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:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''BIOSECURE Act''.

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

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

(1) procure or obtain any biotechnology equipment or service produced or provided by a biotechnology company of concern; or

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

(A) uses biotechnology equipment or services produced or provided by a biotechnology company of concern and acquired after the applicable effective date in subsection (c) in performance of the contract with the executive agency; or

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

(b) PROHIBITION ON LOAN AND GRANT FUNDS.—The head of an executive agency may not obligate or expend loan or grant funds to, and a loan or grant recipient may not use loan or grant funds to—

(1) procure, obtain, or use any biotechnology equipment or services produced or provided by a biotechnology company of concern; or

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

(c) EFFECTIVE DATES.—

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

(2) OTHER ENTITIES.—With respect to the biotechnology companies of concern covered by subsection (f)(2)(B), the prohibitions under subsections (a) and (b) shall take effect 180 days after the issuance of the regulation in subsection (h).

(3) RULES OF CONSTRUCTION.—

(A) CERTAIN ENTITIES.—Prior to January 1, 2032, with respect to biotechnology companies of concern covered by subsections (f)(2)(A), subsections (a)(2) and (b)(2) shall not apply to biotechnology equipment or services produced or provided under a contract or agreement, including previously negotiated contract options, entered into before the effective date under paragraph (1).

(B) OTHER ENTITIES.—Prior to the date that is five years after the issuance of the regulation in subsection (h) that identifies a biotechnology company of concern covered by subsections (f)(2)(B), subsections (a)(2) and (b)(2) shall not apply to biotechnology equipment or services produced or provided under a contract or agreement, including previously negotiated contract options, entered into before the effective date under paragraph (2).

(C) SAFE HARBOR.—The term ''biotechnology equipment or services produced or provided by a biotechnology company of concern'' shall not be construed to refer to any biotechnology equipment or services that were formerly, but are no longer, produced or provided by biotechnology companies of concern.

(d) WAIVER AUTHORITIES.—

(1) SPECIFIC BIOTECHNOLOGY EXCEPTION.—

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

(i) with the approval of the Director of the Office of Management and Budget, in coordination with the Secretary of Defense; and

(ii) if such head submits a notification and justification to the appropriate congressional committees not later than 30 days after granting such waiver.

(B) DURATION.—

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

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

(ii) EXTENSION.—The head of the applicable executive agency, with the approval of the Director of the Office of Management and Budget, and in coordination with the Secretary of Defense, may extend a waiver granted under subparagraph (A) one time, for a period up to 180 days after the date on which the waiver would otherwise expire, if such an extension is in the national security interests of the United States and if such head submits a notification and justification to the appropriate congressional committees not later than 10 days after granting such waiver extension.

(2) OVERSEAS HEALTH CARE SERVICES.—The head of an executive agency may waive the prohibitions under subsections (a) and (b) with respect to a contract, subcontract, or transaction for the acquisition or provision of health care services overseas on a case-by-case basis—

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

(i) necessary to support the mission or activities of the employees of such executive agency described in subsection (e)(2)(A); and

(ii) in the interest of the United States;

(B) with the approval of the Director of the Office of Management and Budget, in consultation with the Secretary of Defense; and

(C) if such head submits a notification and justification to the appropriate congressional committees not later than 30 days after granting such waiver.

(e) EXCEPTIONS.—The prohibitions under subsections (a) and (b) shall not apply to—

(1) any activity subject to the reporting requirements under title V of the National Security Act of 1947 (50 U.S.C. 3091 et seq.) or any authorized intelligence activities of the United States;

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

(A) employees of the United States, including members of the uniformed services (as defined in section 101(a) of title 10, United States Code), whose official duty stations are

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

(B) employees of contractors or subcontractors of the United States—

(i) who are performing under a contract that directly supports the missions or activities of individuals described in subparagraph (A); and

(ii) whose primary duty stations are located overseas or are on permissive temporary duty travel overseas; or

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

(f) EVALUATION OF CERTAIN BIOTECHNOLOGY ENTITIES.—

(1) ENTITY CONSIDERATION.—Not later than 365 days after the date of the enactment of this Act, the Director of the Office of Management and Budget shall publish a list of the entities that constitute biotechnology companies of concern based on a list of suggested entities that shall be provided by the Secretary of Defense in coordination with the Attorney General, the Secretary of Health and Human Services, the Secretary of Commerce, the Director of

National Intelligence, the Secretary of Homeland Security, the Secretary of State, and the National Cyber Director.

(2) BIOTECHNOLOGY COMPANIES OF CONCERN DEFINED.—The term ''biotechnology company of concern'' means—

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

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

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

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

(iii) poses a risk to the national security of the United States based on—

(I) engaging in joint research with, being supported by, or being affiliated with a foreign adversary's

military, internal security forces, or intelligence agencies;

(II) providing multiomic data obtained via biotechnology equipment or services to the government of a foreign adversary; or

(III) obtaining human multiomic data via the biotechnology equipment or services without express and informed consent; and

(C) any subsidiary, parent, affiliate, or successor of entities listed in subparagraphs (A) and (B), provided they meet the criteria in subparagraph (B)(i).

(3) GUIDANCE.—Not later than 120 days after the date of the enactment of this Act for the biotechnology companies of concern named in paragraph (2)(A), and not later than 180 days after the development of the list pursuant to paragraph (1) and any update to the list pursuant to paragraph (4), the Director of the Office of Management and Budget, in coordination with the Secretary of Defense, the Attorney General, the Secretary of Health and Human Services, the Secretary of Commerce, the Director of National Intelligence, the Secretary

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

(4) UPDATES.—The Director of the Office of Management and Budget, in coordination with or based on a recommendation provided by the Secretary of Defense, the Attorney General, the Secretary of Health and Human Services, the Secretary of Commerce, the Director of National Intelligence, the Secretary of Homeland Security, the Secretary of State, and the National Cyber Director, shall periodically, though not less than annually, review and, as appropriate, modify the list of biotechnology companies of concern, and notify the appropriate congressional committees of any such modifications.

(5) NOTICE OF A DESIGNATION AND REVIEW.—

(A) IN GENERAL.—A notice of a designation as a biotechnology company of concern under paragraph (2)(B) shall be issued to any biotechnology company of concern named in the designation—

(i) advising that a designation has been made;

(ii) identifying the criteria relied upon under such subparagraph and, to the extent consistent with national security and law enforcement interests, the information that formed the basis for the designation;

(iii) advising that, within 90 days after receipt of notice, the biotechnology company of concern may submit information and argument in opposition to the designation;

(iv) describing the procedures governing the review and possible issuance of a designation pursuant to paragraph (1); and

(v) where practicable, identifying mitigation steps that could be taken by the biotechnology company of concern that may result in the rescission of the designation.

(B) CONGRESSIONAL NOTIFICATION REQUIREMENTS.—

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

on Homeland Security and Governmental Affairs of the Senate and the Committee on Oversight and Accountability of the House of Representatives.

(ii) INFORMATION AND ARGUMENT IN OPPOSITION TO DESIGNATIONS.—Not later than 7 days after receiving any information and argument in opposition to a designation pursuant to subparagraph (A)(iii), the Director of the Office of Management and Budget shall submit such information to the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Oversight and Accountability of the House of Representatives.

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

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

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

(g) EVALUATION OF NATIONAL SECURITY RISKS POSED BY FOREIGN ADVERSARY ACQUISITION OF AMERICAN MULTIOMIC DATA.—

(1) ASSESSMENT.—Not later than 270 days after the enactment of this Act, the Director of National Intelligence, in consultation with the Secretary of Defense, the Attorney General of the United States, the Secretary of Health and Human Services, the Secretary of Commerce, the Secretary of Homeland Security, the Secretary of State, and the National Cyber Director, shall complete an assessment of risks to national security posed by human multiomic data from United States citizens that is collected or stored by a foreign adversary from the provision of biotechnology equipment or services.

(2) REPORT REQUIREMENT.—Not later than 30 days after the completion of the assessment developed under paragraph (1), the Director of National Intelligence shall submit a report with such assessment to the appropriate congressional committees.

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

(h) REGULATIONS.—Not later than one year after the date of establishment of guidance required under subsection (f)(3), and as necessary for subsequent updates, the Federal Acquisition Regulatory Council shall revise the Federal Acquisition Regulation as necessary to implement the requirements of this section.

(i) REPORTING ON INTELLIGENCE ON NEFARIOUS ACTIVITIES OF BIOTECHNOLOGY COMPANIES WITH HUMAN MULTIOMIC DATA.—Not later than 180 days after the date of the enactment of this Act, and annually thereafter, the Director of National Intelligence, in consultation with the heads of executive agencies, shall submit to the appropriate congressional committees a report on any intelligence in possession of such agencies related to nefarious activities conducted by biotechnology companies with human multiomic data. The report shall include information pertaining to potential threats to national security or public safety from the selling, reselling, licensing, trading, transferring, sharing, or otherwise providing or making available to any foreign country of any forms of multiomic data of a United States citizen.

(j) NO ADDITIONAL FUNDS.—No additional funds are authorized to be appropriated for the purpose of carrying out this section.

(k) DEFINITIONS.—In this section:

(1) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term ''appropriate congressional committees'' means—

(A) the Committee on Armed Services, the Select Committee on Intelligence, and the Committee on Homeland Security and Governmental Affairs of the Senate; and

(B) the Committee on Armed Services, the Permanent Select Committee on Intelligence, the Committee on Foreign Affairs, the Committee on Oversight and Accountability, the Committee on Energy and Commerce, and the Select Committee on Strategic Competition between the United States and the Chinese Communist Party of the House of Representatives.

(2) BIOTECHNOLOGY EQUIPMENT OR SERVICE.—The term ''biotechnology equipment or service'' means—

(A) equipment, including genetic sequencers, combined mass spectrometry technologies, polymerase chain reaction machines, or any

other instrument, apparatus, machine, or device, including components and accessories thereof, that is designed for use in the research, development, production, or analysis of biological materials as well as any software, firmware, or other digital components that are specifically designed for use in, and necessary for the operation of, such equipment;

(B) any service for the research, development, production, analysis, detection, or provision of information, including data storage and transmission related to biological materials, including—

(i) advising, consulting, or support services with respect to the use or implementation of a instrument, apparatus, machine, or device described in subparagraph (A); and

(ii) disease detection, genealogical information, and related services; and

(C) any other service, instrument, apparatus, machine, component, accessory, device, software, or firmware that is designed for use in the research, development, production, or analysis of biological materials that the Direc-

tor of the Office of Management and Budget, in consultation with the heads of Executive agencies, as determined appropriate by the Director of the Office of Management and Budget, determines appropriate in the interest of national security.

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

(4) CONTROL.—The term ''control'' has the meaning given to that term in section 800.208 of title 31, Code of Federal Regulations, or any successor regulations.

(5) EXECUTIVE AGENCY.—The term ''executive agency'' has the meaning given the term ''Executive agency'' in section 105 of title 5, United States Code.

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

(7) MULTIOMIC.—The term ''multiomic'' means data types that include genomics, epigenomics, transcriptomics, proteomics, and metabolomics.

(8) OVERSEAS.—The term ''overseas'' means any area outside of the United States, the Commonwealth of Puerto Rico, or a territory or possession of the United States.