

FOR IMMEDIATE RELEASE September 12, 2022 www.bis.doc.gov BUREAU OF INDUSTRY AND SECURITY Office of Congressional and Public Affairs <u>OCPA@bis.doc.gov</u>

Commerce Furthers Work to Identify Emerging Technologies with National Security Implications

Releases Proposal to Control Automated Peptide Synthesizers and Seeks Public Comment

WASHINGTON, D.C. – Today, the Commerce Department's Bureau of Industry and Security (BIS) has issued an advance notice of proposed rulemaking (ANPRM, or notice) seeking public comments on the potential uses of automated synthesis of peptides (automated peptide synthesizers). The notice seeks to assess whether such technology could provide the United States or our adversaries with a qualitative military or intelligence advantage, and requests public comments on how to ensure that the scope of any controls that may be imposed on this technology would be effective and minimize the potential impact on legitimate commercial or scientific applications.

"Today's advance notice of proposed rulemaking reflects the Bureau of Industry and Security's thoughtful, evidence-based approach to our Congressional mandate to identify and implement appropriate controls on technologies essential to our national security," **said Under Secretary of Commerce for Industry and Security Alan Estevez.** "Accordingly, this notice ensures that BIS will assess automated peptide synthesizers for appropriate controls to address the risk of the proliferation of controlled toxins for biological weapons."

"We have known how to synthesize peptide bonds for over 100 years, but in recent decades advances in our technologies and methods have made it a faster, easier, and more widely used process," **said Assistant Secretary of Commerce for Export Administration Thea D. Rozman Kendler.** "While there are many legitimate uses, the advancement in automated synthesizer technologies also make it easier to produce the kinds of toxins we already control due to their national security concerns. We welcome and encourage the public to provide comments on this important proposal."

The text of the ANPRM released today is available on the Federal Register's website at this <u>link</u>. The rule will formally publish in the Federal Register on September 13. Comments to this ANPRM are due to BIS by no later than 45 days after the date of publication, which is October 28, 2022.

Additional Background:

Section 1758 of the Export Control Reform Act (ECRA) directs the Secretary of Commerce to establish appropriate controls on the export, reexport or transfer (in-country) of emerging and foundational technologies ("Section 1758 technologies") identified by the Secretary pursuant to the process outlined in the law, including through a notice and comment period.

As part of this process, the Secretary must consider the potential end-uses and end-users of Section 1758 technologies, and the countries to which exports from the United States are restricted (e.g., embargoed countries). While the Secretary has discretion to set the level of export controls, at a minimum a license must be required for the export of such technologies to countries subject to a U.S. embargo, including those countries subject to an arms embargo.

Instruments for the automated synthesis of peptides (automated peptide synthesizers) have been identified by BIS for evaluation according to the criteria in Section 1758. BIS assesses that, absent the imposition of additional controls on the export, reexport or transfer (in-country) of certain peptide synthesis technology and instrumentation (e.g., automated peptide synthesizers), there would be an increased risk that such technology and instrumentation could be used to produce controlled toxins for biological weapons purposes.

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