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New BIS controls added for biotech software; could trigger CFIUS filing

Last week, the Bureau of Industry and Security at Commerce published a final rule that included new controls on gene-editing software and related technologies. As usual, we're providing all the details in bulleted format so it's easy to digest, reference and understand; we're also covering below how the new rule overlaps with CFIUS.

WHAT

In short, the new rule adds controls on certain life-sciences software and tools that theoretically can be used to create biological agents and biological weapons. The new controls apply to certain software tools that are:

1. Designed for nucleic acid assemblers and synthesizers; and
2. Capable of designing and building functional genetic elements from digital sequence data

WHY

The new rule was proposed by the BIS last year. It aligns the U.S export-control regime with a similar move made by the Australia Group (more about them below), which updated one of their "Common Control Lists" focusing on dual-use biological equipment.

The software in question is typically used by the life sciences industry for medical and healthcare purposes; the BIS and the AG determined that it can be misused for biological weapons as well.

Specifically, both groups are concerned with software and systems that can generate "pathogens and toxins without the need to acquire controlled genetic elements and organisms (i.e., they are capable of being used in the production of biological agents)."

Judith Alison Lee, a partner at Gibson Dunn & Crutcher, notes that the new rule "does not affect the scope of CFIUS jurisdiction directly," but could trigger potential mandatory CFIUS filings.

WHO

A little bit on the agency and consortium mentioned above:

The first is the Bureau of Industry and Security at the U.S. Commerce

Department. Most Foreign Investment Watch readers know this, but the BIS is primarily responsible for ensuring effective export control and treaty compliance, which helps advance national security, foreign policy, and economic objectives.

As such, the BIS — among other things — regulates the export of sensitive goods and dual-use technologies, and enforces export controls, often cooperating with other countries (which is where the second group comes in, below). By the way, we recently covered the nomination of Alan Estevez to the role of Under Secretary of Commerce for Industry and Security at Commerce; the individual in that role acts as the leader of the BIS.

The second group of relevance here is the Australia Group, or the "AG," which is a consortium of countries looking to harmonize export controls with the goal of limiting the spread of chemical and biological weapons. The AG, which dates back to 1985, includes 40+ countries such as the U.S., Canada, Germany, the EU, the UK and others. The AG has ramped up its activity recently, and held a virtual session in May to update their control lists.

[As an aside — and this may be too "inside baseball" — there's a bit of a chicken-and-egg argument here about "which came first, the BIS proposal or the AG control update?" The official rule in the Federal Register noted it was published "to implement the decision made at the Australia Group," but in fact the BIS proposal last year pre-dated the Australia Group's move.]

Meredith Rathbone of Steptoe & Johnson agrees that biotech companies and their investors will need to be more mindful of the potential for a mandatory CFIUS review of their transactions.

WHEN

The rule is effective immediately; technically it became effective Oct. 5. 2021.

DETAILS

The BIS has amended the Commerce Control List, adding two new classification numbers (known as Export Control Classification Numbers or "ECCNs") and imposing export-license requirements.

The rule impacts "software" (the quotes are theirs) for certain nucleic acid assemblers and synthesizers, and is largely aimed at software for those assemblers that is capable of "designing and building functional genetic elements from digital sequence data."

Also impacted are technologies involved in the development of said software and assemblers, above. More detailed descriptions are available in the actual rule.

LINK TO CFIUS

The new controls could impact CFIUS reviews of biotech or technology companies that have the capability to design, build or edit genetic elements from digital sequence data.

That's because the CFIUS mandate is intrinsically linked to the export control regime. As we reported back in August 2020, the BIS is responsible for identifying "emerging" and "foundational" technologies; those technologies are not only subject to enhanced export controls, but they are now considered "critical technologies" by CFIUS.

As such, these two new export-control classification numbers will fall under CFIUS's purview, which means related

biotech and software companies will need to account for CFIUS risks when considering certain foreign investments.

"This rule does not affect the scope of CFIUS jurisdiction directly," clarifies Judith Alison Lee, a partner at Gibson Dunn & Crutcher. "However," she adds, "this rule expands the scope of potential mandatory CFIUS filings because it adds additional license requirements for the export of software or technology for nucleic acid assemblers/synthesizers."

Meredith Rathbone, a partner at Steptoe & Johnson, agrees. "Biotech companies and their investors will need to be even more mindful of the potential for a mandatory CFIUS review of their transactions." She adds that there will likely be more instances in which CFIUS review of an investment is required, even where the non-U.S. investor is not acquiring a controlling interest in the U.S. company.

Andrew Shoyer at Sidley Austin emphasizes that point. "The technology is now 'critical technology' under FIRRMA," he says, "so going forward, even minority investments by foreign investors in U.S. companies that develop, design, test, or produce this software could trigger a mandatory CFIUS filing, depending on the rights the investor obtains and whether a license would be required to export the technology to the investor's home country.

Rathbone also notes that, even if the parties conclude that a CFIUS filing is not mandatory, "it would be a good idea" to consider whether a voluntary CFIUS filing

Andrew Shoyer, co-leader of the Global Arbitration, Trade and Advocacy practice at Sidley Austin.

is warranted given the increased U.S. government focus on this area. "The last thing a biotech company or its new investors want is to deal with is unwinding what had once seemed like a promising transaction."

Importantly, Shoyer at Sidley says companies should expect more controls. "Cutting-edge biotech is very much in play for export control purposes," he says, noting that the sector is one of 14 emerging technologies for which Commerce said it would seek to impose new controls. "Commerce is under constant pressure from Congress to move the process forward," Shoyer says. "But Commerce wants to avoid creating unilateral U.S. controls, as they would hurt U.S. tech firms without meaningfully constraining access to the technology." As a result, he says, the new BIS rule is a good illustration of what companies should expect in the future.

MORE INFORMATION

Changes to the Commerce Control List, with expanded controls on certain biological equipment software, is available from the always easy-to-read Federal Register (that was a joke, people).

Also available is the Australia Group's Common Control Lists, including the one on dual-use biological equipment referenced above (had not been updated by press time).

More information on the Australia Group can be found on their official website.

The best contact if you have questions about the BIS rule is Dr. Wesley Johnson, in the Chemical and Biological Controls Division of the Bureau of Industry and Security; Dr. Johnson can be reached

at Wesley.Johnson@bis.doc.gov or (202) 482-0091.

Judith Alison Lee at Gibson Dunn & Crutcher, quoted above, can be reached at jalee@gibsondunn.com or (202) 887-3591.

Meredith Rathbone at Steptoe and Johnson, also quoted above, can be reached at mrathbone@steptoe.comor (202) 429-6437.

And Andrew Shoyer at Sidley Austin can be reached at ashoyer@sidley.com or (202) 736-8326.