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## BIOSECURE: Final Sprint for Inclusion in NDAA

Odds Improve with Watered-Down Language?

Relevant Companies



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### »» Our Take & Next Up

**The odds of passage of a watered-down *BIOSECURE* Act may be ticking up with two weeks remaining until the planned year-end recess.** We have said that the prior version of the bill would slip to 2025 ([here](#)) and it still may; however, there is pressure to get something done before the new Administration pivots to tax/immigration (Reconciliation), and new compromise language is emerging to get the bill across the finish line. The scope of both the House and Senate bills have narrowed over the year and appear to be further watered down with the new legislative language ([here](#)). It remains unclear whether it will be enough to get the bill added to the must-pass FY25 *National Defense Authorization Act (NDAA)*, due Dec. 20. Our take on *BIOSECURE* is [here](#) and [here](#). NOTE: We believe that if *BIOSECURE* slips to 2025, 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.

### »» Key Points

**Proposed compromise language in the *BIOSECURE* Act may increase the odds of passage before year-end.** The new language would keep the names of companies identified as “biotechnology companies of concern,” but would likely 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. It remains unclear whether it will be enough to get the bill added to the must-pass FY25 National Defense Authorization Act (NDAA), due Dec. 20. Trump’s victory has given Republicans confidence in the federal government’s ability to assess risks posed by Chinese companies.

***BIOSECURE* could still pass in 2025.** If *BIOSECURE* slips to 2025, it would have to be reintroduced and voted on in House and Senate committees, and would compete with a number of other GOP priorities including immigration, tax, and trade policies. Additionally, the bill has faced opposition in the past from Sen. Rand Paul (R-KY), who will wield more influence as the incoming chair of the Homeland Security and Governmental Affairs Committee in the GOP-controlled Senate next year.

***BIOSECURE* has become less of a risk to life science companies.** 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.

**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 *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.
- A list of banned “biotech companies of concern” will be reviewed annually with the Director of the OMB 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 House 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. The Senate bill has no end date for the grandfathering of contracts prior to the effective date.
- 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.

**Here are some catalysts on our radar that we have written about in the past** (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) (3) NIH & FDA response letters to the House Oversight Committee.

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