

CAPITOL STREET

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BIOSECURE Not Included in NDAA

Look for (Watered-Down) Bill + Anti-China Action 2025+

Relevant Companies



»» Our Take & Next Up

The **BIOSECURE Act** was not included in the National Defense Authorization Bill (NDAA) released late yesterday Dec. 7 ([here](#)), which means it's unlikely to move before year-end. There had been pressure to get something done before the new Administration pivoted to tax/immigration (Reconciliation), and new compromise language was being discussed to get the bill across the finish line. However, anti-China legislation (beyond genomics/CDMO policies) is still likely to be front and center in 2025, and we believe there's a good chance a watered-down version of the bill will move next year. Our take on BIOSECURE is [here](#) and [here](#).

»» Key Points

Anti-China members of Congress are likely to continue the fight in 2025 with Biosecure + more. With the **BIOSECURE Act** being left out of the defense bill, the named companies of concern (BGI, MGI, Complete Genomics, WuXi AppTec, WuXi Biologics) are off the hook for now.

We believe the bill will likely be reintroduced in the next Congress. (1) Trump's victory has given Republicans confidence in the federal government's ability to assess risks posed by Chinese companies. (2) We have also said ([here](#)) that we think the bill is likely to pass despite Sen. Rand Paul (R-KY, also a physician), incoming Chair of the Homeland Security Committee, as he will feel pressured to fall into line with fellow Republicans.

Administrative action may be in the cards ahead of more far-reaching legislation in 2025. The administration can add companies to the DoD or Commerce sanctions lists, but that may be more difficult. Congress could also add language to an appropriations bill -- but that would require getting around Rand Paul (R-KY) at Homeland Security.

Here are some catalysts on our radar that we have written about in the past that we are still on the lookout for as we read the tea leaves for 2025+ (1) The National Security Commission on Emerging Biotechnology recommendations, [expected](#) in early 2025, will likely guide lawmakers' priorities. (2) Final rules on genomics & personal data security related to Feb. Executive order (EO) have yet to be released (3) NIH &

FDA response letters to the House Oversight Committee are likely to have been submitted but have not been released publicly.

BIOSECURE has become less of a risk to life science companies 2H24. Earlier versions would have prohibited the government from contracting with any life sciences company that was party to a covered contract with a biotechnology company of concern. However, the prohibition is now limited to use of biotechnology companies of concern “in performance” of the government contract, meaning companies can work with biotechnology companies of concern on projects that are not related to any federal contracts, loans or grants. Additionally, the compromise language that reportedly was being discussed last week would have aimed to establish a process for the federal government to investigate the companies, rather than apply a blanket ban or sanctions, which has been a major sticking point for opponents.

ABOUT BIOSECURE

BIOSECURE passed the House in September by a vote of 306-81 ([here](#)), but with opposition from a third of House Democrats. The opposition from House Dems likely means that the Senate vote count will be close. House Rules Committee Ranking Member James McGovern (D-MA) issued a Dear Colleague letter objecting to the bill, noting that Chinese companies shouldn't be banned without due process. One of the named companies in the House bill, WuXi Biologics, planned to build a \$300 M biomedical plant in McGovern's district.

As a reminder, the House version of the *BIOSECURE* Act (H.R. 8333) [prohibits](#) federal agencies (and U.S. companies contracted with the government or receiving grants) from working with certain Chinese biotech companies that present a national security risk. There is flexibility for biopharma with grandfathering language that allows delays to implementation for companies that are already contracted with banned companies (see our memo [here](#)).

Chinese companies named in the ban include BGI, MGI, Complete Genomics, WuXi AppTec, WuXi Biologics and any subsidiary, parent affiliate, or successor of such entities. These five cannot contest their designation (though Executive Branch review was being discussed last week (see our memo [here](#)). A list of banned “biotech companies of concern” will be reviewed annually with the Director of the OMB, who incoming Pres Trump has named to be Russell Vought (and who does not approve of excessive spending; architect of Project 2025, and we could see him garnering 51 votes for confirmation) having the power to add and remove companies on the ban list.

On the extent of the ban, the bill prohibits:

- Procuring or obtaining any biotechnology equipment or service produced or provided by a biotechnology company of concern, or
- Entering into a contract or extending or renewing a contract that the agency knows or has reason to believe will require the use such equipment or service, or
- Dispensing a federal loan or a grant for such purposes
- Grandfathering of manufacturers: The bill stipulates that any existing contracts with named Chinese companies will be grandfathered in and allowed until 2032. Any contracts with new “biotech companies of concern” will also be allowed for a 5-year phase-in period.
- A formal notice of designation and review process is also included. A new named company has 90 days to submit information and their arguments against the decision, and the notice of designation can

include mitigating steps that could be taken to rescind the decision.

The Senate Bill (S.3558) ([here](#)) sponsored by Sens. Gary Peters (D-MI) and Bill Hagerty (R-TN), cleared the Senate Committee on Homeland Security and Governmental Affairs in March.

- S. 3558 lists the following entities as “biotechnology companies of concern”: BGI, MGI, Complete Genomics, and WuXi AppTec.
- The Senate version would grandfather all agreements with biotechnology companies of concern prior to the effective date.
- Under both bills, the Act’s “effective date” is defined as 60 days after the issuance of regulations. These regulations must be issued within one year of guidance from the Office of Management and Budget (OMB), which is required to provide such guidance within 120 days of the bill’s enactment. This timeline means the effective date will occur no later than 545 days after the legislation is enacted.

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