

The BIOSECURE Act and the contract manufacturers

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The most concrete American measure directed at Chinese biotechnology concerns contract research and manufacturing. The BIOSECURE Act, first introduced in Congress in 2024, aimed to prohibit federal agencies from contracting with, and federal funds from going to, companies that use "biotechnology companies of concern" in their supply chains. Earlier versions named specific Chinese companies, among them large contract research and manufacturing organisations.¹ After failing to pass in 2024, a revised version without named companies was included in the National Defense Authorization Act for fiscal year 2026 and became law in December 2025. Under that version the designation of companies of concern is left to an administrative process, and transitional periods apply to existing contracts.²

For the contract development and manufacturing organisations of the Basel region, the act has created an opportunity. Lonza, whose business model Part G, Chapters I and II described, and Bachem, a leading manufacturer of peptides and oligonucleotides, compete with Chinese providers for the production of biologics, peptides and other complex molecules.³ American and European customers that want to reduce their exposure to Chinese suppliers may shift orders to Western providers, which strengthens the order books of Lonza and Bachem and justifies investment in capacity. Lonza's acquisition of a large biologics site in Vacaville, California, from Roche in 2024 placed it well to serve customers that require American production.⁴

The opportunity carries compliance obligations. Contract manufacturers must be able to demonstrate to their customers that their own supply chains do not depend on companies of concern, which requires due diligence on suppliers of equipment, reagents, software and services. Customers in turn will ask for representations and warranties in supply

agreements, a task complicated by a designation process under American law that creates a moving target. Swiss companies are not bound by American federal procurement law as such. They are nevertheless affected through their customers, many of whom depend on federal contracts or reimbursement, and through the reputational effects of association with designated entities. The BIOSECURE regime therefore adds a further layer to the compliance agenda described in Part G, Chapter V.

1 Notes

1. BIOSECURE Act, H.R. 8333 (118th Congress), passed by the House of Representatives in September 2024 but not enacted in that Congress; on the companies named in earlier versions, see the congressional record. To be verified. ↩
2. National Defense Authorization Act for Fiscal Year 2026, including the BIOSECURE provisions, signed into law in December 2025; see e.g. Baker McKenzie, "United States: The BIOSECURE Act Becomes Law", January 2026, and Akin Gump, "BIOSECURE Act Becomes Law". Details of designation procedure and transition periods to be verified. ↩
3. On the business models of Lonza and Bachem, see Part G, Chapter I, sections "Lonza: from Visp to the contract manufacturing model" and "The second tier", and Part G, Chapter II, section "Lonza: capital expenditure and portfolio pruning". To be verified. ↩
4. Acquisition by Lonza of the Genentech biologics manufacturing site in Vacaville, California, from Roche, announced in March 2024 for about USD 1.2 billion and completed in 2024. Figures to be verified. ↩

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