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BIOSECURE Act Update: Court Enjoins WuXi AppTec's 1260H Designation, but Strategic and Compliance Clocks Keep Running

Go-To Guide:

- *The ruling*: On Aug. 7, 2026, the U.S. District Court for the District of Columbia preliminarily enjoined the Department of War from giving effect to WuXi AppTec's Section 1260H designation, finding that the agency misread its own evidence on state and military affiliation.
- *Effect of the ruling*: The order binds the Department, not the Office of Management and Budget, which holds an independent, criteria-based pathway to designate biotechnology companies of concern (BCC), which does not rely on the 1260H list under the BIOSECURE Act.
- *The accelerated timeline*: Although certain BIOSECURE implementation deadlines occur later, the FY24 NDAA Sec. 805 supply-chain prohibition reaches Department contractors' sub-tier suppliers on June 30, 2027.
- *The grandfathering asymmetry:* The five-year runway for certain existing contracts is unavailable to entities already designated on the 1260H list, as of Dec. 18, 2025, so remediation and supplier transitions must be sequenced by grandfathering eligibility, not by contract value.

- *Key takeaway:* WuXi AppTec's initial court victory does not impact alternative pathways to BCC designation, and earlier supply-chain restrictions continue to drive near-term compliance and sourcing decisions.

On June 8, 2026, the Department of War (the "Department," also known as the Department of Defense) published an updated 1260H list of Chinese military companies (91 Fed. Reg. 35189), adding roughly 65 entities to bring the list to about 200. Three were biotechnology companies: WuXi AppTec Co., Ltd., a major contract research, development, and manufacturing Organization (CRDMO) with substantial U.S. business, together with Complete Genomics, Inc. and Novogene Company Limited — joining Beijing Genomics Institute (BGI) and MGI Tech Co., Ltd. (MGI) entities already listed. As discussed in our November 2025 GT Alert, under the BIOSECURE Act (P.L. 119-60), enacted Dec. 18, 2025, as sec. 851 of the FY26 National Defense Authorization Act (the NDAA or the Act), 1260H listing is a statutory predicate — not merely an indicator — for one of two pathways to BCC designation. WuXi AppTec challenged its listing, and on Aug. 7, 2026, the district court enjoined the U.S. government from giving effect to the designation. WuXi AppTec Co., Ltd. v. U.S. Dep't of Defense, No. 1:26-cv-02069 (D.D.C.).

Implications of the Preliminary Injunction

Most commentary has centered on the Administrative Procedure Act mechanics. The Department's justification was one sentence: WuXi AppTec is indirectly owned by the state-owned Assets Supervision and Administration Commission (SASAC) and indirectly affiliated with the State Administration of Science, Technology and Industry for National Defense (SASTIND) and the People's Liberation Army (PLA). The court found each rationale factually deficient. A cited "5.32% stake" proved to describe an Aviation Industry Corporation of China fund's own portfolio allocation rather than its ownership of WuXi AppTec, which is closer to 0.001%. In Ministry of Science and Technology study approvals, WuXi AppTec appeared solely as a "Third-Party Laboratory," a category distinct from the institutions actually conducting the research.

A separate consideration is that an arbitrary-and-capricious holding means the agency failed to connect its current evidence to its conclusion — not that no such connection can be drawn on a corrected record. The order expressly permits redesignation, and merits and appellate review remain open. Organizations should consider that the injunction is preliminary and that redesignation and further review remain possible.

The more consequential finding is the court's irreparable-harm analysis: customers and suppliers cancelled contracts and moved programs to competitors within weeks of the June designation. The court cited evidence that customers and suppliers reportedly altered commercial relationships following the designation. Accordingly, organizations may wish to consider earlier compliance and supply-chain milestones in addition to the BIOSECURE implementation timeline.

Why the Injunction Does Not Close the BIOSECURE Door

- *The Act provides two routes to BCC status, and only one is affected*. The first requires 1260H listing, plus an OMB finding of involvement in biotechnology equipment or services. The second, at sec. 851(f)(2)(B), requires only that OMB find an entity is controlled by or acts for a foreign adversary government, is to any extent involved in biotechnology equipment or services, and poses a national security risk under the statutory criteria. OMB is not a party to this litigation, and the second pathway never references the 1260H list, so it remains fully available notwithstanding the injunction. The relevant designation is placement on the OMB list of biotechnology companies of concern, and the

December timing is statutory rather than discretionary: Sec. 851 directs OMB to publish its initial BCC list within one year of enactment, i.e., by Dec. 18, 2026. OMB could therefore name WuXi AppTec to that first list on the second pathway alone, and a designation made on that basis would carry the same consequences as one predicated on 1260H listing — federal agencies could not procure the company's biotechnology equipment or services, and could not contract with, or extend grant or loan funds to, entities that use them in federally funded performance.

- *Designation is contestable but not quickly reversible*. A designated entity may petition OMB for removal, and the Director must respond within 90 days; OMB-pathway designations also carry a notice-and-review process before a final determination. If the composition of the initial list remains contested and shifts after publication, that would argue for planning against a range of outcomes rather than a single expected list.

Potential Implications of the December 2025 Cliff

- *The immediate cliff*. BGI and MGI entities were on the 1260H list on Dec. 18, 2025. If OMB finds they meet the biotechnology-involvement threshold, existing contracts with them fall entirely outside the five-year legacy-contract protection — the Act's rule of construction, under which an agency may continue to obtain a designated company's biotechnology equipment or services under a contract or agreement entered into before the prohibitions take effect, for a further five years from that effective date. Sequencing instruments, reagents, consumables, and associated data-analysis services tied to these entities may face different grandfathering treatment and may warrant earlier review.
- *The full runway*. WuXi AppTec, Complete Genomics, and Novogene were added on June 8, 2026. If designated, their pre-effective-date contracts receive five years from the FAR revision as to that entity, stretching potentially into the early 2030s. CRDMO transition can therefore be sequenced behind genomics-equipment transition — that is, qualifying replacement suppliers for the sequencing instruments, reagents, consumables, and associated data-analysis services currently sourced from the BGI and MGI entities described above — where capital and qualified capacity are constrained.
- *Relief around the edges is narrow*. A safe harbor applies to equipment or services that were formerly, but no longer, produced by a BCC. However, the safe harbor does not cover ongoing service, software, or firmware support. Exceptions reach certain intelligence activities, overseas healthcare, publicly available multiomic data, declared public health emergencies, and Medicaid and Medicare Part B drug payments via Federal Supply Schedules. The agency-head waiver requires OMB Director approval and congressional notification, which may present practical challenges for organizations considering reliance on a waiver.

Key Milestones and the Impact Schedule

The Act uses a cascading series of not-to-exceed periods rather than a single effective date, and the operative date depends on the designation pathway. One planning approach is to assume that agencies use the full periods provided by statute. The schedule below also includes the nearer deadlines that bind independently of BIOSECURE implementation.

Date (Outer Limit)	Event	Strategic Impact
Jun. 30, 2026 (in effect)	Sec. 805, FY24 NDAA — entity prohibition	The Department may not enter into, renew, or extend contracts directly with a 1260H-listed entity or an entity under its control.

Date (Outer Limit)	Event	Strategic Impact
Dec. 18, 2026	OMB publishes the initial BCC list, as Sec. 851 of the BIOSECURE Act requires within one year of the Act's Dec. 18, 2025, enactment	Publication of the list may affect procurement, diligence, and disclosure considerations.
March 13, 2027	Treasury final COINS Act regulations	The Comprehensive Outbound Investment National Security Act of 2025 (COINS Act), enacted as part of the same FY26 NDAA, codifies and expands the U.S. outbound investment security program — which restricts U.S. investment into designated technology sectors in countries of concern — and directs Treasury to issue implementing regulations within 450 days. Treasury may add biotechnology as a covered sector by rule, bypassing the need for new legislation.
By June 2027	OMB implementing guidance (180 days after the list)	First formal agency guidance regarding application of the prohibitions.
June 30, 2027	**Sec. 805 — goods and services prohibition**	**Extends to contracts incorporating a listed entity's goods or services anywhere in the supply chain — the first true flow-down duty, and it lands before BIOSECURE.**
By June 2028	FAR Council revises the FAR, triggering the effective dates	Prohibitions attach 60 days later (1260H pathway) and 90 days later (OMB pathway) — c. August–September 2028.
c. June 2033	End of five-year rule of construction	Legacy contracts protected until this point — except those with entities on the 1260H list as of Dec. 18, 2025, which get no runway at all.

Actions to Consider Before the December 2026 List

- *Legal, deal structuring, and compliance*. Prohibitions attach only where BCC equipment or services are used in performance of a federal contract, grant, or loan, and there is no carve-out for research or preclinical activity — so the question is not whether you use a Chinese CRDMO but whether that use sits within a federally funded scope of work. Because liability turns on what a contractor knows at any supply-chain tier, federal contractors and grant recipients should consider adopting a written procedure that escalates supplier information from scientific and procurement functions to a documented decision point. Companies with public reporting obligations should also consider confirming that SEC risk-factor language rests on the same mapping. Pair standard BCC and 1260H representations with designation-contingent termination or substitution rights, notice obligations, and an express allocation of transition and technology-transfer costs.
- *Supply chain, and CMC considerations*. Any portfolio touching Department work should evaluate tier-2 and tier-3 identification against the 1260H list to preempt the second phase of the Sec. 805 prohibition, which takes effect June 30, 2027. The phase now in force bars the Department only from contracting directly with a 1260H-listed entity or an entity it controls; the June 2027 phase extends the bar to any contract for goods or services that incorporate a listed entity's goods or services anywhere in

the supply chain. That is the flow-down duty: it reaches sub-tier suppliers a prime contractor may never have contracted with directly, and it obliges the contractor to know who they are. Because biologics technology transfer runs 12 to 24 months, publication of the OMB list in December 2026 will convert latent demand into simultaneous demand for a finite pool of qualified capacity, on terms that will not favor late movers. The under-appreciated constraint is regulatory rather than commercial: a manufacturing site change proceeds through a prior approval supplement, and initiating one against a pending application can extend the review clock. For assets approaching a Prescription Drug User Fee Act date or a late-cycle review meeting, the transition decision is a scheduling decision — sponsors should consider modeling that transition against the application calendar before the list publishes, not after.

- *Cross-border transactions and the widening perimeter*. BIOSECURE is one instrument within a converging set of authorities. The Biotech Investment National Security Act, introduced in the House on June 2, 2026 (H.R. 9102) and the Senate on Aug. 6, 2026, would add biotechnology as a covered sector under the COINS Act — which today reaches outbound U.S. investment in semiconductors and microelectronics, artificial intelligence, quantum information technologies, high-performance computing, and hypersonic systems, but not biotechnology — and extend review to in- and out-licensing structures and joint ventures sitting entirely outside the federal procurement nexus; Treasury may reach a similar result sooner by rulemaking. Running the other way, PRC State Council Order No. 837, effective July 1, 2026, applies export controls and security review across the life cycle of Chinese outbound investment, constraining know-how transfer from the counterparty's side. Companies and investors with pending or contemplated cross-border transactions should consider stress-testing transactions running past mid-2027 against both expansions at once while monitoring potential future legislative and regulatory developments.

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