

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 8333  
OFFERED BY MR. COMER OF KENTUCKY**

Strike all after the enacting clause and insert the following:

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

1 (B) enters into any contract the perform-  
2 ance of which such entity knows or has reason  
3 to believe will require, in performance of the  
4 contract with the executive agency, the use of  
5 biotechnology equipment or services produced or  
6 provided by a biotechnology company of concern  
7 and acquired after the applicable effective date  
8 in subsection (e).

9 (b) PROHIBITION ON LOAN AND GRANT FUNDS.—  
10 The head of an executive agency may not obligate or ex-  
11 pend loan or grant funds to, and a loan or grant recipient  
12 may not use loan or grant funds to—

13 (1) procure, obtain, or use any biotechnology  
14 equipment or services produced or provided by a bio-  
15 technology company of concern; or

16 (2) enter into a contract or extend or renew a  
17 contract with an entity described in subsection  
18 (a)(2).

19 (c) EFFECTIVE DATES.—

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

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

6           (3) RULES OF CONSTRUCTION.—

7                   (A) CERTAIN ENTITIES.—Prior to January  
8                   1, 2032, with respect to biotechnology compa-  
9                   nies of concern covered by subsections  
10                   (f)(2)(A), subsections (a)(2) and (b)(2) shall  
11                   not apply to biotechnology equipment or serv-  
12                   ices produced or provided under a contract or  
13                   agreement, including previously negotiated con-  
14                   tract options, entered into before the effective  
15                   date under paragraph (1).

16                   (B) OTHER ENTITIES.—Prior to the date  
17                   that is five years after the issuance of the regu-  
18                   lation in subsection (h) that identifies a bio-  
19                   technology company of concern covered by sub-  
20                   sections (f)(2)(B), subsections (a)(2) and (b)(2)  
21                   shall not apply to biotechnology equipment or  
22                   services produced or provided under a contract  
23                   or agreement, including previously negotiated  
24                   contract options, entered into before the effec-  
25                   tive date under paragraph (2).

1           (C) SAFE HARBOR.—The term “bio-  
2           technology equipment or services produced or  
3           provided by a biotechnology company of con-  
4           cern” shall not be construed to refer to any bio-  
5           technology equipment or services that were for-  
6           merly, but are no longer, produced or provided  
7           by biotechnology companies of concern.

8           (d) WAIVER AUTHORITIES.—

9           (1) SPECIFIC BIOTECHNOLOGY EXCEPTION.—

10           (A) WAIVER.—The head of the applicable  
11           executive agency may waive the prohibition  
12           under subsections (a) and (b) on a case-by-case  
13           basis—

14                   (i) with the approval of the Director  
15                   of the Office of Management and Budget,  
16                   in coordination with the Secretary of De-  
17                   fense; and

18                   (ii) if such head submits a notification  
19                   and justification to the appropriate con-  
20                   gressional committees not later than 30  
21                   days after granting such waiver.

22           (B) DURATION.—

23                   (i) IN GENERAL.—Except as provided  
24                   in clause (ii), a waiver granted under sub-

1 paragraph (A) shall last for a period of not  
2 more than 365 days.

3 (ii) EXTENSION.—The head of the ap-  
4 plicable executive agency, with the ap-  
5 proval of the Director of the Office of  
6 Management and Budget, and in coordina-  
7 tion with the Secretary of Defense, may  
8 extend a waiver granted under subpara-  
9 graph (A) one time, for a period up to 180  
10 days after the date on which the waiver  
11 would otherwise expire, if such an exten-  
12 sion is in the national security interests of  
13 the United States and if such head sub-  
14 mits a notification and justification to the  
15 appropriate congressional committees not  
16 later than 10 days after granting such  
17 waiver extension.

18 (2) OVERSEAS HEALTH CARE SERVICES.—The  
19 head of an executive agency may waive the prohibi-  
20 tions under subsections (a) and (b) with respect to  
21 a contract, subcontract, or transaction for the acqui-  
22 sition or provision of health care services overseas on  
23 a case-by-case basis—

24 (A) if the head of such executive agency  
25 determines that the waiver is—

1 (i) necessary to support the mission or  
2 activities of the employees of such execu-  
3 tive agency described in subsection  
4 (e)(2)(A); and

5 (ii) in the interest of the United  
6 States;

7 (B) with the approval of the Director of  
8 the Office of Management and Budget, in con-  
9 sultation with the Secretary of Defense; and

10 (C) if such head submits a notification and  
11 justification to the appropriate congressional  
12 committees not later than 30 days after grant-  
13 ing such waiver.

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

16 (1) any activity subject to the reporting require-  
17 ments under title V of the National Security Act of  
18 1947 (50 U.S.C. 3091 et seq.) or any authorized in-  
19 telligence activities of the United States;

20 (2) the acquisition or provision of health care  
21 services overseas for—

22 (A) employees of the United States, includ-  
23 ing members of the uniformed services (as de-  
24 fined in section 101(a) of title 10, United  
25 States Code), whose official duty stations are

1 located overseas or are on permissive temporary  
2 duty travel overseas; or

3 (B) employees of contractors or sub-  
4 contractors of the United States—

5 (i) who are performing under a con-  
6 tract that directly supports the missions or  
7 activities of individuals described in sub-  
8 paragraph (A); and

9 (ii) whose primary duty stations are  
10 located overseas or are on permissive tem-  
11 porary duty travel overseas; or

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

15 (f) EVALUATION OF CERTAIN BIOTECHNOLOGY EN-  
16 TITIES.—

17 (1) ENTITY CONSIDERATION.—Not later than  
18 365 days after the date of the enactment of this Act,  
19 the Director of the Office of Management and Budg-  
20 et shall publish a list of the entities that constitute  
21 biotechnology companies of concern based on a list  
22 of suggested entities that shall be provided by the  
23 Secretary of Defense in coordination with the Attor-  
24 ney General, the Secretary of Health and Human  
25 Services, the Secretary of Commerce, the Director of

1 National Intelligence, the Secretary of Homeland Se-  
2 curity, the Secretary of State, and the National  
3 Cyber Director.

4 (2) BIOTECHNOLOGY COMPANIES OF CONCERN  
5 DEFINED.—The term “biotechnology company of  
6 concern” means—

7 (A) BGI, MGI, Complete Genomics, WuXi  
8 AppTec, and WuXi Biologics;

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

12 (i) is subject to the administrative  
13 governance structure, direction, control, or  
14 operates on behalf of the government of a  
15 foreign adversary;

16 (ii) is to any extent involved in the  
17 manufacturing, distribution, provision, or  
18 procurement of a biotechnology equipment  
19 or service; and

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

22 (I) engaging in joint research  
23 with, being supported by, or being af-  
24 filiated with a foreign adversary’s



1 military, internal security forces, or  
2 intelligence agencies;

3 (II) providing multiomic data ob-  
4 tained via biotechnology equipment or  
5 services to the government of a for-  
6 eign adversary; or

7 (III) obtaining human multiomic  
8 data via the biotechnology equipment  
9 or services without express and in-  
10 formed consent; and

11 (C) any subsidiary, parent, affiliate, or  
12 successor of entities listed in subparagraphs (A)  
13 and (B), provided they meet the criteria in sub-  
14 paragraph (B)(i).

15 (3) GUIDANCE.—Not later than 120 days after  
16 the date of the enactment of this Act for the bio-  
17 technology companies of concern named in para-  
18 graph (2)(A), and not later than 180 days after the  
19 development of the list pursuant to paragraph (1)  
20 and any update to the list pursuant to paragraph  
21 (4), the Director of the Office of Management and  
22 Budget, in coordination with the Secretary of De-  
23 fense, the Attorney General, the Secretary of Health  
24 and Human Services, the Secretary of Commerce,  
25 the Director of National Intelligence, the Secretary

1 of Homeland Security, the Secretary of State, and  
2 the National Cyber Director, shall establish guidance  
3 as necessary to implement the requirements of this  
4 section.

5 (4) UPDATES.—The Director of the Office of  
6 Management and Budget, in coordination with or  
7 based on a recommendation provided by the Sec-  
8 retary of Defense, the Attorney General, the Sec-  
9 retary of Health and Human Services, the Secretary  
10 of Commerce, the Director of National Intelligence,  
11 the Secretary of Homeland Security, the Secretary  
12 of State, and the National Cyber Director, shall pe-  
13 riodically, though not less than annually, review and,  
14 as appropriate, modify the list of biotechnology com-  
15 panies of concern, and notify the appropriate con-  
16 gressional committees of any such modifications.

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

18 (A) IN GENERAL.—A notice of a designa-  
19 tion as a biotechnology company of concern  
20 under paragraph (2)(B) shall be issued to any  
21 biotechnology company of concern named in the  
22 designation—

23 (i) advising that a designation has  
24 been made;

1 (ii) identifying the criteria relied upon  
2 under such subparagraph and, to the ex-  
3 tent consistent with national security and  
4 law enforcement interests, the information  
5 that formed the basis for the designation;

6 (iii) advising that, within 90 days  
7 after receipt of notice, the biotechnology  
8 company of concern may submit informa-  
9 tion and argument in opposition to the  
10 designation;

11 (iv) describing the procedures gov-  
12 erning the review and possible issuance of  
13 a designation pursuant to paragraph (1);  
14 and

15 (v) where practicable, identifying miti-  
16 gation steps that could be taken by the  
17 biotechnology company of concern that  
18 may result in the rescission of the designa-  
19 tion.

20 (B) CONGRESSIONAL NOTIFICATION RE-  
21 QUIREMENTS.—

22 (i) NOTICE OF DESIGNATION.—The  
23 Director of the Office of Management and  
24 Budget shall submit the notice required  
25 under subparagraph (A) to the Committee

1 on Homeland Security and Governmental  
2 Affairs of the Senate and the Committee  
3 on Oversight and Accountability of the  
4 House of Representatives.

5 (ii) INFORMATION AND ARGUMENT IN  
6 OPPOSITION TO DESIGNATIONS.—Not later  
7 than 7 days after receiving any informa-  
8 tion and argument in opposition to a des-  
9 ignation pursuant to subparagraph (A)(iii),  
10 the Director of the Office of Management  
11 and Budget shall submit such information  
12 to the Committee on Homeland Security  
13 and Governmental Affairs of the Senate  
14 and the Committee on Oversight and Ac-  
15 countability of the House of Representa-  
16 tives.

17 (C) EXCEPTIONS.—The provisions under  
18 subparagraphs (A) and (B) shall not apply to  
19 an entity listed under paragraph (2)(A).

20 (6) NO IMMEDIATE PUBLIC RELEASE.—Any  
21 designation made under paragraph (1) or paragraph  
22 (4) shall not be made publicly available until the Di-  
23 rector of the Office of Management and Budget, in  
24 coordination with appropriate agencies, reviews all  
25 information submitted under paragraph (5)(A)(iii)

1 and issues a final determination that a company  
2 shall remain listed as a biotechnology company of  
3 concern.

4 (g) EVALUATION OF NATIONAL SECURITY RISKS  
5 POSED BY FOREIGN ADVERSARY ACQUISITION OF AMER-  
6 ICAN MULTIOMIC DATA.—

7 (1) ASSESSMENT.—Not later than 270 days  
8 after the enactment of this Act, the Director of Na-  
9 tional Intelligence, in consultation with the Secretary  
10 of Defense, the Attorney General of the United  
11 States, the Secretary of Health and Human Serv-  
12 ices, the Secretary of Commerce, the Secretary of  
13 Homeland Security, the Secretary of State, and the  
14 National Cyber Director, shall complete an assess-  
15 ment of risks to national security posed by human  
16 multiomic data from United States citizens that is  
17 collected or stored by a foreign adversary from the  
18 provision of biotechnology equipment or services.

19 (2) REPORT REQUIREMENT.—Not later than 30  
20 days after the completion of the assessment devel-  
21 oped under paragraph (1), the Director of National  
22 Intelligence shall submit a report with such assess-  
23 ment to the appropriate congressional committees.

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

4           (h) REGULATIONS.—Not later than one year after  
5           the date of establishment of guidance required under sub-  
6           section (f)(3), and as necessary for subsequent updates,  
7           the Federal Acquisition Regulatory Council shall revise  
8           the Federal Acquisition Regulation as necessary to imple-  
9           ment the requirements of this section.

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

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

4 (k) DEFINITIONS.—In this section:

5 (1) APPROPRIATE CONGRESSIONAL COMMIT-  
6 TEES.—The term “appropriate congressional com-  
7 mittees” means—

8 (A) the Committee on Armed Services, the  
9 Select Committee on Intelligence, and the Com-  
10 mittee on Homeland Security and Govern-  
11 mental Affairs of the Senate; and

12 (B) the Committee on Armed Services, the  
13 Permanent Select Committee on Intelligence,  
14 the Committee on Foreign Affairs, the Com-  
15 mittee on Oversight and Accountability, the  
16 Committee on Energy and Commerce, and the  
17 Select Committee on Strategic Competition be-  
18 tween the United States and the Chinese Com-  
19 munist Party of the House of Representatives.

20 (2) BIOTECHNOLOGY EQUIPMENT OR SERV-  
21 ICE.—The term “biotechnology equipment or serv-  
22 ice” means—

23 (A) equipment, including genetic sequenc-  
24 ers, combined mass spectrometry technologies,  
25 polymerase chain reaction machines, or any

1 other instrument, apparatus, machine, or de-  
2 vice, including components and accessories  
3 thereof, that is designed for use in the research,  
4 development, production, or analysis of biologi-  
5 cal materials as well as any software, firmware,  
6 or other digital components that are specifically  
7 designed for use in, and necessary for the oper-  
8 ation of, such equipment;

9 (B) any service for the research, develop-  
10 ment, production, analysis, detection, or provi-  
11 sion of information, including data storage and  
12 transmission related to biological materials, in-  
13 cluding—

14 (i) advising, consulting, or support  
15 services with respect to the use or imple-  
16 mentation of a instrument, apparatus, ma-  
17 chine, or device described in subparagraph  
18 (A); and

19 (ii) disease detection, genealogical in-  
20 formation, and related services; and

21 (C) any other service, instrument, appa-  
22 ratus, machine, component, accessory, device,  
23 software, or firmware that is designed for use  
24 in the research, development, production, or  
25 analysis of biological materials that the Direc-



1           tor of the Office of Management and Budget, in  
2           consultation with the heads of Executive agen-  
3           cies, as determined appropriate by the Director  
4           of the Office of Management and Budget, de-  
5           termines appropriate in the interest of national  
6           security.

7           (3) CONTRACT.—Except as the term is used  
8           under subsection (b)(2) and subsection (c)(3), the  
9           term “contract” means any contract subject to the  
10          Federal Acquisition Regulation issued under section  
11          1303(a)(1) of title 41, United States Code.

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

16          (5) EXECUTIVE AGENCY.—The term “executive  
17          agency” has the meaning given the term “Executive  
18          agency” in section 105 of title 5, United States  
19          Code.

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

1           (7) MULTIOMIC.—The term “multiomic” means  
2     data types that include genomics, epigenomics,  
3     transcriptomics, proteomics, and metabolomics.

4           (8) OVERSEAS.—The term “overseas” means  
5     any area outside of the United States, the Common-  
6     wealth of Puerto Rico, or a territory or possession  
7     of the United States.

