

# The New (and Politically Improved?) BIOSECURE Act

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Regular readers of the ML Strategies blog are familiar with the legislative wrangling that surrounded the BIOSECURE Act as drafted (and re-drafted) in the last Congress. The BIOSECURE Act is proposed legislation designed to prevent U.S. federal agencies from procuring or using biotechnology equipment and services from companies deemed a national security risk, primarily those with ties to China. Last December, the bill failed to pass before the congressional session ended.

This year, however, a [new version](#) of the BIOSECURE Act has emerged and its prospects may be improved. Last week, the Senate approved the bill as an amendment to the National Defense Authorization Act (NDAA), a must-pass piece of legislation that deals with the various programs of the armed forces. Having passed its version of the NDAA in September without the BIOSECURE Act included, the House will need to reconcile that and other differences between its bill and the Senate's version in a conference committee. The conference process for NDAA will take place should be completed before Congress recesses for Christmas. The following explains what was included in the Senate's version of the NDAA, though it is subject to change or complete removal as the NDAA process moves forward.

## Key Changes to the Legislation

There are notable differences between the 2024 BIOSECURE Act and the Senate amendment. These alterations were made to alleviate the concerns of key lawmakers that held up the bill at the end of 2024. Still, though, the thrust of the bill is a prohibition of biotech equipment or services from companies of concern in the performance of federal contracts.

Previous versions of the bill named specific companies that the Congress wanted to prohibit from contracting with the federal government. This raised concerns due process for these companies from some notable members of Congress. Sen. Rand Paul (R-Ky.), the chairman of the Senate Committee on Homeland Security & Government Affairs (the Senate committee of jurisdiction) vocally opposed the bill and Rep. Jim McGovern (D-Mass.) whipped **81 No votes** including two Republicans when the bill came to the floor. Instead of naming specific companies, the new bill establishes two ways for companies of concern to be prohibited from contracting with the federal government:

- **Inclusion on the 1260H List.** Any biotech company included on the defense department's [annually-published list](#) of Chinese military companies doing business in the United States will be considered a company of concern under the BIOSECURE Act. Companies on this list will be prohibited from federal contracting 60 days after the Federal Acquisition Regulation (FAR) is revised. The bill does not provide a grandfathering period or appeal process for these companies. Notably, the list published in January of 2025 includes BGI Group and its subsidiaries, a company also listed in last year's version of the BIOSECURE Act.
- **Other biotech companies of concern.** The bill also establishes a process for the Office of Management and Budget (OMB), in coordination with the Departments of Defense, Justice, Health and Human Services, State, and Homeland Security, as well as the Director of National Intelligence and National Cyber Director, to publish and update a list of biotech companies of concern that will be prohibited from federal contracting. These companies will have 180 days from the revision of the relevant FAR before the prohibition takes effect. Before making designations public, OMB will provide companies with an opportunity to respond with information or arguments against the decision and, when practicable, OMB will provide mitigation steps the company may take to avoid inclusion in the published list. Finally, the bill provides a five-year grandfathering period for contracts entered into before the prohibitions took effect.

# What Happens Next

The NDAA Conference Committee process will provide an opportunity to work out any remaining issues with the legislation, including a mitigation process for companies on the 1260H List, the interaction of the two lists, and the definition of federal contract and whether the prohibitions apply to certain Medicare and Medicaid programs. While not necessarily opposed to the Senate amendment, we expect at least one House Democrat who voted against the BIOSECURE Act last year to sit on the committee and possibly take the lead in offering final adjustments.

ML Strategies will continue to monitor the BIOSECURE Act's progress through the legislative process and provide updates as appropriate. In the meantime, please do not hesitate to contact the post's author.

## Authors



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