMMIT-
21 TEES.—The term “appropriate congressional com-
22 mittees” means—

23 (A) the Committee on Armed Services, the
24 Select Committee on Intelligence, and the Com-

1 committee on Homeland Security and Govern-
2 mental Affairs of the Senate; and

3 (B) the Committee on Armed Services, the
4 Permanent Select Committee on Intelligence,
5 the Committee on Foreign Affairs, the Com-
6 mittee on Oversight and Accountability, the
7 Committee on Energy and Commerce, and the
8 Select Committee on Strategic Competition be-
9 tween the United States and the Chinese Com-
10 munist Party of the House of Representatives.

11 (2) BIOTECHNOLOGY EQUIPMENT OR SERV-
12 ICE.—The term “biotechnology equipment or serv-
13 ice” means—

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

1 (B) any service for the research, develop-
2 ment, production, analysis, detection, or provi-
3 sion of information, including data storage and
4 transmission related to biological materials, in-
5 cluding—

6 (i) advising, consulting, or support
7 services with respect to the use or imple-
8 mentation of a instrument, apparatus, ma-
9 chine, or device described in subparagraph
10 (A); and

11 (ii) disease detection, genealogical in-
12 formation, and related services; and

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

24 (3) CONTRACT.—Except as the term is used
25 under subsection (b)(2) and subsection (c)(3), the

1 term “contract” means any contract subject to the
2 Federal Acquisition Regulation issued under section
3 1303(a)(1) of title 41, United States Code.

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

8 (5) EXECUTIVE AGENCY.—The term “executive
9 agency” has the meaning given the term “Executive
10 agency” in section 105 of title 5, United States
11 Code.

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

16 (7) MULTIOMIC.—The term “multiomic” means
17 data types that include genomics, epigenomics,
18 transcriptomics, proteomics, and metabolomics.

19 (8) OVERSEAS.—The term “overseas” means
20 any area outside of the United States, the Common-

1 wealth of Puerto Rico, or a territory or possession
2 of the United States.

Passed the House of Representatives September 9,
2024.

Attest:

Clerk.

118TH CONGRESS
2^D SESSION

H. R. 8333

AN ACT

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