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BIS Proposes Designating Automated Peptide Synthesizers as a Section 1758 Technology

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On September 13, 2022, the U.S. Commerce Department's Bureau of Industry and Security (BIS) published in the Federal Register (87 FR 55930) an Advance Notice of Proposed Rulemaking (ANPRM) and request for comments regarding certain instruments for the automated synthesis of peptides (automated peptide synthesizers). This proposed rule seeks to identify such automated peptide synthesizers as emerging and foundational technologies pursuant to section 1758 of the Export Control Reform Act of 2018 (ECRA) ("Section 1758 Technologies").

Section 1758 Technologies

Under the proposed rule, BIS identified automated peptide synthesizers for evaluation as Section 1758 Technologies. Section 1758 of ECRA requires BIS to establish appropriate export, reexport, or transfer (in-country) controls on "emerging and foundational technologies" essential to national security.

Automated Peptide Synthesizers

BIS seeks to designate automated peptide synthesizers as a Section 1758 Technology because they pose an increased risk to the proliferation of biological weapons. Peptides and polypeptides are polymeric chains of amino acids, linked together by peptide bonds. Proteins are three-dimensional (3D) macromolecules composed of one or more folded large chains of polypeptides. Advances in peptide synthesis technology and instruments enable more efficient production of peptides and proteins with a length of more than 100 amino acids. Most protein toxins that are controlled under Export Control Classification Number (ECCN) 1C351 on the Commerce Control List (CCL) are over 100 amino acids in length and have an average length of 300 amino acids (with the exception of conotoxins, which range between 10-100 amino acids). The technology and instrumentation for certain peptide synthesis could be used to produce controlled toxins for biological weapons purposes.

Public Comment Period

1. BIS is seeking comments from the public on this proposed rule. Specifically, BIS is interested in comments on the following questions: What is the current state of development of automated peptide synthesizers in the United States, including those having primarily

academic or commercial applications, and how does this compare with that of other countries? If possible, identify supporting, publicly available studies.

2. What is the current availability and predominate application(s) of automated peptide synthesizers in the United States and how does this compare with that of other countries?

3. To what extent are custom peptide synthesis services available in the United States and other countries, and would the availability of such services (particularly for academic or commercial applications) likely impact domestic or foreign demand for automated peptide synthesizers?

4. To what extent are current or near-term developments in peptide synthesis technology expected to address the challenges of peptide length, sequence fidelity, and protein folding (e.g., are efforts currently underway to integrate protein folding into the automation process)?

5. To what extent would the establishment of Section 1758 technology export controls on automated peptide synthesizer instruments, and related “software” and “technology,” impact U.S. technological leadership in this field (e.g., within the academic or commercial spheres) and would this impact be distinctly different if controls were placed primarily on “software” as opposed to hardware, or vice versa?

6. To what extent would the imposition of Section 1758 technology export controls on automated peptide synthesizer instruments, and related “software” and “technology,” likely be effective in terms of limiting the proliferation of these items abroad (including the potential use of such items to produce controlled toxins for biological weapons purposes)?

7. To what extent has the increased availability of lower cost coupling reagents, together with recent advances in automated peptide synthesizers and related technology, overcome economic or technological factors that previously might have limited the availability and use of this technology, abroad?

8. To what extent should Section 1758 technology export controls on peptide synthesizer technology be implemented multilaterally (rather than unilaterally), in the interest of increasing their effectiveness and minimizing their impact on U.S. industry?

Parties wishing to submit a comment may do so either through the Federal eRulemaking Portal at http://www.regulations.gov, or by submitting an email to PublicComments@bis.doc.gov. The docket number for this proposed rule is BIS-2022-0023 or RIN 0694-AI84. Comments are due no later than October 28, 2022.

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