

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Part 774**

[Docket No. 200930–0261]

RIN 0694–AI08

Commerce Control List: Proposed Controls on “Software” for the Operation of Certain Automated Nucleic Acid Assemblers and Synthesizers; Request for Comments**AGENCY:** Bureau of Industry and Security, Commerce.**ACTION:** Proposed rule.

SUMMARY: The Bureau of Industry and Security (BIS), Department of Commerce, maintains controls on the export, reexport and transfer (in-country) of dual-use items and less sensitive military items through the Export Administration Regulations, including the Commerce Control List (CCL). Certain items that could be of potential concern for export control purposes are not yet listed on the CCL or controlled multilaterally, because they represent emerging technologies. Among these items is “software” for the operation of nucleic acid assemblers and synthesizers controlled under Export Control Classification Number (ECCN) 2B352 that is capable of designing and building functional genetic elements from digital sequence data.

BIS has determined 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. In an effort to address this concern, this rule proposes to amend the CCL by adding a new ECCN 2D352 to control such “software.” This rule also requests public comments to ensure that the scope of these proposed controls will be effective and appropriate (with respect to their potential impact on legitimate commercial or scientific applications).

DATES: Comments must be received by BIS no later than December 21, 2020.

ADDRESSES: You may submit comments, identified by docket number BIS–2020–0024 or RIN 0694–AI08, through any of the following:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

You can find this proposed rule by searching for its regulations.gov docket number, which is BIS–2020–0024.

- *Email:* PublicComments@bis.doc.gov. Include RIN 0694–AI08 in the subject line of the message.

All filers using the portal or email should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters “BC.” Any page containing business confidential information must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page. The corresponding non-confidential version of those comments must be clearly marked “PUBLIC.” The file name of the non-confidential version should begin with the character “P.” The “BC” and “P” should be followed by the name of the person or entity submitting the comments or rebuttal comments. Any submissions with file names that do not begin with a “P” or “BC” will be assumed to be public and will be made publicly available through <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: For questions on the chemical and biological weapons (CB) controls that would apply to the “software” proposed for control under ECCN 2D352, 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. For questions on the submission of comments in response to this proposed rule, contact Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:**Background**

As part of the National Defense Authorization Act (NDAA) for Fiscal Year 2019, Public Law 115–232, Congress enacted the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. 4801–4852. Section 1758 of ECRA (as codified under 50 U.S.C. 4817)

authorizes BIS to establish appropriate controls on the export, reexport or transfer (in-country) of emerging and foundational technologies. Pursuant to ECRA, on November 19, 2018, the Bureau of Industry and Security (BIS) published an advance notice of public rulemaking (November 19 ANPRM) (83 FR 58201). That ANPRM identified biotechnology as part of a representative list of technology categories concerning which BIS, through an interagency process, sought public comment to determine whether there are specific emerging technologies that are important to U.S. national security for which effective controls can be implemented. As indicated by the May 23, 2019 (84 FR 23886), final rule that imposed multilateral controls on a number of items, consistent with the 2018 Plenary changes to the Wassenaar Arrangement List of Dual-Use Goods and Technologies, emerging technologies can include “software” and commodities. (See, e.g., Export Control Classification Number 3D005, 84 FR 23894.)

Comments to the November 19 ANPRM on Biotechnology

The biotechnology-related comments submitted to BIS in response to its November 19 ANPRM did not specifically address the question of export controls on “software” for the operation of nucleic acid assemblers and synthesizers controlled under Export Control Classification Number (ECCN) 2B352.

Process To Identify and Control Emerging Technology

Under ECRA, emerging and foundational technologies are those essential to the national security of the United States, but not described in Section 721(a)(6)(A)(i)–(v) of the Defense Production Act of 1950 (50 U.S.C. 4565(a)), as amended. Section 1758(a) of ECRA (50 U.S.C. 4817(a)) outlines an interagency process for identifying emerging and foundational technologies that considers both public and classified information, as well as information from the Emerging Technology Technical Advisory Committee and the Committee on Foreign Investment in the United States. In identifying specific emerging technologies, the process also takes into account:

- The development of the emerging technologies in foreign countries;
- The effect export controls might have on the development of the emerging technologies in the United States; and

• The effectiveness of export controls on limiting the proliferation of the emerging technologies in foreign countries.

In addition, Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)) requires that the interagency process for identifying emerging technologies include a notice and comment period.

The Secretary of Commerce must establish appropriate controls on the export, reexport or transfer (in-country) of technology identified pursuant to the Section 1758 process, and in doing so, must consider the potential end-uses and end-users of emerging and foundational 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 he must require a license for the export of such technologies to countries subject to a U.S. embargo, including those countries subject to an arms embargo.

“Software” for the operation of nucleic acid assemblers and synthesizers controlled under ECCN 2B352.j on the Commerce Control List (CCL), in Supplement No. 1 to part 774 of the Export Administration Regulations (EAR) (15 CFR parts 730–774), has been identified as a technology to be evaluated as an emerging technology, consistent with the process described in Section 1758 of ECRA. This identification is based on a finding that such “software” is capable of being utilized in the production of pathogens and toxins and, consequently, the absence of export controls on such “software” could be exploited for biological weapons purposes.

Consistent with BIS’s authority to evaluate the level of controls that would be appropriate for the export, reexport or transfer (in-country) of emerging technologies, this rule proposes to amend the CCL by adding a new ECCN 2D352 to control such “software.” This “software” is not currently included on any of the Australia Group (AG) common control lists—consequently, the controls on this “software,” as proposed by this rule, would be unilateral in nature, absent the adoption of comparable controls by the Australia Group.

In addition, although this rule does not propose to amend ECCN 2E001 (which controls, *inter alia*, “technology” for the “development” of the nucleic acid assemblers and synthesizers described in ECCN 2B352.j), the heading of ECCN 2E001 indicates that, with limited exceptions, ECCN 2E001 controls “technology for the “development” of “software” listed

under Category 2D of the CCL.

Consequently, if the changes proposed in this rule were to go into effect, ECCN 2E001 would control “technology” for the “development” of the “software” that would be controlled under new ECCN 2D352. This expansion in the scope of ECCN 2E001 would be unilateral in nature.

Public comments submitted to BIS in response to this proposed rule will help BIS and other U.S. Government agencies to apply the criteria set forth in Section 1758 of ECRA and identify and assess the appropriate level of controls that should apply to the “software” proposed for control under ECCN 2D352 and “technology” for the “development” of such “software,” as proposed to be controlled under ECCN 2E001.

Request for Comments

BIS is publishing this proposed rule to obtain public comments on the proposed application of CB controls to “software” for the operation of nucleic acid assemblers and synthesizers described in ECCN 2B352.j, and to “technology” related to such “software” that would satisfy the controls described in ECCN 2E001. Consistent with Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), this proposed rule provides the public with notice and the opportunity to comment on controlling this technology as described herein. Specifically, BIS welcomes any comments on this proposed rule relevant to the following:

(1) Whether the proposed controls are clear and adequately address “emerging and foundational technologies” within the context of biological weapons related capabilities and developments (to the extent that this is not the case, comments should identify specific control text that would be more appropriate to these ends);

(2) The current capability for the “development” of such “software” in the United States and other countries, including the extent to which the proposed controls would affect “software” that is currently being produced and/or sold, either within or outside the United States (*e.g.*, whether the proposed controls would inadvertently control any “software” that is suitable almost exclusively for legitimate commercial or scientific applications);

(3) The effect that implementation of the proposed controls would have on the future “development” of such “software” and related “technology” in the United States; and

(4) The effectiveness of the proposed controls in terms of limiting the

availability of such “software” and related “technology” abroad.

BIS also welcomes comments concerning whether these controls should be implemented multilaterally (rather than unilaterally), in the interest of increasing their effectiveness and minimizing their impact on U.S. industry (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). In this regard, note that Section 1758(c) of ECRA (as codified under 50 U.S.C. 4817(c)) provides 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 subsection (a) [of ECRA] be added to the list of technologies controlled by the relevant multilateral export control regimes”. Subsection (a) of section 1758 (as codified under 50 U.S.C. 4817(a)) addresses the interagency process for identifying emerging technologies.

The public comments submitted in response to this proposed rule should address specific aspects of the proposed addition of ECCN 2D352 to the CCL in relation to the criteria described above (*e.g.*, identify the specific aspects in which the proposed controls would satisfy these criteria or fail to do so).

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, the rule has been reviewed by the Office of Management and Budget (OMB).

The cost-benefit analysis required pursuant to Executive Orders 13563 and 12866 indicates that this rule is intended to improve national security as its primary direct benefit. Specifically, implementation, in a timely manner, of the proposed changes described herein would enhance the national security of the United States by reducing the risk

that global international trade involving dual-use chemical/biological items would contribute to the proliferation of chemical and biological weapons (CBW) of mass destruction. These controls are essential given that the international chemical and biotechnology industries are a target for proliferators as a source of materials for CBW programs. In calculating the costs that would be imposed by this rule, BIS estimates that no more than 15 additional license applications would have to be submitted to BIS, annually, as a result of the implementation of the amendments described in this rule (see Rulemaking Requirements #2, below). Application of the cost-benefit analysis required under Executive Orders 13563 and 12866 to this rule, as described above, indicates that this rule is intended to improve the national security of the United States as its primary direct benefit. Accordingly, consistent with the stated purpose of the proposed addition of ECCN 2D352 to the Commerce Control List (CCL), the changes proposed by this rule meet the requirements set forth in the April 5, 2017, OMB guidance implementing Executive Order 13771 (82 FR 9339, February 3, 2017), regarding what constitutes a regulation issued “with respect to a national security function of the United States,” and this rule is, therefore, exempt from the requirements of E.O. 13771.

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 proposed rule would make important changes to the EAR for items controlled for chemical/biological (CB) reasons, BIS believes the overall increase in costs and burdens due to this rule would be minimal if implemented in a final rule. Specifically, BIS expects the burden hours associated with these collections would 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. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet Sehra, Office of Management and Budget, by email to *Jasmeet_K_Sehra@omb.eop.gov* or by fax to (202) 395–7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th Street & Pennsylvania Avenue NW, Room 2705, Washington, DC 20230 or by email to *RPD2@bis.doc.gov*.

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

4. Pursuant to Section 1762 of the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 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. Notwithstanding, BIS believes this rule would benefit from public comment prior to issuance. Consistent with the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*), BIS has prepared the following initial regulatory flexibility analysis (IRFA) of the impact that this proposed rule, if adopted, would have on small businesses.

Description of the Reasons Why Action Is Being Considered

The policy reasons for issuing this proposed rule are discussed in the background section of the preamble of this document and, consequently, are not repeated here.

Statement of the Objectives of, and Legal Basis for, the Proposed Rule; Identification of All Relevant Federal Rules Which May Duplicate, Overlap or Conflict With the Proposed Rule

The objective of this proposed rule, and any other emerging technology proposed rules published by BIS, is to control emerging and foundational technologies identified by BIS and its interagency partners as being essential to U.S. national security. The legal basis for this proposed rule is as follows: 50 U.S.C. 4801–4852.

No other federal rules duplicate, overlap, or conflict with this proposed rule.

Number and Description of Small Entities Regulated by the Proposed Action

This proposed rule would apply to all persons engaged in the export, reexport or transfer (in-country) of the “software” proposed for control under ECCN 2D352 and related “technology” subject to the EAR. Presently, this “software” and related “technology” is used in research and development activities in many U.S. university and military laboratories. Therefore, BIS anticipates that the proposed controls would result in “deemed” export license applications (for exports to foreign nationals located within the United States) to allow access to this “technology” by foreign students and faculty at U.S. universities, as well as by non-U.S. employees of U.S. biochemical firms. There would most likely also be “deemed” reexport license applications for the release of this “technology” to third-country foreign nationals located in foreign countries who are engaged in research and development activities involving this “technology.”

BIS does not collect or maintain the data necessary to determine how many of the affected persons are small entities as that term is used by the Small Business Administration. Prior to issuing this proposed rule, BIS received 36 comments on biotechnology in response to the November 19 ANPRM. None of these commenters specifically identified themselves as small businesses, but small businesses may have chosen to provide input through larger entities, such as trade associations.

However, BIS was able to estimate the number of license applications that the agency anticipates receiving as a result of this proposed rule and is using that estimate as a means of assessing the impact on small businesses. Using the North American Industry Classification System Codes (NAICS) 325414 (Biological Product (except Diagnostic Manufacturing)), BIS determined that the standard small business size in this industry is 1,250 employees. Using Table 1a of the Census Bureau's 2016 Exports by Company Type and Employment Size and extrapolating to 1,250 employees, BIS then estimated that 41% of all identified companies that export in this industry are small businesses. BIS also estimates that it will receive 15 license applications per year for the items described in this proposed rule (see the PRA estimates described in Rulemaking Requirements #2, above). Based on that information, BIS estimates that the agency will receive approximately 6 license applications per year from small businesses, or roughly 41% of the 15 estimated license applications.

In addition, based on the burden estimate for OMB under control numbers 0694-0088 (Simplified Network Application Processing System) and 0694-0096 (Five Year Records Retention Period), BIS expects that the total burden hours for small businesses associated with these EAR-related collections would increase only slightly, by just under 3 hours and 4 minutes (*i.e.*, 6 applications \times 30.6 minutes per response), for a total estimated cost increase of just under \$92 (*i.e.*, 3 hours and 4 minutes \times \$30 per hour).

The amendments proposed in this rule, if implemented, also would trigger a small information collection burden under the U.S. Census Bureau's Foreign Trade Regulations (FTR) (15 CFR part 30), which contain the Electronic Export Information (EEI) filing requirements under the Automated Export System (AES). This FTR-related information collection has been approved by OMB under control number 0607-0152 (Automated Export System (AES) Program) and carries a burden hour estimate of 3 minutes per electronic submission. This collection, together with the aforementioned EAR-related information collections, would result in a total estimated cost increase to small businesses of just under \$94 (*i.e.*, 3 hours and 7 minutes \times \$30 per hour). Note that, for purposes of consistency, the \$30 per hour cost estimate used for the EAR-related information collections described above is also applied to this FTR-related information collection

(which also would involve work performed by export compliance specialists).

Based on the analysis provided above, the amendments proposed in this rule would not impose a significant economic impact on a substantial number of small businesses.

Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

The changes proposed in this rule, if adopted, would mean that certain items currently eligible for export, reexport or transfer (in-country) to most destinations under the No License Required (NLR) designation would require an EAR authorization (*i.e.*, in accordance with the terms and conditions of an EAR license exception or a license issued by BIS). Adding these items to the CCL, to be controlled under a new ECCN 2D352, may also change the export clearance requirements under the FTR for certain exports of these items by triggering an EEI filing requirement in AES—this requirement generally does not apply to items below a certain value that are classified as EAR99.

To the extent that compliance with the changes proposed in this rule would impose a burden on persons, including small businesses, BIS believes the burden would be minimal. The reclassification process would need to be done only once per license applicant for exports, reexports or transfers (in-country) of these emerging technology items and, consequently, would constitute a one-time burden for each applicant. Similarly, assessing the availability of license exceptions and/or applying for and using BIS licenses would impose some minimal burden on persons, including small businesses.

However, it should be noted that these EAR requirements would likely have less impact than might otherwise be the case, because of the resources that BIS makes available to all exporters, including small businesses. Specifically, BIS's website has free on-line training explaining export basics, including instructions on how to register for and use BIS's online license application tool. BIS also provides free export counseling by telephone and email via both its Washington, DC and Western Regional offices. In addition, BIS accepts requests for commodity classifications and processes them without charge to assist those exporters who need assistance in classifying their items for the purpose of determining whether any CCL-based license requirements would apply.

Significant Alternatives and Underlying Analysis

As noted above, BIS does not believe that the amendments proposed in this rule, if published in a final rule, would have a significant economic impact on small businesses. Nevertheless, consistent with 5 U.S.C. 603(c), BIS considered significant alternatives to these proposed amendments to assess whether the alternatives would: (1) Accomplish the stated objectives of this rule (consistent with the emerging technology requirements in ECRA); and (2) minimize any significant economic impact of this rule on small entities. BIS could have proposed a much broader control on "software" capable of operating nucleic acid assemblers and synthesizers controlled under ECCN 2B352 that would have captured a greater amount of such "software" and related "technology." That in turn would have had a greater impact not only on small businesses, but also on research and development laboratories (both academic and corporate), which are involved in advancing biological technology. BIS has determined that proposing focused controls on specific "software" and related "technology" (*i.e.*, the "software" proposed for control under new ECCN 2D352 and corresponding "development" "technology" in ECCN 2E001) is the least disruptive alternative for implementing export controls in a manner consistent with controlling technology that has been determined, through the emerging technology interagency process authorized under ECRA, to be essential to U.S. national security.

BIS is not proposing different compliance or reporting requirements for small businesses. If a small business is subject to a compliance requirement for the export, reexport or transfer (in-country) of this "software" and related "technology," then it would submit a license application using the same process as any other company (*i.e.*, electronically via SNAP-R). The license application process is free of charge to all entities, including small businesses. In addition, as noted above, the resources and other compliance tools made available by BIS typically serve to lessen the impact of any EAR license requirements on small businesses.

Lastly, consistent with 5 U.S.C. 603(c), BIS assessed the use of performance standards rather than design standards and also considered whether an exemption for small businesses was practical under the circumstances (*i.e.*, within the context of the changes proposed in this rule).

The “software” proposed for control under new ECCN 2D352 and related “technology” that warrant control under this proposed rule are 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 (*i.e.*, they are capable of being used in the production of biological agents). However, because this “software” and related “technology” are dual-use items, they also have legitimate commercial and scientific applications. Consequently, controlling this “software” and related “technology” based on design standards is the most appropriate way to control these items. In the absence of such controls, there may be an unacceptable risk of diversion of these items to biological weapons end-uses.

This proposed rule does not contain an exemption for small businesses from this license requirement, because BIS and its interagency partners are assessing whether these controls are essential to U.S. national security. Specifically, this “software” and related “technology” could be used for biological weapons purposes and, as such, controlling these items on the CCL is essential to U.S. national security. An exemption for small businesses would undermine the effectiveness of these proposed controls.

Conclusion

BIS has identified the “software” and related “technology” addressed in this proposed rule as an emerging technology that warrants public notice and comment. Consequently, consistent with the Regulatory Flexibility Act, BIS has prepared this IRFA addressing the impact that this proposed rule, if adopted, would have on small entities. BIS’s assessment indicates that the amendments proposed in this rule would not have a significant economic impact on a substantial number of small entities.

Please submit any comments concerning this IRFA in accordance with the instructions provided in the **ADDRESSES** section of this proposed rule.

List of Subjects in 15 CFR Part 774

Exports, Reporting and recordkeeping requirements, Terrorism.

For the reasons stated in the preamble, part 774 of the Export Administration Regulations (15 CFR parts 730–774) is proposed to be amended as follows:

PART 774—[AMENDED]

■ 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.*; 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.

Supplement No. 1 to Part 774—[Amended]

■ 2. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2 –Materials Processing,” ECCN 2D352 is added, immediately following ECCN 2D351, to read as follows:

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

* * * * *

2D352 “Software” for the operation of 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.

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Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–24322 Filed 11–5–20; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG–122462–20]

RIN 1545–BP97

Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: Elsewhere in this issue of the **Federal Register**, the IRS is issuing temporary regulations regarding coverage of preventive health services to implement section 3203 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which shortens the timeframe under which non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must cover without cost sharing qualifying coronavirus preventive services, including recommended COVID–19 immunizations. The IRS is issuing the temporary regulations at the same time that the Employee Benefits Security Administration of the Department of Labor and the Office of Consumer Information and Insurance Oversight of the Department of Health and Human Services (HHS) are issuing substantially similar interim final rules with request for comments. The text of those temporary regulations also serves as the text of these proposed regulations.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 4, 2021.

ADDRESSES: In commenting, please refer to file code CMS–9912–IFC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9912–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.