Control(s)	*Country chart (see Supp. No. 1 to part 738)*
NS applies to entire entry except 7A611.y.	NS Column 1.
MT applies to commodities in 7A611.a that meet or exceed the parameters in 7A103.b or .c.	MT Column 1.
RS applies to entire entry except 7A611.y.	RS Column 1.
RS applies to 7A611.y.	China, Russia, or Venezuela (see § 742.6(a)(7)).
AT applies to entire entry.	AT Column 1.
UN applies to entire entry except 7A611.y.	See § 746.1(b) for UN controls.

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: $1500
GBS: N/A

Special Conditions for STA

STA: Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any item in 7A611.

List of Items Controlled

Related Controls: (1) Military fire control, laser, imaging, and guidance equipment that are enumerated in USML Category XII, and technical data (including software) directly related thereto, are subject to the ITAR. (2) See Related Controls in ECCNs 0A504, 2A984, 6A002, 6A003, 6A004, 6A005, 6A007, 6A008, 6A107, 7A001, 7A002, 7A003, 7A005, 7A101, 7A102, and 7A103. (3) See ECCN 3A611 and USML Category XI for controls on countermeasure equipment. (4) See ECCN 0A919 for foreign-made ''military commodities'' that incorporate more than a *de minimis* amount of U.S. origin ''600 series'' controlled content.

Related Definitions: N/A

Items:

a. Guidance or navigation systems, not elsewhere specified on the USML, that are ''specially designed'' for a defense article on the USML or for a 600 series item.

b. to w. [Reserved]

x. ''Parts,'' ''components,'' ''accessories,'' and ''attachments,'' including accelerometers, gyros, angular rate sensors, gravity meters (gravimeters), and inertial measurement units (IMUs), that are ''specially designed'' for defense articles controlled by USML Category XII or items controlled by 7A611, and that are NOT:

x.1. Enumerated or controlled in the USML or elsewhere within ECCN 7A611;

x.2. Described in ECCNs 6A007, 6A107, 7A001, 7A002, 7A003, 7A101, 7A102 or 7A103; or

x.3. Elsewhere specified in ECCN 7A611.y or 3A611.y.

y. Specific ''parts,'' ''components,'' ''accessories,'' and ''attachments'' ''specially designed'' for a commodity subject to control in this ECCN or a defense article in Category XII and not elsewhere specified on the USML or in the CCL, as follows, and ''parts,'' ''components,'' ''accessories,'' and ''attachments'' ''specially designed'' therefor:

y.1 [Reserved]

* * * * *

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2021–20649 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 742 and 774

[Docket No. 210928–0198]

RIN 0694–AI08

Commerce Control List: Expansion of Controls on Certain Biological Equipment ''Software''

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) publishes this final rule to amend the Export Administration Regulations (EAR) to implement the decision made at the Australia Group (AG) Virtual Implementation Meeting session held in May 2021, and later adopted pursuant to the AG's silence procedure. This decision updated the AG Common Control List for dual-use biological equipment by adding controls on nucleic acid assembler and synthesizer ''software'' that is capable of designing and building functional genetic elements from digital sequence data. Prior to this AG decision, BIS, consistent with the interagency process described in the Export Control Reform Act of 2018 (ECRA), identified this ''software'' as a technology to be evaluated as an emerging technology. The decision by BIS to amend the CCL to include this ''software'' complies with the requirements of ECRA and also reflects the decision of the AG to add it to the regime's Common Control List, thereby making exports of this ''software'' subject to multilateral control through the implementation of these changes by individual AG participating countries (including the United States).

DATES: This rule is effective October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Wesley Johnson, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482–0091, Email: *Wesley.Johnson@bis.doc.gov.*

SUPPLEMENTARY INFORMATION: The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the decision made at the Australia Group (AG) Virtual Implementation Meeting session held in May 2021, and subsequently adopted pursuant to the AG silence procedure (the AG silence procedure provides for the adoption of a measure, subsequent to its provisional acceptance at an AG plenary or intersessional meeting, provided that no participating country submits an objection on or before a specified date). The AG is a multilateral forum consisting of 42 participating countries and the European Union. These participants maintain export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

Addition of New Export Control Classification Number (ECCN) 2D352—''Software'' for Nucleic Acid Assemblers/Synthesizers

This final rule amends the Commerce Control List (CCL), in Supplement No. 1 to part 774 of the EAR, to add a new ECCN 2D352 to reflect a decision made at the May 2021 Virtual Implementation Meeting session to modify the AG biological equipment list to add controls on ''software'' that is: (1) Designed for nucleic acid assemblers and synthesizers described on this AG Common Control List; and (2) capable of designing and building functional genetic elements from digital sequence data. Specifically, new ECCN 2D352 controls ''software'' designed for nucleic acid assemblers and synthesizers controlled by ECCN 2B352.j that is capable of designing and building functional genetic elements from digital sequence data.

This ''software,'' as controlled under new ECCN 2D352, requires a license for chemical and biological weapons (CB) reasons and anti-terrorism (AT) reasons to the destinations indicated under CB Column 2 and AT Column 1, respectively, on the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR (also see the AT license requirements described in part 742 that apply to Iran, North Korea and Syria). A license also is required to certain

destinations in accordance with the embargoes and other special controls described in part 746 of the EAR.

ECCN 2E001 Amended To Include ''technology'' for New ECCN 2D352

In addition, this rule amends ECCN 2E001 (which controls, *inter alia,* ''technology'' for the ''development'' of the nucleic acid assemblers and synthesizers described in ECCN 2B352.j) to indicate that ''technology'' for the ''development'' of ''software'' controlled by new ECCN 2D352 is controlled by ECCN 2E001 for CB reasons and AT reasons to the destinations indicated under CB Column 2 and AT Column 1, respectively, on the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR. The CB control entry in the License Requirements table for ECCN 2E001 is amended to reflect this change. The heading of ECCN 2E001 does not need to be amended to reflect this change because the ECCN heading indicates that, with limited specified exceptions, this ECCN controls ''technology'' for the ''development'' of ''software'' listed under Category 2D of the CCL, which now includes new ECCN 2D352.

Conforming Amendments to § 742.2 (Proliferation of Chemical and Biological Weapons)

Consistent with the May 2021 AG decision described above, this final rule amends Section 742.2 of the EAR by revising paragraphs (a)(2)(viii) and (a)(2)(ix) to reflect the addition of ECCN 2D352 to the CCL and to indicate that ''technology'' for the ''development'' of ''software'' controlled by new ECCN 2D352 is controlled by ECCN 2E001. These changes were not included in a proposed rule that BIS published on November 6, 2020 (85 FR 71012), which is described in more detail, below. However, because they are merely conforming changes that cross reference the aforementioned amendments to the CCL, BIS is making the changes in this final rule.

Evaluation of Nucleic Acid Assembler/Synthesizer ''Software'' as an Emerging Technology

Prior to the addition of nucleic acid assembler/synthesizer ''software'' to the AG biological equipment list, BIS identified this ''software'' as a technology to be evaluated as an emerging technology, consistent with the interagency process described in Section 1758 of the Export Control Reform Act of 2018 (ECRA) (codified at 50 U.S.C. 4817). This identification was based on a finding that this ''software'' is capable of being used to operate nucleic acid assemblers and synthesizers controlled under ECCN 2B352 for the purpose of generating pathogens and toxins without the need to acquire controlled genetic elements and organisms. Consequently, the absence of export controls on this ''software'' could be exploited for biological weapons purposes.

Consistent with the emerging and foundational technologies notice and comment requirements in Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), BIS published a proposed rule on November 6, 2020 (85 FR 71012) (hereinafter, ''November 6 proposed rule''), to provide the public with notice and the opportunity to comment on adding new ECCN 2D352 to control ''software'' for the operation of nucleic acid assemblers and synthesizers described in ECCN 2B352.j that is capable of designing and building functional genetic elements from digital sequence data. The November 6 proposed rule also indicated that ''technology'' for the ''development'' of such ''software'' would be controlled under ECCN 2E001.

As stated above, the imposition of controls on this ''software'' by this final rule (under new ECCN 2D352) reflects a decision by the AG to add this ''software'' to its biological equipment control list. Consequently, this action by BIS also conforms with Section 1758(c) of ECRA, which specifies that ''the Secretary of State, in consultation with the Secretary [of Commerce] and the Secretary of Defense, and the heads of other Federal agencies, as appropriate, shall propose that any technology identified pursuant to Section 1758(a) of ECRA be added to the list of technologies controlled by the relevant multilateral export control regimes.''

Comments Submitted in Response to BIS's November 6 Proposed Rule

BIS received comments from four respondents in response to the publication of its November 6 proposed rule. The comments from these respondents, together with BIS's responses, are described below.

Comment: One respondent stated that BIS should not treat commodities and ''software'' as potential emerging technologies, because Section 1758 of ECRA, which provides the statutory standard for establishing new controls on emerging and foundational technologies, refers only to ''technology,'' as defined in Section 1742 of ECRA (codified at 50 U.S.C. 4801). The respondent noted that Section 1758 of ECRA makes no mention of commodities or ''software,'' which, together with ''technology,'' are included in the statutory definition of ''item.'' The respondent further observed that the term ''item'' is included in other sections of ECRA and that its absence from Section 1758 is given meaning by considering only ''technology'' as defined in Section 1742 of ECRA. The respondent also noted that this interpretation would be consistent with the EAR definition of ''technology,'' which does not include commodities or ''software.'' Consequently, the respondent recommended that BIS should follow this interpretation of the statute, as well as its own regulations regarding the definition of ''technology,'' by identifying only emerging ''technology'' and not related emerging commodities and ''software.''

BIS response: The terms ''technologies,'' ''emerging technologies'' and ''critical technologies'' are used in Section 1758 of ECRA (50 U.S.C. 4817) and Section 721(a)(6) of the Defense Production Act of 1950 (DPA), as amended (50 U.S.C. 4565(a)(6)), with the latter defining ''critical technologies'' to mean those described in 50 U.S.C. 4565(a)(6)(A)(i) through (vi). The DPA indicates that the term ''critical technologies'' includes by definition emerging and foundational technologies controlled pursuant to Section 1758 of ECRA, as well as ''items included on the Commerce Control List'' for multilateral reasons or for surreptitious listening or regional stability reasons. As the respondent noted, the term ''items'' includes ''commodities,'' ''software'' and ''technology.'' Consequently, the term ''technologies,'' as used within the context of these ECRA and DPA provisions, encompasses ''commodities,'' ''software'' and ''technology,'' and not ''technology'' only (*e.g.,* as that term is more narrowly defined in Section 1742 of ECRA). Furthermore, note that BIS's August 27, 2020 (85 FR 52934), advance notice of proposed rulemaking on the identification and review of controls for certain foundational technologies stated that the term ''technologies,'' as used in Section 1758 of ECRA, includes not only ''technology,'' but also ''commodities'' and ''software'' as those terms are used in the EAR.

Comment: One respondent observed that the ''capable of'' standard does not place sufficient emphasis upon the purpose for which an item is designed. Consequently, this standard might inadvertently control technology that is not designed to produce a controlled item, even when the ability of the technology to produce the controlled item is wholly unrelated to the primary

purpose of the technology. Furthermore, the respondent noted that an exporter could be unaware that a given technology is ''capable of'' performing a function for which the technology was not designed and for which it is not commonly used.

BIS response: The consensus of the interagency process followed in accordance with Section 4817 of ECRA was that emerging technology controls should apply to ''software'' designed for nucleic acid assemblers and synthesizers controlled by 2B352.j that is ''capable of'' designing and building functional genetic elements from digital sequence data. The scope of this control is also consistent with the decision made at the AG's May 2021 Virtual Implementation Meeting session to add this ''software'' to its ''Control List of Dual-Use Biological Equipment and Related Technology and Software.'' If the controls on this ''software'' applied only to ''software'' ''designed'' or ''specially designed'' for the purpose of generating pathogens and toxins without the need to acquire controlled genetic elements and organisms, the scope of the controls would have been far too narrow. Consequently, there would have been a significantly increased risk that certain ''software'' not captured by narrower controls could have been exploited for biological weapons purposes.

Comment: One respondent stated that the ''software'' controls proposed to be implemented in new ECCN 2D352, and all future emerging and foundational technology controls, should be implemented multilaterally, rather than unilaterally. The respondent noted that a multilateral approach to export controls would increase their effectiveness and minimize their impact on U.S. industry. Specifically, multilateral export controls are preferable to unilateral controls, because the former typically place U.S. industry on a more level playing field versus producers/suppliers in other countries.

BIS response: This final rule imposes controls on ''software'' designed for nucleic acid assemblers and synthesizers controlled by 2B352.j to reflect the decision made at the AG's May 2021 Virtual Implementation Meeting session to add such ''software'' to its ''Control List of Dual-Use Biological Equipment and Related Technology and Software.'' This action by BIS is in accordance with Section 4817(c) of ECRA, which specifies that ''the Secretary of State, in consultation with the Secretary [of Commerce] and the Secretary of Defense, and the heads of other Federal agencies, as appropriate, shall propose that any technology identified pursuant to Section 4817(a) of ECRA be added to the list of technologies controlled by the relevant multilateral export control regimes.''

Comment: One respondent recommended that BIS issue emerging and foundational technology controls as proposed rules and closely follow ECRA's statutory requirements and guidance. This would provide industry with the opportunity to provide formal comments to government officials so that the latter could address industry's questions and concerns. The respondent further noted that such consultations are critical to the effectiveness of regulations in achieving national security goals, without placing undue or unintended burdens on U.S. exports.

BIS response: Consistent with the emerging and foundational technologies notice and comment requirements in Section 4817(a)(2)(C) of ECRA, BIS published a proposed rule on November 6, 2020 (85 FR 71012), to provide the public with notice and the opportunity to comment on adding a new ECCN 2D352 to control ''software'' for the operation of nucleic acid assemblers and synthesizers described in ECCN 2B352.j that is capable of designing and building functional genetic elements from digital sequence data. As indicated above, BIS received comments from four respondents in response to the publication of its November 6 proposed rule. These comments are addressed by BIS in the preamble of this final rule.

Comment: One respondent expressed concern that the acquisition of the nucleic acid assembler and synthesizer ''software'' proposed for control under new ECCN 2D352 by BIS's November 6 proposed rule could be used to generate pathogens and toxins without the need to directly acquire controlled genetic elements and organisms. This respondent indicated that ''the capabilities of this ''software'' lower the bar for acquisition of controlled genetic elements and so represent an increase in the risk of proliferation of biological weapons-related technology.'' According to this respondent, automated benchtop synthesis devices could allow unskilled individuals to create DNA sequences that might be used to produce a biological weapon. This respondent also expressed a growing concern about the potential for active circumvention of ''software'' for the operation of nucleic acid assemblers and synthesizers. For example, ''software'' for operating benchtop nucleic acid synthesis devices could be written to incorporate biosecurity screening onboard the device. Consequently, if such ''software'' were easily acquired (*e.g.,* in the absence of export controls), these devices could be hacked to circumvent biosecurity screening, thereby enabling covert synthesis of otherwise controlled genetic elements. For this reason, these devices (and, in certain instances, their components and operating ''software'') should be subject to export controls. In this regard, the respondent indicated a preference for multilateral export controls (*e.g.,* the adoption of export controls by the Australia Group).

BIS Response: The views expressed by this respondent support, and expand upon, the rationale provided by BIS (both in its November 6 proposed rule and in this final rule) for the imposition of controls on this nucleic acid assembler/synthesizer ''software'' under new ECCN 2D352. In addition, as noted in response to other comments described in this final rule, the controls on this ''software'' reflect the decision made at the AG's May 2021 Virtual Implementation Meeting session and, consequently, are being imposed multilaterally by all AG participating countries (including the United States).

Comment: One respondent expressed concern that the establishment by BIS of more restrictive controls on ''software'' for the operation of certain automated nucleic acid assemblers and synthesizers could damage trade and collaboration in this field with certain U.S. allies and thereby decrease the United States' global competitiveness in this field. Consequently, this respondent stated that any controls that are placed on such ''software'' should not impair the ability of the United States and its allies to trade in intermediate goods or to collaborate on R&D, both of which are crucial to maintaining their shared advantages vis-à-vis other foreign competitors. In this regard, the respondent noted that the methods for manipulating, growing, recovering, concentrating, stabilizing, and testing biological materials for use in weapons employ many of the same materials and equipment used to produce vaccines, pharmaceuticals, and a wide variety of food products.

BIS response: As indicated above, new ECCN 2D352 controls ''software'' designed for nucleic acid assemblers and synthesizers controlled by 2B352.j, consistent with the decision made at the AG's May 2021 Virtual Implementation Meeting session to add such ''software'' to its ''Control List of Dual-Use Biological Equipment and Related Technology and Software.'' This ''software,'' as controlled under new ECCN 2D352, requires a license for CB reasons and AT reasons to the destinations indicated under CB

Column 2 and AT Column 1, respectively, on the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR. Consequently, this ''software'' generally does not require a license for export, reexport or transfer (in-country) to destinations located in AG-participating countries. That being the case, the controls that apply to this ''software'' under new ECCN 2D352 should not impair the ability of the United States to trade in intermediate goods with most of its allies or to collaborate on R&D with such countries.

Comment: One respondent asserted that the nucleic acid assembler and synthesizer ''software'' proposed for control under new ECCN 2D352 by BIS's November 6 proposed rule is currently subject to the controls described in Category XIV (m) of the United States Munitions List (USML) (22 CFR 121.1), as well as the controls described in USML Category XIV(f)(8). Specifically, this respondent stated that such ''software'' involves technical data directly related to the defense articles enumerated in paragraphs (a) through (l) and (n) of USML Category XIV and that, as such, it is subject to the export licensing jurisdiction of the Directorate of Defense Trade Controls, U.S. Department of State, under the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120–130). Furthermore, the respondent asserted that such ''software'' is also restricted per USML Category XIV(f)(8)(ii) and (f)(8)(iii), which apply to any part, component, accessory, attachment, equipment, or system that is either manufactured using classified production data or being developed using classified information.

BIS Response: The ''software'' that this final rule controls under new ECCN 2D352 on the CCL is dual-use ''software'' that, as noted above, was added to the AG ''Control List of Dual-Use Biological Equipment and Related Technology and Software'' following a decision made at the AG's May 2021 Virtual Implementation Meeting session. As indicated in its title, all of the items included on this AG common control list are dual-use items—not military items. Consequently, the respondent is mistaken in claiming that such ''software'' is restricted per USML Category XIV(f)(8)(ii) and (f)(8)(iii), which apply to any part, component, accessory, attachment, equipment, or system that is either manufactured using classified production data or being developed using classified information. New ECCN 2D352 does not control ''software'' that was manufactured, or is in the process of being developed, using classified information subject to control under the ITAR or the regulations of any other U.S. Government agency.

Saving Clause

Shipments of items removed from eligibility for export, reexport or transfer (in-country) under a license exception or without a license (*i.e.,* under the designator ''NLR'') as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on October 5, 2021, pursuant to actual orders for export, reexport or transfer (in-country) to a foreign destination, may proceed to that destination under the previously applicable license exception or without a license (NLR) so long as they are exported, reexported or transferred (in-country) before December 6, 2021. Any such items not actually exported, reexported or transferred (in-country) before midnight, on December 6, 2021, require a license in accordance with this regulation.

''Deemed'' exports of ''technology'' and ''source code'' removed from eligibility for export under a license exception or without a license (under the designator ''NLR'') as a result of this regulatory action may continue to be made under the previously available license exception or without a license (NLR) before December 6, 2021. Beginning at midnight on December 6, 2021, such ''technology'' and ''source code'' may no longer be released, without a license, to a foreign national subject to the ''deemed'' export controls in the EAR when a license would be required to the home country of the foreign national in accordance with this regulation.

Export Control Reform Act of 2018

The Export Control Reform Act of 2018 (ECRA), as amended, codified at 50 U.S.C. 4801–4852, serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including: Potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits and of reducing costs, harmonizing rules, and promoting flexibility. This rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, this rule has been reviewed by the Office of Management and Budget.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule contains the following collections of information subject to the requirements of the PRA. These collections have been approved by OMB under control numbers 0694–0088 (Simplified Network Application Processing System) and 0694–0096 (Five Year Records Retention Period). The approved information collection under OMB control number 0694–0088 includes license applications, among other things, and carries a burden estimate of 29.6 minutes per manual or electronic submission for a total burden estimate of 31,833 hours. The approved information collection under OMB control number 0694–0096 includes recordkeeping requirements and carries a burden estimate of less than 1 minute per response for a total burden estimate of 248 hours.

Although this final rule makes important changes to the EAR for items controlled for chemical/biological (CB) reasons, BIS has determined that the overall increase in costs and burdens due to this rule will be minimal. Specifically, BIS expects the burden hours associated with these collections will increase, slightly, by 7 hours and 39 minutes (*i.e.,* 15 applications × 30.6 minutes per response) for a total estimated cost increase of $230 (*i.e.,* 7 hours and 39 minutes × $30 per hour). The $30 per hour cost estimate for OMB control number 0694–0088 is consistent with the salary data for export compliance specialists currently available through *glassdoor.com* (*glassdoor.com* estimates that an export compliance specialist makes $55,280 annually, which computes to roughly $26.58 per hour). This increase is not expected to exceed the existing estimates currently associated with OMB control numbers 0694–0088 and 0694–0096.

Written comments and recommendations for the information collections referenced above should be sent within 30 days of the publication of this final rule to: *www.reginfo.gov/public/do/PRAMain.* Find these

particular information collections by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. As stated in the preamble of this final rule, the amendments contained in this rule reflect a decision made at the Australia Group (AG) Virtual Implementation Meeting session held in May 2021, and later adopted pursuant to the AG's silence procedure. Therefore, pursuant to Section 1762 of the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. Sec. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation and delay in effective date.

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this final rule by the APA or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*), are not applicable.

Consistent with the emerging and foundational technologies notice and comment requirements in Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), BIS published a proposed rule on November 6, 2020 (85 FR 71012), to provide the public with notice and the opportunity to comment on its proposal to add a new ECCN 2D352 to the Commerce Control List (CCL), for the purpose of controlling ''software'' for certain nucleic acid synthesizers and assemblers for chemical/biological (CB) reasons. In addition, consistent with the Regulatory Flexibility Act, BIS prepared an initial regulatory flexibility analysis (IRFA) of the impact that the proposed rule, if adopted, would have on small businesses. The IRFA prepared by BIS requested comments on the analyses and conclusions contained therein, including the overall conclusion that the amendments in BIS's November 6 proposed rule would not have a significant economic impact on a substantial number of small entities.

BIS received comments from four respondents on its November 6 proposed rule—these comments and BIS's responses are summarized in the preamble of this final rule. BIS did not receive any comments in response to the analyses and conclusions contained in the IRFA for its November 6 proposed rule. Accordingly, no regulatory flexibility analysis is required for this final rule, and none has been prepared.

List of Subjects

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements, Terrorism.

For the reasons stated in the preamble, parts 742 and 774 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 742—CONTROL POLICY—CCL BASED CONTROLS

■ 1. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 12, 2020, 85 FR 72897 (November 13, 2020).

■ 2. Section 742.2 is amended by revising paragraphs (a)(2)(viii) and (ix) to read as follows:

§ 742.2 Proliferation of chemical and biological weapons.

(a) * * *

(2) * * *

(viii) Software identified in ECCN 2D351 or 2D352, as follows:

(A) Dedicated software identified in ECCN 2D351 for the ''use'' of toxic gas monitoring systems and their dedicated detecting components controlled by ECCN 2B351;

(B) Software designed for nucleic acid assemblers and synthesizers controlled by 2B352.j that is capable of designing and building functional genetic elements from digital sequence data.

(ix) Technology identified in ECCN 2E001 for the ''development'' of software controlled by ECCN 2D351 or 2D352.

* * * * *

PART 774—THE COMMERCE CONTROL LIST

■ 3. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 4. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2, add an entry for ECCN 2D352 immediately following ECCN 2D351, and revise ECCN 2E001 to read as follows:

Supplement No. 1 to Part 774—The Commerce Control List

* * * * *

2D352 ''Software'' designed for nucleic acid assemblers and synthesizers controlled by 2B352.j that is capable of designing and building functional genetic elements from digital sequence data.

License Requirements

Reason for Control: CB, AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
CB applies to entire entry.	CB Column 2.
AT applies to entire entry.	AT Column 1.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: N/A

List of Items Controlled

Related Controls: See ECCN 1E001 for ''development'' or ''production ''technology'' for genetic elements controlled by ECCN 1C353.

Related Definitions: See Section 772.1 of the EAR for the definitions of ''software,'' ''program,'' and ''microprogram.''

Items: The list of items controlled is contained in the ECCN heading.

* * * * *

2E001 ''Technology'' according to the General Technology Note for the ''development'' of equipment or ''software'' controlled by 2A (except 2A983, 2A984, 2A991, or 2A994), 2B (except 2B991, 2B993, 2B996, 2B997, 2B998, or 2B999), or 2D (except 2D983, 2D984, 2D991, 2D992, or 2D994).

License Requirements

Reason for Control: NS, MT, NP, CB, AT

Control(s)	*Country chart (see Supp. No. 1 to part 738)*
NS applies to ''technology'' for items controlled by 2A001, 2B001 to 2B009, 2D001 or 2D002.	NS Column 1.

Control(s)	Country chart (see Supp. No. 1 to part 738)
MT applies to ''technology'' for items controlled by 2B004, 2B009, 2B104, 2B105, 2B109, 2B116, 2B117, 2B119 to 2B122, 2D001, or 2D101 for MT reasons.	MT Column 1.
NP applies to ''technology'' for items controlled by 2A225, 2A226, 2B001, 2B004, 2B006, 2B007, 2B009, 2B104, 2B109, 2B116, 2B201, 2B204, 2B206, 2B207, 2B209, 2B225 to 2B233, 2D001, 2D002, 2D101, 2D201, or 2D202 for NP reasons.	NP Column 1.
NP applies to ''technology'' for items controlled by 2A290, 2A291, or 2D290 for NP reasons.	NP Column 2.
CB applies to ''technology'' for equipment controlled by 2B350 to 2B352, valves controlled by 2A226 having the characteristics of those controlled by 2B350.g, and software controlled by 2D351 or 2D352.	CB Column 2.
AT applies to entire entry.	AT Column 1.

Reporting Requirements

See § 743.1 of the EAR for reporting requirements for exports under License Exceptions, and Validated End-User authorizations.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: Yes, except N/A for MT

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit ''technology'' according to the General Technology Note for the ''development'' of ''software'' specified in the License Exception STA paragraph in the License Exception section of ECCN 2D001 or for the ''development'' of equipment as follows: ECCN 2B001 entire entry; or ''Numerically controlled'' or manual machine tools as specified in 2B003 to any of the destinations listed in Country Group A:6 (See Supplement No. 1 to part 740 of the EAR).

List of Items Controlled

Related Controls: See also 2E101, 2E201, and 2E301

Related Definitions: N/A

Items:

The list of items controlled is contained in the ECCN heading.

Note 1 to 2E001: ECCN 2E001 includes ''technology'' for the integration of probe systems into coordinate measurement machines specified by 2B006.a.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

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FEDERAL TRADE COMMISSION

16 CFR Part 1

Procedures for Submission of Rules Under the Horseracing Integrity and Safety Act

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') is issuing rules pursuant to the Horseracing Integrity and Safety Act (''Act'') to provide procedures for the Horseracing Integrity and Safety Authority (''Authority'') to submit its proposed rules and proposed rule modifications to the Commission for review.

DATES: These rule revisions are effective on October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Austin King (202–326–3166), Associate General Counsel for Rulemaking, Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The Horseracing Integrity & Safety Act,[1] enacted on December 27, 2020, directs the Federal Trade Commission to oversee the activities of a private, self-regulatory organization called the Horseracing Integrity and Safety Authority.

Section 4(a) of the Act, 15 U.S.C. 3053(a), requires the Authority to submit to the Commission, in accordance with such rules as the Commission may prescribe under Section 553 of Title 5, United States Code, any proposed rule, or proposed modification to a rule, of the Authority relating to: (1) The bylaws of the Authority; (2) a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods; (3) laboratory standards for accreditation and protocols; (4) standards for racing surface quality maintenance; (5) racetrack safety standards and protocols; (6) a program for injury and fatality data analysis; (7) a program of research and education on safety, performance, and anti-doping and medication control; (8) a description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons; (9) a schedule of civil sanctions for violations; (10) a process or procedures for disciplinary hearings; and (11) a formula or methodology for determining the assessments described in 15 U.S.C. 3052(f).

Accordingly, the Commission is adding a new subpart S to part 1 of its Rules of Practice, to provide procedures for the Authority to file its proposed rules and proposed modifications to existing rules with the Commission for review.

I. Section 1.140—Definitions

Section 1.140 defines relevant terms used in the proposed regulations. Each definition is based on a corresponding definition contained in Section 2 of the Act, 15 U.S.C. 3051, except as otherwise noted below.

The definition of ''HISA Guidance'' derives from Section 5(g)(1) of the Act, 15 U.S.C. 3054(g)(1), which states the Authority may issue guidance that ''sets forth an interpretation of an existing rule, standard, or procedure of the Authority'' or a ''policy or practice with respect to the administration or enforcement of such an existing rule, standard, or procedure'' and ''relates solely to the administration of the Authority; or any other matter, as specified by the Commission, by rule, consistent with the public interest and the purposes of this subsection [15 U.S.C. 3054(g)(1)].'' The Commission is adopting this definition and adding that HISA Guidance does not have the force of law, to distinguish HISA Guidance from a proposed modification to a rule.

The Act does not contain definitions for ''proposed rule'' or ''proposed modification.'' However, because these terms are used frequently throughout the regulations, the Commission is defining them for clarity. ''Proposed rule'' is defined as any rule proposed by the Authority pursuant to the Act. ''Proposed rule modification'' or ''modification'' is defined as any proposed modification to a rule, proposed rule change, or any interpretation or statement of policy or practice relating to an existing rule of the Authority that is not HISA Guidance and would have the force of law if

[1] 15 U.S.C. 3051 through 3060.