

BIS imposes new emerging technology controls on certain software and related technology designed for nucleic acid assemblers and synthesizers

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On October 5, 2021, the Bureau of Industry and Security (“BIS”) amended the Export Administration Regulations (“EAR”) to control certain nucleic acid assembler and synthesizer software capable of designing and building functional genetic elements from digital sequence data. BIS also imposed controls on technology for the development of software subject to the new controls. These changes had immediate effect.

As a result of the change, software – whether source or object code – with the specified capabilities is classified under new Export Control Classification Number (“ECCN”) 2D352, which is subject to control for chemical/biological weapons (CB) reasons. Development technology for software classified 2D352 is now controlled under ECCN 2E001.

BIS had previously identified nucleic acid assembler / synthesizer software for evaluation as an “emerging technology” under the Export Control Reform Act of 2018 (“ECRA”), and had proposed a rule to control such software in November 2020. Nucleic acid assemblers / synthesizers themselves have been subject to control under ECCN 2B352.j. However, software designed for these items was not subject to controls, which presented a risk that the software could be exploited for chemical and biological weapons uses.

As a result of the change, software that is designed for nucleic acid assemblers controlled under 2B352.j and that is capable of designing and building functional genetic elements from digital sequence data is now controlled under ECCN 2D352. Technology for the development of such software is also controlled under 2E001. Such software and technology will require an export license to any destination listed in the Commerce Country Chart with an “X” under CB Column 2. Companies affected by these new controls will also need to be mindful of deemed export issues relating to newly-controlled technology.

Imposing export controls on emerging technologies is a key feature of ECRA, and is an important component of the United States’ “whole of government” approach to address national security risks. Indeed, the new export controls on software and technology for nucleic acid assemblers / synthesizers will impact transactions that do not necessarily involve exports at all. Such software and technology now fall within the definition of “critical technology” under the regulations of the Committee on Foreign Investment in the United States (“CFIUS”), which will subject many U.S. businesses that produce, design, develop, or test such software to enhanced CFIUS scrutiny if they accept certain foreign investments. Mandatory CFIUS declarations may even be required pre-closing for foreign investment in such U.S. businesses, depending on the nationality of the investor or investors.

Dentons’ federal regulatory and compliance team continues to monitor developments in export controls, sanctions, and CFIUS regulations. Please reach out to the authors of this article or your regular Dentons contacts if you would like to discuss this or other relevant regulatory developments.

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