

SUMMARY OF THE BIOSECURE ACT

A BILL TO PROHIBIT CONTRACTING WITH CERTAIN BIOTECHNOLOGY PROVIDERS, AND FOR OTHER PURPOSES

On May 10, Reps. Brad Wenstup (R-OH) and Raja Krishnamoorthi (D-IL) introduced the BIOSECURE Act ([H.R. 8333](#)), which aims to protect national security by prohibiting federal agencies from contracting with certain biotechnology companies with ties to the Democratic People's Republic of North Korea, the People's Republic of China, the Russian Federation, and the Islamic Republic of Iran. Specifically, the bill would prohibit federal agencies from: (1) procuring or obtaining biotechnology equipment or services from a biotechnology company of concern as defined by the legislation; and (2) entering into or renewing existing contracts with an entity that uses biotechnology equipment or services produced or provided by a biotechnology company of concern or entering into or renewing existing contracts with an entity that enters into any contract the performance of which would require the use of biotechnology equipment or services produced or provided by a biotechnology company of concern after a certain date.

The bill would also prohibit federal agencies from expending or obligating loans to procure or obtain any such equipment. However, agency heads would be permitted to waive the outlined prohibitions with exceptions being made on a case-by-case basis.

Notably, the bill was considered during a [markup](#) in the House Committee on Oversight and Accountability on May 15, where it was reported favorably as amended [40-1] to the House floor to be voted upon at a later date. A similar version of the bill ([S. 3558](#)) has also been introduced in the Senate and was [advanced](#) [11-1] by the Senate Committee on Homeland Security and Government Affairs on March 6.

Effective Dates

Prior to January 1, 2032, the restriction prohibiting federal agencies from obtaining biotechnology equipment or services produced or provided by a biotechnology company of concern would not apply to equipment or services produced by BGI, MGI, Complete Genomics, WuXi Apptec, or WuXi Biologics, so long as the contract was entered into before the effective date of the legislation. This provision would also apply to negotiated contract years. Additionally, the prohibitions of the bill would also not apply to any equipment or services produced by the companies of concern identified by OMB for five years if the federal agency entered into contract with any of these entities prior to the effective date of the bill.

- Safe Harbor — The bill includes a safe harbor that would permit federal agencies to procure, obtain, or use biotechnology equipment that was once produced or provided by, but is no longer, biotechnology companies of concern.

Biotechnology Companies of Concern

- **Definition** — Within one year of enactment of the bill, the Director of the Office of Management and Budget (OMB), would be required to publish a list constituting the “biotechnology companies of concern” based on a list of suggested entities provided by the Secretaries of Defense, Health and Human Services, Commerce, Homeland Security, State, the Attorney General, and the Director of National Security. The bill would also require such individuals to establish guidance for implementing the prohibitions within the same allotted time.

The bill identifies such companies as BGI, MGI, Complete Genomics, Wuxi Aptec, WuXi Biologics and their subsidiaries, affiliates, parents, or successors. Additionally, the bill defines the term to mean any entity that: (1) is subject to the direction, control, or operates on behalf of the government of a foreign adversary; (2) is involved in any aspect of the manufacturing or distribution of biotechnology equipment or services; and (3) poses a risk to U.S. national security based on engaging in or being affiliated with a foreign adversary’s military or intelligence agencies, providing multiomic data obtained using the biotechnology equipment or services of a foreign adversary, or obtaining human multiomic data via the biotechnology equipment without informed consent. As defined under 10 USC 4872, foreign adversaries include the Democratic People’s Republic of North Korea, the People’s Republic of China, the Russian Federation, and the Islamic Republic of Iran. Notably, the OMB Director would also be required to annually update the list of biotechnology companies of concern.

- **Notice of Designation** — Entities identified as a biotechnology company of concern by OMB would be issued a notice of designation that: (1) advises the designation has been made; (2) identifies the criteria used to form the designation; (3) advises that biotechnology company of concern may submit information opposing the designation within 90 days of receipt of notice; (4) describes the procedures governing the review; and (5) identifies possible mitigation steps following the notice. The OMB Director would be required to submit the notice to the Senate Committee on Homeland Security and the House Committee on Oversight and Accountability. Additionally, within seven days of receiving any information in opposition to a designation, the OMB Director would also submit such information to the same committees.

Waivers of Prohibition Against Federal Government Contracting with Biotechnology Companies of Concerns

There are two types of waivers that would permit exceptions to prohibitions on federal agencies contracting with certain biotechnology companies with ties to North Korea, China, Russia, and Iran:

- **Specific Biotechnology Exception** — The head of a federal agency would be permitted to waive the outlined prohibitions provided: (1) approval from the OMB Director in coordination with the Secretary of Defense; and (2) submission of a notification and justification to the

appropriate congressional committee within 30 days of granting such waiver. Such a waiver may last for up to 365 days with the possibility of being granted a one-time extension of up to 180 days.

- Overseas Health Care Services — Agency heads may also be permitted to waive the prohibitions of the bill if they determine that a waiver is necessary to support U.S. employees of such agency and it is in the interest of the U.S. Additionally, agency heads would need to receive: (1) approval from the OMB Director in coordination with the Secretary of Defense; and (2) submission of a notification and justification to the appropriate congressional committee within 30 days of granting such waiver.

Exception to the Prohibitions Against Federal Government Contracting with Biotechnology Companies of Concerns

Notably, the legislation also outlines several exceptions that the prohibitions outlined in the bill would not apply to, including:

- Any authorized intelligence activities of the U.S.;
- The acquisition of health care services overseas for: (1) employees of the U.S. or uniformed services whose official duty station is overseas; or (2) employees of U.S. contractors who are supporting authorized U.S. intelligence services or whose primary duty station is overseas; or
- The acquisition or use of human multiomic data — meaning any data related to genomics, epigenomics, transcriptions, proteomics, or metabolics — that is commercially or publicly available.

Evaluation of National Security Risks and Reporting on Nefarious Activities by Foreign Adversaries with Human Multiomic Data

- National Security Risk Evaluation — Within 270 days of enactment of the bill, the Director of National Intelligence, in consultation with the Secretaries of Defense, Health and Human Services, Commerce, Homeland Security, and State would be directed to complete an assessment of the national security risks posed by human multiomic data collected by a foreign adversary.
- Reporting on Nefarious Activities — Within 180 days of enactment of the bill, the Director of National Intelligence would be required to submit a report on the intelligence possessed by any executive agency on the nefarious activities conducted by biotechnology companies with human multiomic data. Under the bill, the report would include any information relating to threats to national security resulting from the selling, reselling, licensing, trading, or other form of making multiomic data of a U.S. citizen available to a foreign country.