SUPPLEMENT NO. 1 TO PART 745—SCHEDULES OF CHEMICALS—Continued

	CAS registry No.
16. Methyldiethanolamine	105–59–9
17. Triethanolamine	102–71–6

Note to Supplement 1: The numerical sequence of the ''Schedule 1'' Toxic Chemicals and Precursors is not consecutive so as to align with the December 23, 2019, consolidated textual changes to ''Schedule 1'' of the Annex on Chemicals to the Chemical Weapons Convention (CWC), which reflect the decisions adopted by the CWC Conference of the States Parties in November 2019.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 742 and 774

[Docket No. 201208–0330]

RIN 0694–AI09

Commerce Control List: Clarifications to the Scope of Export Control Classification Number 1C991 To Reflect Decisions Adopted at the June 2019 Australia Group Plenary Meeting

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 clarify the scope of the export controls that apply to certain vaccines and medical products, consistent with the release (*i.e.,* exclusion) notes contained in the Australia Group (AG) ''Human and Animal Pathogens and Toxins for Export Control'' common control list.

DATES: This rule is effective January 7, 2021.

FOR FURTHER INFORMATION CONTACT: Dr. Kimberly Orr, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482–4201, Email: *Kimberly.Orr@bis.doc.gov.*

SUPPLEMENTARY INFORMATION: The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to clarify the scope of the export controls that apply to certain vaccines, consistent with the vaccine release (*i.e.,* exclusion) note contained in the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control'' common control list, as updated by a decision made at the AG Plenary meeting held in Paris, France, in June 2019. The AG is a multilateral forum consisting of 42 participating countries and the European Union that 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.

The AG specifically excludes certain vaccines from control under its ''List of Human and Animal Pathogens and Toxins for Export Control'' and the associated Warning List. However, prior to the June 2019 Plenary changes to this AG common control list, it was not clear if the release note therein applied not only to vaccines containing those human and animal pathogens and toxins identified on the list, but also to vaccines containing the genetic elements and genetically modified organisms identified therein. Recent changes to this AG common control list, based in part on a decision made at the June 2019 Plenary meeting, clarify that this release note applies to vaccines containing the genetic elements and genetically modified organisms identified on this list, as well as vaccines containing the viruses, bacteria, and toxins identified on this list.

Specifically, this rule amends Export Control Classification Number (ECCN) 1C991 on the Commerce Control List (CCL) to indicate that it includes vaccines containing, or designed for use against, any of the items identified in ECCN 1C351, 1C353 or 1C354. Prior to the effective date of this final rule, ECCN 1C991 indicated that it controlled vaccines ''against'' such items, but was not specific about whether all vaccines ''containing'' such items were controlled, irrespective of whether the vaccines were designed for use ''against'' such items.

This rule also expands the scope of medical products controlled under ECCN 1C991 to include those containing genetically modified organisms and genetic elements described in ECCN 1C353.a.3. In addition, this rule clarifies the definition of 'immunotoxin' that appears in ECCN 1C351 and ECCN 1C991 and removes the definition of 'subunit' from ECCN 1C351.

Finally, this rule renumbers ECCN 1C991.c and .d by listing medical products that are subject to chemical/biological (CB) controls, as well as anti-terrorism (AT) controls, under ECCN 1C991.c and listing medical products that are subject only to AT controls under ECCN 1C991.d. A conforming amendment is made to § 742.2(a)(3) of the EAR to reflect this change in paragraph sequencing.

ECCN 1C991 (Vaccines, Immunotoxins, Medical Products, Diagnostic and Food Testing Kits)

This final rule amends ECCN 1C991 on the Commerce Control List (CCL) (Supplement No. 1 to part 774 of the EAR) to make the description of the vaccines controlled by this ECCN more closely reflect the scope of the vaccine release note contained in the AG ''List of Human and Animal Pathogens and Toxins for Export Control.'' ECCN 1C991 does not control any of the human and animal pathogens and toxins or genetic elements and genetically modified organisms identified on this AG list; however, it does control vaccines, immunotoxins, medical products, and diagnostic and food testing kits that contain certain of these AG-listed items.

The amendments contained in this final rule are intended to clarify the scope of the vaccine controls described in ECCN 1C991. Prior to the effective date of this final rule, the control text for vaccines described in ECCN 1C991.a indicated that this ECCN controlled ''vaccines against items controlled by ECCN 1C351, 1C353 or 1C354.'' The use of the term ''against'' in the control text created some uncertainty concerning the extent to which ECCN 1C991.a applied to vaccines that ''contain'' items controlled by ECCN 1C351, 1C353 or

1C354, but that act against agents (or other disease causing organisms) that are not identified in any of these ECCNs. This uncertainty caused some concern among manufacturers and exporters about the correct classification and licensing policies for such vaccines.

The clarifications in this rule to the scope of the vaccine controls in ECCN 1C991.a are also in response to recent scientific and medical developments. For example, viruses controlled under ECCN 1C351 (*e.g.,* vesicular stomatitis virus, yellow fever virus, and Newcastle disease virus) are being modified to express surface proteins of other target organisms or cells for stimulating immune response to the surface protein, thus acting as vaccines against those targets. These medical products can be designed for the following purposes: (1) Vaccination against agents controlled by ECCN 1C351 (*e.g.,* Ebolavirus or Chikungunya virus); (2) to protect against uncontrolled agents; or (3) as oncolytic medical products for treating specific cancers (oncolytic virotherapy is an emerging treatment that uses replication competent viruses to destroy cancers).

This final rule addresses industry's concerns and the recent scientific and medical developments described above by revising ECCN 1C991.a to read as follows: ''Vaccines containing, or designed for use against, items controlled by ECCN 1C351, 1C353 or 1C354.'' As a result of this change, ECCN 1C991.a now clearly indicates that it controls all vaccines that ''contain'' items controlled by ECCN 1C351, 1C353 or 1C354, as well as those vaccines that are designed for use ''against'' these items.

This rule also amends ECCN 1C991 by expanding the scope of medical products controlled under this ECCN, consistent with the release (*i.e.,* exclusion) note for such products in the ''List of Human and Animal Pathogens and Toxins for Export Control,'' to include medical products containing genetically modified organisms or genetic elements controlled under ECCN 1C353.a.3. In addition, the control text for medical products in ECCN 1C991 is renumbered by listing medical products that are subject to chemical/biological (CB) controls, as well as anti-terrorism (AT) controls, under ECCN 1C991.c and listing medical products that are subject only to AT controls, under ECCN 1C991.d. Prior to the effective date of this final rule, the former were listed under ECCN 1C991.d, while the latter were listed under ECCN 1C991.c. This change is intended to emphasize the more stringent controls that apply to the medical products now described in ECCN 1C991.c (*i.e.,* CB controls, in addition to AT controls) and to clearly indicate that the CB controls that apply to most of the medical products controlled under this ECCN do not apply to the medical products now controlled under ECCN 1C991.d, which are subject only to AT controls (the controls that apply to items in ECCN 1C991 are described in more detail, below). A conforming amendment is made to § 742.2(a)(3) of the EAR to reflect this change in paragraph sequencing.

This rule also makes a technical correction to the definition of 'medical products' in the ''Related Definitions'' paragraph under the List of Items Controlled for ECCN 1C991 by adding the parenthetical phrase ''(or veterinary)'' to the criterion describing pharmaceutical formulations. The criterion, as corrected, reads as follows: ''(1) pharmaceutical formulations designed for testing and human (or veterinary) administration in the treatment of medical conditions.'' In addition, the definition of 'immunotoxins' in the ''Related Definitions'' paragraph of ECCN 1C351 and ECCN 1C991 is clarified to read as follows: ''immunotoxins are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact.''

This rule also adds a *Technical Note* at the beginning of the ''*Items*'' paragraph in the List of Items Controlled under ECCN 1C991 to clarify that, for purposes of the controls described in this ECCN, 'toxins' means those toxins, or their subunits, controlled under ECCN 1C351.d.

Note that all items controlled by ECCN 1C991, including the vaccines described in ECCN 1C991.a, require a license for AT reasons to the destinations indicated under AT Column 1 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 of the EAR that apply to Iran, North Korea, Sudan and Syria). In addition, the medical products now controlled by ECCN 1C991.c (as renumbered by this rule) require a license for CB reasons, as well as AT reasons, to the destinations indicated under CB Column 3 and AT Column 1, respectively, on the Commerce Country Chart. A license also is required to certain destinations in accordance with the embargoes and other special controls described in part 746 of the EAR.

Anticipated Impact of This Final Rule

Prior to the publication of this final rule, paragraph (a) of ECCN 1C991 included only those vaccines designed to protect against biological agents controlled under ECCN 1C351, 1C353 or 1C354 on the CCL. For example, the vaccine for protection against Ebola was previously (and continues to be) classified for control under ECCN 1C991, because Ebola, itself, is a controlled biological agent. The Ebola vaccine also contains genetic elements for recombinant vesicular stomatitis virus (VSV), a controlled virus, and a common vector for vaccine development.

However, ECCN 1C991 did not previously include vaccines containing controlled biological agents that were not also designed to protect against a controlled agent. Other VSV-based vaccines against EAR99 agents (*i.e.,* agents not controlled on the CCL), such as SARS-CoV–2, were controlled to all destinations under ECCN 1C353, because they did not act against a controlled agent as previously required by the ECCN 1C991 vaccine control text.

This rule amends the vaccine controls in paragraph (a) of ECCN 1C991 to more accurately reflect the scope of the AG release note for vaccines, which exempts vaccines from control under the AG List of Human and Animal Pathogens and Toxins. Specifically, the AG release note exempts from control all vaccines containing one or more of the biological agents identified on this AG common control list.

Although certain COVID vaccines are not affected by this rule, the development of an unknown number of other vaccines, COVID and otherwise, is expected to be greatly facilitated as a result of these amendments to the vaccine controls in ECCN 1C991.

Effective with the publication of this rule, COVID vaccines containing genetic elements of items controlled by ECCN 1C353 (such as VSV) are now controlled under ECCN 1C991, instead of ECCN 1C353. Consequently, instead of requiring a license for export or reexport to all destinations, a license is required only to a much more limited number of destinations (*i.e.,* countries of concern for anti-terrorism (AT) reasons).

A specific example of the impact of this rule is a VSV–SARS-CoV–2 vaccine, which is a vesicular stomatitis virus modified by adding the gene for the coronavirus spike protein. Because this vaccine acts against SARS-CoV–2, which is not controlled under ECCN 1C351, it was not classified as an ECCN 1C991 vaccine, prior to the publication of this rule. Instead, it was controlled under ECCN 1C353, in spite of having received FDA approval and being packaged for patient use, because it contains genetic elements from VSV (a

controlled virus). Consequently, this vaccine previously required a license to all destinations. Effective with the publication of this final rule, this vaccine is now controlled under ECCN 1C991 and requires a license only to designated countries of concern for AT reasons.

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 January 7, 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 March 8, 2021. Any such items not actually exported, reexported or transferred (in-country) before midnight, on March 8, 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 March 8, 2021. Beginning at midnight on March 8, 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, the rule has been reviewed by the Office of Management and Budget.

The cost-benefit analysis required pursuant to Executive Orders 13563 and 12866, as described below, indicates that this rule is intended to improve national security as its primary direct benefit and that this benefit significantly outweighs the costs of this rule. Specifically, implementation, in a timely manner, of the Australia Group (AG) agreements described herein will enhance the national security of the United States by reducing the risk that international trade involving dual-use chemical and biological items would contribute to the proliferation of chemical and biological weapons of mass destruction. The principal objective of AG participating countries is to use licensing measures to ensure that exports of certain chemicals, biological agents, and dual-use chemical and biological manufacturing facilities and equipment, do not contribute to the proliferation of chemical and biological weapons of mass destruction, which has been identified as a threat to domestic and international peace and security. The AG achieves this objective by harmonizing participating countries' national export licensing measures. These controls are essential, given that the international chemical and biotechnology industries are a target for proliferators as a source of materials for chemical and biological weapons programs.

In calculating what costs (if any) will be imposed by this rule, BIS estimates that 10 fewer license applications will need to be submitted to BIS, annually, as a result of the implementation of the amendments described in this rule (see Rulemaking Requirements #2, below). By applying the cost-benefit analysis required under Executive Orders 13563 and 12866 to this rule, as described herein, BIS has determined that the benefits of this rule (*i.e.,* the enhancement of our national security through the fulfillment our multilateral obligations as an AG participating country, together with the anticipated reduction in the number of license applications that would have to be submitted to export certain items affected by this rule) significantly outweigh any potential costs (*i.e.,* the incidental costs to exporters of adjusting their export control procedures for certain items affected by this rule). Furthermore, consistent with the stated purpose of the amendments to ECCN 1C991 (*i.e.,* to enhance the national security of the United States), this rule meets the requirements set forth in the April 5, 2017, Office of Management and Budget (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 it 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 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.

This rule contains minor clarifications to the EAR for certain vaccines controlled by ECCN 1C991.a for anti-terrorism (AT) reasons. Specifically, BIS expects the burden hours associated with these collections will decrease by 5 hours and 6 minutes (*i.e.,* 10 applications × 30.6 minutes per response) for a total estimated decrease in cost of $153 (*i.e.,* 5 hours and 6 minutes × $30 per hour). The $30 per hour cost estimate for OMB control numbers 0694–0088 and 0694–0096 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). Consequently, the burden hours associated with exports of the items affected by this rule will remain within the range of 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. Pursuant to section 1762 of the Export Control Reform Act of 2018 (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 rule by the APA or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

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 742 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, 2019, 84 FR 61817 (November 13, 2019).

■ 2. In § 742.2, paragraph (a)(3) is revised to read as follows:

§ 742.2 Proliferation of chemical and biological weapons.

(a) * * *

(3) If CB Column 3 of the Country Chart (Supplement No. 1 to part 738 of the EAR) is indicated in the appropriate ECCN, a license is required to Country Group D:3 (see Supplement No. 1 to part 740 of the EAR) for medical products identified in ECCN 1C991.c.

* * * * *

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, Category 1, ECCN 1C351 is revised to read as follows:

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

* * * * *

1C351 Human and animal pathogens and ''toxins,'' as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, CW, AT

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

CW applies to 1C351.d.11 and d.12 and a license is required for CW reasons for all destinations, including Canada, as follows: CW applies to 1C351.d.11 for ricin in the form of (1) Ricinus communis AgglutininII (RCAII), also known as ricin D or Ricinus Communis LectinIII (RCLIII) and (2) Ricinus communis LectinIV (RCLIV), also known as ricin E. CW applies to 1C351.d.12 for saxitoxin identified by C.A.S. #35523–89–8. See § 742.18 of the EAR for licensing information pertaining to chemicals subject to restriction pursuant to the Chemical Weapons Convention (CWC). The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons.

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

License Requirement Notes: *1. All vaccines and 'immunotoxins' are excluded from the scope of this entry. Certain medical products and diagnostic and food testing kits that contain biological toxins controlled under paragraph (d) of this entry, with the exception of toxins controlled for CW reasons under d.11 and d.12, are excluded from the scope of this entry. Vaccines, 'immunotoxins,' certain medical products, and diagnostic and food testing kits excluded from the scope of this entry are controlled under ECCN 1C991.*

2. For the purposes of this entry, only saxitoxin is controlled under paragraph d.12; other members of the paralytic shellfish poison family (e.g., neosaxitoxin) are designated EAR99.

3. Clostridium perfringens strains, other than the epsilon toxin-producing strains of Clostridium perfringens described in c.12, are excluded from the scope of this entry, since they may be used as positive control cultures for food testing and quality control.

4. Unless specified elsewhere in this ECCN 1C351 (e.g., in License Requirement Notes 1–3), this ECCN controls all biological agents and ''toxins,'' regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including small quantities or attenuated strains of select biological agents or ''toxins'' that are excluded from the lists of select biological agents or ''toxins'' by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), in accordance with their regulations in 9 CFR part 121 and 42 CFR part 73, respectively.

5. Biological agents and pathogens are controlled under this ECCN 1C351 when they are an isolated live culture of a pathogen agent, or a preparation of a toxin agent that has been isolated or extracted from any source or material, including living material that has been deliberately inoculated or contaminated with the agent. Isolated live cultures of a pathogen agent include live cultures in dormant form or in dried preparations, whether the agent is natural, enhanced or modified.

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

LVS: N/A
GBS: N/A

Special Conditions for STA

STA: (1) Paragraph (c)(1) of License Exception STA (§ 740.20(c)(1)) may be used for items in 1C351.d.1 through 1C351.d.10 and 1C351.d.13 through 1C351.d.18. See § 740.20(b)(2)(vi) for restrictions on the quantity of any one toxin that may be exported in a single shipment and the number of shipments that may be made to any one end user in a single calendar year. Also see the Automated Export System (AES) requirements in § 758.1(b)(4) of the EAR. (2) Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any items in 1C351.

List of Items Controlled

Related Controls: (1) Certain forms of ricin and saxitoxin in 1C351.d.11. and d.12 are CWC Schedule 1 chemicals (see § 742.18 of the EAR). The U.S. Government must provide advance notification and annual reports to the OPCW of all exports of Schedule 1 chemicals. See § 745.1 of the EAR for notification procedures. See 22 CFR part 121, Category XIV and § 121.7 for CWC Schedule 1 chemicals that are ''subject to the ITAR.'' (2) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (for APHIS, see 7 CFR 331.3(b), 9 CFR 121.3(b), and 9 CFR 121.4(b); for CDC, see 42 CFR 73.3(b) and 42 CFR 73.4(b)). (3) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are ''subject to the ITAR.''

Related Definitions: For the purposes of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact.

Items:

a. Viruses identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:

a.1. African horse sickness virus;

a.2. African swine fever virus;

a.3. Andes virus;

a.4. Avian influenza (AI) viruses identified as having high pathogenicity (HP), as follows:

a.4.a. AI viruses that have an intravenous pathogenicity index (IVPI) in 6-week-old chickens greater than 1.2; *or*

a.4.b. AI viruses that cause at least 75% mortality in 4- to 8-week-old chickens infected intravenously.

Note: *Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in 1C351.a.4 (specifically, 1C351.a.4.a or a.4.b) should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is controlled under 1C351.a.4.*

a.5. Bluetongue virus;

a.6. Chapare virus;

a.7. Chikungunya virus;

a.8. Choclo virus;

a.9. Classical swine fever virus (Hog cholera virus);

a.10. Crimean-Congo hemorrhagic fever virus;

a.11. Dobrava-Belgrade virus;

a.12. Eastern equine encephalitis virus;

a.13. Ebolavirus (includes all members of the Ebolavirus genus);

a.14. Foot-and-mouth disease virus;

a.15. Goatpox virus;

a.16. Guanarito virus;

a.17. Hantaan virus;

a.18. Hendra virus (Equine morbillivirus);

a.19. Japanese encephalitis virus;

a.20. Junin virus;

a.21. Kyasanur Forest disease virus;

a.22. Laguna Negra virus;

a.23. Lassa virus;

a.24. Louping ill virus;

a.25. Lujo virus;

a.26. Lumpy skin disease virus;

a.27. Lymphocytic choriomeningitis virus;

a.28. Machupo virus;

a.29. Marburgvirus (includes all members of the Marburgvirus genus);

a.30. Middle East respiratory syndrome-related coronavirus (MERS-related coronavirus);

a.31. Monkeypox virus;

a.32. Murray Valley encephalitis virus;

a.33. Newcastle disease virus;

a.34. Nipah virus;

a.35. Omsk hemorrhagic fever virus;

a.36. Oropouche virus;

a.37. Peste-des-petits ruminants virus;

a.38. Porcine Teschovirus;

a.39. Powassan virus;

a.40. Rabies virus and all other members of the Lyssavirus genus;

a.41. Reconstructed 1918 influenza virus;

Technical Note: *1C351.a.41 includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.*

a.42. Rift Valley fever virus;

a.43. Rinderpest virus;

a.44. Rocio virus;

a.45. Sabia virus;

a.46. Seoul virus;

a.47. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);

a.48. Sheeppox virus;

a.49. Sin Nombre virus;

a.50. St. Louis encephalitis virus;

a.51. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);

a.52. Swine vesicular disease virus;

a.53. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus—see 1C351.b.3 for Siberian subtype);

a.54. Variola virus;

a.55. Venezuelan equine encephalitis virus;

a.56. Vesicular stomatitis virus;

a.57. Western equine encephalitis virus; *or*

a.58. Yellow fever virus.

b. Viruses identified on the APHIS/CDC ''select agents'' lists (see Related Controls paragraph #2 for this ECCN), but not identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:

b.1. [Reserved];

b.2. [Reserved]; *or*

b.3. Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus—see 1C351.a.53 for Far Eastern subtype).

c. Bacteria identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:

c.1. Bacillus anthracis;

c.2. Brucella abortus;

c.3. Brucella melitensis;

c.4. Brucella suis;

c.5. Burkholderia mallei (Pseudomonas mallei);

c.6. Burkholderia pseudomallei (Pseudomonas pseudomallei);

c.7. Chlamydia psittaci (Chlamydophila psittaci);

c.8. Clostriduim argentinense (formerly known as Clostridium botulinum Type G), botulinum neurotoxin producing strains;

c.9. Clostridium baratii, botulinum neurotoxin producing strains;

c.10. Clostridium botulinum;

c.11. Clostridium butyricum, botulinum neurotoxin producing strains;

c.12. Clostridium perfringens, epsilon toxin producing types;

c.13. Coxiella burnetii;

c.14. Francisella tularensis;

c.15. Mycoplasma capricolum subspecies capripneumoniae (''strain F38'');

c.16. Mycoplasma mycoides subspecies mycoides SC (small colony) (a.k.a. contagious bovine pleuropneumonia);

c.17. Rickettsia prowazekii;

c.18. Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi);

c.19. Shiga toxin producing Escherichia coli (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups;

Note: *Shiga toxin producing Escherichia coli (STEC) includes, inter alia, enterohaemorrhagic E. coli (EHEC), verotoxin producing E. coli (VTEC) or verocytotoxin producing E. coli (VTEC).*

c.20. Shigella dysenteriae;

c.21. Vibrio cholerae; *or*

c.22. Yersinia pestis.

d. ''Toxins'' identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows, or their subunits:

d.1. Abrin;

d.2. Aflatoxins;

d.3. Botulinum toxins;

d.4. Cholera toxin;

d.5. Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins;

d.6. Conotoxins;

d.7. Diacetoxyscirpenol;

d.8. HT-2 toxin;

d.9. Microcystins (Cyanginosins);

d.10. Modeccin;

d.11. Ricin;

d.12. Saxitoxin;

d.13. Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);

d.14. Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F);

d.15. T-2 toxin;

d.16. Tetrodotoxin;

d.17. Viscumin (Viscum album lectin 1); *or*

d.18. Volkensin.

e. ''Fungi'', as follows:

e.1. Coccidioides immitis; *or*

e.2. Coccidioides posadasii.

■ 5. In Supplement No. 1 to part 774, Category 1, ECCN 1C991 is revised to read as follows:

1C991 Vaccines, immunotoxins, medical products, diagnostic and food testing kits, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

Control(s)	*Country chart (see supp. No. 1 to part 738)*
CB applies to 1C991.c.	CB Column 3.
AT applies to entire entry.	AT Column 1.

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

LVS: N/A
GBS: N/A

List of Items Controlled

Related Controls: (1) Medical products containing ricin or saxitoxin, as follows, are controlled for CW reasons under ECCN 1C351:

(a) Ricinus communis AgglutininII (RCAII), also known as ricin D, or Ricinus Communis LectinIII (RCLIII);

(b) Ricinus communis LectinIV (RCLIV), also known as ricin E; or

(c) Saxitoxin identified by C.A.S. #35523–89–8.

(2) The export of a ''medical product'' that is an ''Investigational New Drug'' (IND), as defined in 21 CFR 312.3, is subject to certain U.S. Food and Drug Administration (FDA) requirements that are independent of the export requirements specified in this ECCN or elsewhere in the EAR. These FDA requirements are described in 21 CFR 312.110 and must be satisfied in addition to any requirements specified in the EAR.

(3) Also see 21 CFR 314.410 for FDA requirements concerning exports of new drugs and new drug substances.

Related Definitions: For the purpose of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact. For the purpose of this entry, 'medical products' are: (1) Pharmaceutical formulations designed for testing and human (or veterinary) administration in the treatment of medical conditions, (2) prepackaged for distribution as clinical or medical products, and (3) approved by the U.S. Food and Drug Administration either to be marketed as clinical or medical products or for use as an ''Investigational New Drug'' (IND) (see 21 CFR part 312). For the purpose of this entry, 'diagnostic and food testing kits' are specifically developed, packaged and marketed for diagnostic or public health purposes. Biological toxins in any other configuration, including bulk shipments, or for any other end-uses are controlled by ECCN 1C351. For the purpose of this entry, 'vaccine' is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.

Items:

Technical Note: *For purposes of the controls described in this ECCN, 'toxins' refers to those toxins, or their subunits, controlled under ECCN 1C351.d.*

a. Vaccines containing, or designed for use against, items controlled by ECCN 1C351, 1C353 or 1C354.

b. Immunotoxins containing toxins controlled by 1C351.d;

c. Medical products that contain any of the following:

c.1. Toxins controlled by ECCN 1C351.d (*except for* botulinum toxins controlled by ECCN 1C351.d.3, conotoxins controlled by ECCN 1C351.d.6, or items controlled for CW reasons under ECCN 1C351.d.11 or .d.12); *or*

c.2. Genetically modified organisms or genetic elements controlled by ECCN 1C353.a.3 (*except for* those that contain, or code for, botulinum toxins controlled by ECCN 1C351.d.3 or conotoxins controlled by ECCN 1C351.d.6);

d. Medical products not controlled by 1C991.c that contain any of the following:

d.1. Botulinum toxins controlled by ECCN 1C351.d.3;

d.2. Conotoxins controlled by ECCN 1C351.d.6; *or*

d.3. Genetically modified organisms or genetic elements controlled by ECCN 1C353.a.3 that contain, or code for, botulinum toxins controlled by ECCN 1C351.d.3 or conotoxins controlled by ECCN 1C351.d.6;

e. Diagnostic and food testing kits containing toxins controlled by ECCN 1C351.d (*except for* items controlled for CW reasons under ECCN 1C351.d.11 or .d.12).

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

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COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 39 and 140

RIN 3038–AE65

Exemption From Derivatives Clearing Organization Registration

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (Commission) is adopting policies and procedures that the Commission will follow with respect to granting exemptions from registration as a derivatives clearing organization (DCO). In addition, the Commission is amending certain related delegation provisions in its regulations.

DATES: Effective February 8, 2021.

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SUPPLEMENTARY INFORMATION:

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