

interim staff guidance in the **Federal Register** (76 FR 1100) for public comment. Two comment letters were received and considered during the revision of the draft interim staff guidance. The guidance was also enhanced based on comments received on the proposed rule.

The interim staff guidance document describes methods acceptable to the NRC staff for implementing the new requirements in the Distribution of Source Material Rule. The approaches and methods described in the document are provided for information only. Methods and solutions different from those described in the document are acceptable if they meet the revised requirements. The guidance is provided in the form of questions and answers on the primary provisions of the Distribution of Source Material Rule. Guidance consistent with the revised 10 CFR part 40 will be incorporated into the next revision of relevant volumes of NUREG-1556, "Consolidated Guidance About Materials Licenses" (current ADAMS Accession Nos. ML022830847 and ML003681951).

Congressional Review Act

This interim staff guidance is a rule as designated in the Congressional Review Act of 1996 (5 U.S.C. 801-808). However, the Office of Management and Budget has not found it to be a major rule as designated in the Congressional Review Act.

Dated at Rockville, Maryland, this 30th day of May, 2013.

For the Nuclear Regulatory Commission.

Brian J. McDermott,

Director, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs.

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 740, 742, and 774

[Docket No. 120806310-2310-01]

RIN 0694-AF76

Implementation of the Understandings Reached at the 2012 Australia Group (AG) Plenary Meeting and the 2012 AG Intersessional Decisions; Changes to Select Agent Controls

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 understandings reached at the June 2012 plenary meeting of the Australia Group (AG) and the 2012 AG intersessional decisions. Specifically, this rule amends the Commerce Control List (CCL) entry in the EAR that controls human and zoonotic pathogens and "toxins" to reflect changes to the AG "List of Biological Agents for Export Control" that were made based on the understandings adopted at the June 2012 AG plenary meeting. These changes included the addition of three pathogens and clarifications to two other items. This rule also amends the CCL entry in the EAR that controls plant pathogens to reflect: The 2012 AG Plenary agreement to add five pathogens to the AG "List of Plant Pathogens for Export Control;" and the AG intersessional clarifications to six pathogens identified on this AG list. In addition, the CCL entry in the EAR that controls equipment capable of handling biological materials is amended to reflect the 2012 AG intersessional decision to add certain spray-drying equipment to the AG "Control List of Dual-Use Biological Equipment and Related Technology and Software." This rule also removes the CCL entry that controls select agents not identified on any of the AG common controls lists, but identified on the CCL because they are (or were, until recently) subject to controls maintained by the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, and the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, on their possession, use, and transfer within the United States. Rather than continuing to control these select agents in a separate CCL entry, this rule adds those select agents that remain subject to the CDC/APHIS controls (as well as a recent addition to the list of select agents) to the AG-related CCL entries that control human and zoonotic pathogens and "toxins" and plant pathogens, respectively.

DATES: This rule is effective June 5, 2013.

ADDRESSES: Send comments regarding this collection of information, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget (OMB), by email to Jasmeet_K_Seehra@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.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sangine, Director, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482-3343.

SUPPLEMENTARY INFORMATION:

Background

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the understandings reached at the Australia Group (AG) plenary meeting held in Paris, France, on June 12-15, 2012. This rule also implements the recommendations presented at the AG intersessional implementation meeting held in Ottawa, Canada, on February 14-16, 2012, and adopted pursuant to the AG silent approval procedure, which closed on March 23, 2012. The AG is a multilateral forum consisting of 40 participating countries 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.

June 2012 AG Plenary Changes

The June 2012 AG plenary meeting adopted understandings that affected the AG "List of Biological Agents for Export Control" and the AG "List of Plant Pathogens for Export Control."

This rule amends Export Control Classification Number (ECCN) 1C351 to reflect the AG plenary changes to the "List of Biological Agents for Export Control." Specifically, ECCN 1C351 (Human and zoonotic pathogens and "toxins") is amended by adding botulinum neurotoxin producing strains of the following bacteria to 1C351.c: *Clostridium argentinense* (formerly known as *Clostridium botulinum* Type G); *Clostridium baratii*; and *Clostridium butyricum*. ECCN 1C351.c is partially renumbered to control these bacteria under 1C351.c.8., .c.9, and .c.11, respectively, while the bacteria previously controlled under these subparagraphs (*Clostridium botulinum*; *Clostridium perfringens*, epsilon toxin producing types; and *Coxiella burnetii*) are now controlled under 1C351.c.10, .c.12, and .c.13, respectively. In addition, bacteria previously controlled under 1C351.c.12 through .c.17 are now controlled under 1C351.c.14 through

.c.16 (*Francisella tularensis*; *Rickettsia prowazekii*; and *Salmonella typhi*) and 1C351.c.18 through .c.20 (*Shigella dysenteriae*; *Vibrio cholerae*; and *Yersinia pestis*). Also note, with respect to ECCN 1C351.c.15 as amended by this rule, that the listing for the bacterium “*Rickettsia prowazekii* (a.k.a. *Rickettsia prowazekii*)” is amended to read “*Rickettsia prowazekii*,” consistent with the listing of this bacterium in the AG “List of Biological Agents for Export Control” and the commonly accepted spelling of this bacterium within the scientific community.

This rule also amends ECCN 1C351.c to clarify that the controls on “*Escherichia coli* and other verotoxin producing serotypes” apply to “*Shiga toxin producing Escherichia coli* (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups.” These bacteria are now controlled under 1C351.c.17. Prior to the publication of this rule and the partial renumbering of 1C351.c, these bacteria were controlled under 1C351.c.11. In addition, this rule amends 1C351.d.14 to clarify that the controls on “*Staphylococcus aureus* toxins” apply to “*Staphylococcus aureus enterotoxins*, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as *Staphylococcus enterotoxin F*).”

This rule amends ECCN 1C354 (Plant pathogens) to reflect the AG plenary changes to the “List of Plant Pathogens for Export Control.” Specifically, ECCN 1C354 is amended by adding the following five fungi to 1C354.b: *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*); *Sclerophthora rayssiae* var. *zeae*; *Synchytrium endobioticum*; *Tilletia indica*; and *Thecaphora solani*. These fungi are controlled under 1C354.b.7 through .b.11, respectively.

2012 AG Intersessional Changes

This rule also implements the recommendations presented at the AG intersessional implementation meeting held in February 2012 and adopted pursuant to the AG silent approval procedure. These recommendations included changes to the AG “List of Plant Pathogens for Export Control” and the AG “Control List of Dual-Use Biological Equipment and Related Technology and Software.” This rule amends ECCN 1C354 (Plant pathogens) to reflect the AG intersessional changes to the “List of Plant Pathogens for Export Control.” Specifically, ECCN 1C354.a (Bacteria) is amended to clarify that the controls for “*Xanthomonas campestris* pv. *citri*” in 1C354.a.2 apply to “*Xanthomonas axonopodis* pv. *citri*

(*Xanthomonas campestris* pv. *citri* A) (*Xanthomonas campestris* pv. *citri*)” and that the controls for “*Ralstonia solanacearum*” in 1C354.a.5 apply to “*Ralstonia solanacearum*, race 3, biovar 2.” This rule also amends ECCN 1C354.b (Fungi) to reorder the wording of the controls for “*Colletotrichum coffeanum* var. *virulans* (*Colletotrichum kahawae*)” in 1C354.b.1 to read “*Colletotrichum kahawae* (*Colletotrichum coffeanum* var. *virulans*).” In addition, this rule amends the controls for “*Puccinia graminis*” in 1C354.b.4 to clarify that they apply to “*Puccinia graminis* ssp. *graminis* var. *graminis*/*Puccinia graminis* ssp. *graminis* var. *stakmanii* (*Puccinia graminis* [syn. *Puccinia graminis* f. *tritici*])” and the controls for “*Magnaporthe grisea*” in 1C354.b.6 to clarify that they apply to “*Magnaporthe oryzae* (*Pyricularia oryzae*).” Furthermore, this rule amends 1C354.c to clarify the controls for “*Potato Andean latent tymovirus*” in 1C354.c.1 to read “*Andean potato latent virus* (*Potato Andean latent tymovirus*).”

In addition, this rule amends ECCN 2B352 (Equipment capable of use in handling biological materials) to reflect the AG intersessional changes to the “Control List of Dual-Use Biological Equipment and Related Technology and Software.” Specifically, this rule adds controls for certain spray-drying equipment under 2B352.f. Those items that were controlled under 2B352.f through .h, prior to the publication of this rule, are now controlled under 2B352.g through .i, respectively. ECCN 2B352.f, as revised by this rule, now controls spray-drying equipment capable of drying toxins or pathogenic microorganisms and having all of the following characteristics: (1) A water evaporation capacity of ≥ 0.4 kg/h and ≤ 400 kg/h; (2) the ability to generate a typical mean product particles size of ≤ 10 micrometers with existing fittings or by minimal modification of the spray-dryer with atomization nozzles enabling generation of the required particle size; and (3) capable of being sterilized or disinfected in situ.

Select Agent Changes to the CCL

This rule removes ECCN 1C360 (Select agents). This ECCN controlled select agents not included on any of the AG common controls lists that were identified on the CCL because they are (or were, until recently) subject to controls maintained by 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, on their possession, use, and transfer within the United States.

As a result of amendments by CDC to the list of “HHS select agents” in 42 CFR 73.3 and the list of “Overlap select agents and toxins” in 42 CFR 73.4 and amendments by APHIS to the list of “Plant Protection and Quarantine (PPQ) select agents and toxins” in 7 CFR 331.3 and the list of “Veterinary Services (VS) select agents and toxins” in 9 CFR 121.3, ten of the eighteen select agents that were listed in ECCN 1C360 are no longer included on the CDC/APHIS select agents lists. For this reason, as well as to assist exporters to more easily identify all of the select agents that are subject to the chemical/biological (CB) controls described in Section 742.2(a)(1) of the EAR (i.e., CB Column 1), BIS is removing ECCN 1C360 from the CCL and adding the select agents that were controlled by ECCN 1C360, and continue to be identified on the CDC/APHIS lists, to the appropriate AG-related ECCNs on the CCL (i.e., ECCNs 1C351 and 1C354). Prior to the publication of this rule, the CDC/APHIS select agents listed in these ECCNs included only those select agents that were also identified on one of the AG common control lists.

As a result of the changes described above, the following select agents that were controlled by ECCN 1C360 are no longer listed on the CCL: Central European tick-borne encephalitis viruses (i.e., Absettarov, Hanzalova, Hypr, and Kumlinge); Cercopithecine herpesvirus 1 (Herpes B virus); Flexal virus; Akabane virus; Bovine spongiform encephalopathy agent; Camel pox virus; Malignant catarrhal fever virus; Menangle virus; *Ehrlichia ruminantium* (a.k.a. *Cowdria ruminantium*); and *Xylella fastidiosa* pv. *citrus variegated chlorosis* (CVC).

Three select agents that were controlled under ECCN 1C360 and continue to be identified on the CDC/APHIS select agents lists are now controlled on the CCL, as follows: Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (now controlled under ECCN 1C351.b.1); *Rathayibacter toxicus* (now controlled under ECCN 1C354.a.6); and *Phoma glycinicola*, formerly *Pyrenochaeta glycinis* (now controlled under ECCN 1C354.b.12). None of these select agents are identified on any of the AG common control lists; however, they continue to be subject to CB controls (for those destinations indicated under CB Column 1 on the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR), as well as anti-terrorism

(AT) controls (for those destinations indicated under AT Column 1 on the Commerce Country Chart—Country Group E:1, in Supplement No. 1 to part 740 of the EAR, lists those countries designated as “terrorist-supporting countries” for purposes of the AT controls in the EAR).

In addition, three select agents that were controlled under ECCN 1C360, and continue to be identified on the APHIS select agents lists, have been added to the AG “List of Plant Pathogens for Export Control,” in accordance with the understandings reached at the 2012 AG Plenary (see the discussion of the 2012 AG Plenary changes, above). These select agents are now controlled on the CCL as follows: *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*) (now controlled under ECCN 1C354.b.7); *Sclerophthora rayssiae* var. *zeae* (now controlled under ECCN 1C354.b.8); and *Synchytrium endobioticum* (now controlled under ECCN 1C354.b.9). This rule also amends ECCN 1C354.a.3 to include the species of proteobacteria identified as *Xanthomonas oryzae*, which is identified on the APHIS list of PPQ select agents and toxins; however, only the pathovar *Xanthomonas oryzae* pv. *oryzae* (syn. *Pseudomonas campestris* pv. *oryzae*) is identified on the AG “List of Plant Pathogens for Export Control.” Like all other items controlled under ECCN 1C354, these select agents are subject to CB Column 1 controls, as well as AT Column 1 controls.

Furthermore, this rule eliminates redundant controls on two bacteria of the *Mycoplasma mycoides* cluster: *Mycoplasma capricolum* subspecies *capripneumoniae* and *Mycoplasma mycoides* subspecies *mycoides* small colony. These bacteria were identified under ECCN 1C360.b.2 and ECCN 1C352.b.1, prior to the publication of this rule, but are now controlled under ECCN 1C352.b.1, only. Both bacteria continue to be identified on the list of “VS Select Agents and Toxins” maintained by APHIS, as well as the AG “List of Plant Pathogens for Export Control.” Like all other items controlled under ECCN 1C352, these bacteria are subject to CB Column 1 controls, as well as AT Column 1 controls.

This rule also amends ECCN 1C351 by adding SARS-associated coronavirus (SARS-CoV) under 1C351.b.2 and tick-borne encephalitis virus (Siberian subtype) under 1C351.b.3. Both viruses were recently included in CDC’s list of “HHS select agents and toxins,” but are not identified on any of the AG common control lists. However, like all other items controlled under ECCN 1C351, these viruses are subject to CB Column

1 controls, as well as AT Column 1 controls. Another tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus) is controlled under ECCN 1C351.a.35 and is currently included in both CDC’s list of “HHS select agents and toxins” and the AG “List of Biological Agents for Export Control.” This rule amends ECCN 1C351.a.35 to reflect the current nomenclature (i.e., Far Eastern subtype) used by the International Committee on Taxonomy of Viruses.

In addition to the select agents changes described above, this rule makes conforming changes to Sections 740.20 and 742.2 of the EAR and to ECCNs 1C353, 1C991, 1E001 and 1E351 to reflect the removal of ECCN 1C360 from the CCL. Specifically, Section 740.20(b)(2)(v) is amended by removing two references to ECCN 1C360 from the description of biological items that are not eligible for License Exception Strategic Trade Authorization (STA). The items that were controlled under ECCN 1C360 and that remain on the CCL are now controlled under ECCN 1C351.a or .b, ECCN 1C352 or ECCN 1C354, all of which are identified in paragraph (b)(2)(v). Section 742.2(a)(1)(i) of the EAR is amended by removing the reference to ECCN 1C360 from the description of the license requirements that apply to items controlled for CB reasons to destinations indicated under CB Column 1 on the Commerce Country Chart. ECCN 1C353 is amended by removing references to ECCN 1C360 from the following: The Related Controls paragraph; paragraphs a.1. and b.1. in the Items paragraph under the List of Items Controlled; and Technical Note 3. ECCN 1C991 is amended by removing references to ECCN 1C360 from the fourth sentence of the Related Definitions paragraph and from paragraph a. in the Items paragraph under the List of Items Controlled. ECCN 1E001 is amended by removing the reference to ECCN 1C360 from the control language for “Country Chart—CB Column 1” in the License Requirements section. ECCN 1E351 is amended by removing references to ECCN 1C360 from the ECCN heading and from the controls language for “Country Chart—CB Column 1” in the License Requirements section.

Finally, this rule amends ECCNs 1C351, 1C352, 1C353, and 1C354 by revising the License Requirements Note(s) in the License Requirements section of each ECCN to add a note indicating that ECCNs 1C351, 1C352, 1C353, and 1C354 control all biological agents or “toxins,” regardless of quantity or attenuation, that are

identified in the List of Items Controlled for each ECCN (or, in the case of ECCN 1C353, genetic elements or genetically modified organisms for such agents or “toxins”), 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 APHIS or CDC, in accordance with the APHIS regulations in 7 CFR part 331 or 9 CFR part 121 or the CDC regulations in 42 CFR part 73. These changes do not affect the scope of ECCNs 1C351, 1C352, 1C353, and 1C354 and conform with the controls described in the AG common control lists and in the AG “Guidelines for Transfers of Sensitive Chemical or Biological Items,” neither of which provide an exemption from control for attenuated strains of biological agents or toxins. In conjunction with these changes, this rule amends the Related Controls paragraph in each of these four ECCNs to add a sentence referencing 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are subject to the export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.

Effect of This Rule on the Scope of the CB Controls in the EAR

The changes made by this rule only marginally affect the scope of the EAR controls on biological agents and toxins. With the removal of ECCN 1C360 from the CCL, ten select agents that were controlled under this ECCN prior to the publication of this rule are no longer identified on the CCL and are classified as EAR99, instead. All of these select agents were recently removed from the CDC/APHIS select agents lists. In addition, six other select agents that were controlled under ECCN 1C360 have been moved to ECCN 1C351 or ECCN 1C354 and continue to require a license for CB reasons to destinations indicated under CB Column 1 on the Commerce Country Chart and for AT reasons to destinations indicated under AT Column 1—all of these select agents continue to be identified on the CDC/APHIS select agents lists. Two additional select agents (*Mycoplasma capricolum* subspecies *capripneumoniae* and *Mycoplasma mycoides* subspecies *mycoides* small colony) also were controlled under ECCN 1C360 and continue to be identified on the CDC/APHIS select agents lists. As indicated above, this rule did not add these select agents to ECCN 1C352 because they were already described in ECCN 1C352.b.1 (i.e., the ECCN 1C360 controls on these select agents duplicated the controls in ECCN

1C352). This rule also adds two viruses that were recently included in CDC's list of "HHS select agents and toxins" (i.e., SARS-associated coronavirus and tick-borne encephalitis virus, Siberian subtype) to ECCN 1C351.b.

Based on the understandings reached at the June 2012 AG Plenary meeting, this rule also adds three bacteria to ECCN 1C351 and two fungi to ECCN 1C354, none of which were identified on the CCL prior to the publication of this rule. The AG Plenary also added three additional fungi to the "List of Plant Pathogens for Export Control," but these fungi were already controlled under ECCN 1C360, based on their inclusion by APHIS on the list of PPQ select agents and toxins (7 CFR part 331), and are now controlled under ECCN 1C354 (i.e., these fungi are among the six select agents that have been moved by this rule from ECCN 1C360 to ECCN 1C351 or ECCN 1C354, as indicated above).

To summarize the biological agent and toxin changes described above, this rule removes ten CDC/APHIS select agents from the CCL, while adding three AG-listed bacteria and two fungi, as well as two viruses that were recently identified on CDC's list of "HHS select agents and toxins." These changes are not expected to significantly affect the scope of the EAR controls on biological agents and toxins, because BIS estimates that there will be no increase in the number of license applications for these items.

Finally, this rule expands the scope of the EAR controls that apply to dual-use equipment capable of handling biological materials by amending ECCN 2B352 to add certain spray-drying equipment. This change is not expected to significantly affect the scope of the EAR controls on such equipment, because BIS anticipates only a small increase in the number of license applications.

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 15, 2012, 77 FR 49699 (August 16, 2012), has continued the EAR in effect under the International Emergency Economic Powers Act.

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, of reducing costs, of harmonizing rules, and of 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.

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 a collection of information subject to the requirements of the PRA. This collection has been approved by OMB under Control Number 0694-0088 (Multi-Purpose Application), which carries a burden hour estimate of 58 minutes to prepare and submit form BIS-748. 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 (OMB), and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, as indicated in the ADDRESSES section of this rule.

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

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (See 5 U.S.C. 553(a)(1)). Immediate implementation of these amendments is non-discretionary and fulfills the United States' international obligation to the Australia Group (AG). The AG contributes to international security and regional stability through the harmonization of export controls and seeks to ensure that exports do not contribute to the development of chemical and biological weapons. The AG consists of 40 member countries that act on a consensus basis and the

amendments set forth in this rule implement the understandings reached at the June 2012 AG plenary meeting, the 2012 AG intersessional changes, and other changes that are necessary to ensure consistency with the controls maintained by the AG. Since the United States is a significant exporter of the items in this rule, immediate implementation of this provision is necessary for the AG to achieve its purpose. Any delay in implementation will create a disruption in the movement of affected items globally because of disharmony between export control measures implemented by AG members, resulting in tension between member countries. Export controls work best when all countries implement the same export controls in a timely and coordinated manner.

Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are not applicable. Therefore, this regulation is issued in final form.

List of Subjects

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, parts 740, 742, and 774 of the Export Administration Regulations (15 CFR parts 730-774) are amended as follows:

PART 740—[AMENDED]

■ 1. The authority citation for 15 CFR Part 740 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 15, 2012, 77 FR 49699 (August 16, 2012).

■ 2. Section 740.20 is amended by revising paragraph (b)(2)(v) to read as follows:

§ 740.20 License Exception Strategic Trade Authorization (STA).

* * * * *
(b) * * *
(2) * * *

(v) License Exception STA may not be used for any item controlled by ECCN 1C351.a, .b, .c, d.11, .d.12 or .e, ECCNs 1C352, 1C353, 1C354, 1E001 (i.e., for technology, as specified in ECCN 1E001, for items controlled by ECCN 1C351.a, .b, .c, .d.11, .d.12 or .e or ECCNs 1C352, 1C353, or 1C354) or ECCN 1E351.

PART 742—[AMENDED]

■ 3. The authority citation for 15 CFR Part 742 continues to read as follows:

Authority: 50 U.S.C. app. 2401 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 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 15, 2012, 77 FR 49699 (August 16, 2012); Notice of November 9, 2011, 76 FR 70319 (November 10, 2011).

§ 742.2 [Amended]

■ 4. Section 742.2 is amended by removing the phrase “ECCNs 1C351, 1C352, 1C353, 1C354, and 1C360” in paragraph (a)(1)(i) and adding in its place the phrase “ECCNs 1C351, 1C352, 1C353, and 1C354”.

PART 774—[AMENDED]

■ 5. The authority citation for 15 CFR Part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 et seq.; 50 U.S.C. 1701 et seq.; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 et seq., 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 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; Notice of August 15, 2012, 77 FR 49699 (August 16, 2012).

Supplement No. 1 to Part 774—[Amended]

■ 6. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, “Microorganisms” and “Toxins,” ECCN 1C351 is amended by adding a new Note 4 in the “License Requirements Notes” under the License Requirements section, by revising the “Related Controls” paragraph under the List of

Items Controlled section, and, in the “Items” paragraph under the List of Items Controlled section, by revising the heading of paragraph a., by revising paragraph a.35, by adding a new paragraph b., by revising paragraph c., by revising the heading of paragraph d., and by revising paragraph d.14 to read as follows:

1C351 Human and zoonotic pathogens and “toxins”, as follows (see List of Items Controlled).

License Requirements

* * * * *
License Requirement Notes: * * *

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, or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, in accordance with their regulations in 9 CFR part 121 and 42 CFR part 73, respectively.

List of Items Controlled
Unit: * * *

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 export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls. (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 export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.

Related Definitions: * * *
Items:

- a. Viruses identified on the Australia Group (AG) “List of Biological Agents for Export Control,” as follows:
* * * * *
a.35. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian

Spring-Summer encephalitis virus—see 1C351.b.3 for Siberian subtype);
* * * * *

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 Biological Agents for Export Control,” as follows:

b.1. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments;

b.2. SARS-associated coronavirus (SARS-CoV); or

b.3. Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus—see 1C351.a.35 for Far Eastern subtype).

c. Bacteria identified on the Australia Group (AG) “List of Biological Agents 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. Chlamydomyces psittaci (formerly known as Chlamydomyces psittaci);

c.8. Clostridium 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. Rickettsia prowazekii;

c.16. Salmonella typhi;

c.17. 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) is also known as enterohaemorrhagic E. coli (EHEC) or verocytotoxin producing E. coli (VTEC).

c.18. Shigella dysenteriae;

c.19. Vibrio cholerae; or

c.20. Yersinia pestis.

d. “Toxins” identified on the Australia Group (AG) “List of Biological Agents for Export Control,” as follows, and “subunits” thereof:

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

* * * * *

■ 7. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, “Microorganisms” and “Toxins,” ECCN 1C352 is amended by revising the “License Requirement Note” under the License Requirements section and by

revising the “Related Controls” paragraph under the List of Items Controlled section to read as follows:

1C352 Animal pathogens, as follows (see List of Items Controlled).

License Requirements

* * * * *

License Requirements Notes:

1. All vaccines are excluded from the scope of this ECCN. See ECCN 1C991 for vaccines.

2. Unless specified elsewhere in this ECCN 1C352 (e.g., in License Requirement Note 1), this ECCN controls all biological agents, 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 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, or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, in accordance with their regulations in 9 CFR part 121 and 42 CFR part 73, respectively.

* * * * *

List of Items Controlled

Unit: * * *

Related Controls: (1) 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)). (2) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are subject to the export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.

Related Definitions: * * *

Items:

* * * * *

■ 8. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, “Microorganisms” and “Toxins,” ECCN 1C353 is amended, under the License Requirements section, by revising the “License Requirements Note” and, under the List of Items Controlled section, by revising the “Related Controls” paragraph, by revising paragraphs a.1. and b.1. in the “Items” paragraph, and by revising Technical Note 3, to read as follows:

1C353 Genetic elements and genetically modified organisms, as follows (see List of Items Controlled).

License Requirements

* * * * *

License Requirements Notes:

1. Vaccines that contain genetic elements or genetically modified organisms identified in this ECCN are controlled by ECCN 1C991.

2. Unless specified elsewhere in this ECCN 1C353 (e.g., in License Requirement Note 1), this ECCN controls genetic elements or genetically modified organisms for all biological agents and “toxins,” regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including genetic elements or genetically modified organisms for 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, or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, in accordance with the APHIS regulations in 7 CFR part 331 and 9 CFR part 121 and the CDC regulations in 42 CFR part 73.

* * * * *

List of Items Controlled

Unit: * * *

Related Controls: (1) 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, including (but not limited to) certain genetic elements, recombinant nucleic acids, and recombinant organisms associated with the agents or toxins in ECCN 1C351, 1C352, or 1C354 (for APHIS, see 7 CFR 331.3(c), 9 CFR 121.3(c), and 9 CFR 121.4(c); for CDC, see 42 CFR 73.3(c) and 42 CFR 73.4(c)). (2) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are subject to the export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.

Related Definition: * * *

Items:

- a. * * *
- a.1. Genetic elements that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a to .c, 1C352, or 1C354;
- a.2. * * *
- b. * * *
- b.1. Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a to .c, 1C352, or 1C354;
- b.2. * * *

Technical Notes:

* * * * *

3. “Nucleic acid sequences associated with the pathogenicity of any of the microorganisms controlled by 1C351.a to .c, 1C352, or 1C354” means any sequence specific to the relevant controlled microorganism that:

- a. In itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health; or
- b. Is known to enhance the ability of a microorganism controlled by 1C351.a to .c,

1C352, or 1C354, or any other organism into which it may be inserted or otherwise integrated, to cause serious harm to human, animal or plant health.

* * * * *

■ 9. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, “Microorganisms” and “Toxins,” ECCN 1C354 is amended by revising the “License Requirements Note” under the License Requirements section and by revising the “Related Controls” paragraph and the “Items” paragraph under the List of Items Controlled section to read as follows:

1C354 Plant pathogens, as follows (see List of Items Controlled).

License Requirements

* * * * *

License Requirements Notes:

1. All vaccines are excluded from the scope of this ECCN. See ECCN 1C991 for vaccines.

2. Unless specified elsewhere in this ECCN 1C354 (e.g., in License Requirement Note 1), this ECCN controls all biological agents, 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 that are excluded from the list of PPQ select agents and “toxins” by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, in accordance with their regulations in 7 CFR part 331.

* * * * *

List of Items Controlled

Unit: * * *

Related Controls: (1) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, maintains controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (see 7 CFR 331.3(c), 9 CFR 121.3(c), and 9 CFR 121.4(c)). (2) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are subject to the export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.

Related Definition: * * *

Items:

- a. Bacteria, as follows:
- a.1. *Xanthomonas albilineans*;
- a.2. *Xanthomonas axonopodis* pv. *citri* (*Xanthomonas campestris* pv. *citri* A) (*Xanthomonas campestris* pv. *citri*);
- a.3. *Xanthomonas oryzae* [this species of proteobacteria is identified on the APHIS “select agents” list (see Related Controls paragraph for this ECCN), but only the pathovar *Xanthomonas oryzae* pv. *oryzae* (syn. *Pseudomonas campestris* pv. *oryzae*) is identified on the Australia Group (AG) “List of Plant Pathogens for Export Control”];
- a.4. *Clavibacter michiganensis* subspecies *sepedonicus* (syn. *Corynebacterium michiganensis* subspecies *sepedonicum* or *Corynebacterium sepedonicum*);

a.5. *Ralstonia solanacearum*, race 3, biovar 2;

a.6. *Raythayibactor toxicus* [this bacterium is identified on the APHIS "select agents" list (see the Related Controls paragraph for this ECCN), but is not identified on the Australia Group (AG) "List of Plant Pathogens for Export Control"].

b. Fungi, as follows:

b.1. *Colletotrichum kahawae*

(*Colletotrichum coffeanum* var. *virulans*);

b.2. *Cochliobolus miyabeanus*

(*Helminthosporium oryzae*);

b.3. *Microcyclus ulei* (syn. *Dothidella ulei*);

b.4. *Puccinia graminis* ssp. *graminis* var. *graminis*/*Puccinia graminis* ssp. *graminis* var. *stakmanii* (*Puccinia graminis* [syn. *Puccinia graminis* f. sp. *tritici*]);

b.5. *Puccinia striiformis* (syn. *Puccinia glumarum*);

b.6. *Magnaporthe oryzae* (*Pyricularia oryzae*);

b.7. *Peronosclerospora philippinensis*

(*Peronosclerospora sacchari*);

b.8. *Sclerophthora rayssiae* var. *zeae*;

b.9. *Synchytrium endobioticum*;

b.10. *Tilletia indica*;

b.11. *Thecaphora solani*;

b.12. *Phoma glycinicola* (formerly *Pyrenochaeta glycinis*) [this fungus is identified on the APHIS "select agents" list (see the Related Controls paragraph for this ECCN), but is not identified on the Australia Group (AG) "List of Plant Pathogens for Export Control"].

c. Viruses, as follows:

c.1. Andean potato latent virus (Potato Andean latent tymovirus);

c.2. Potato spindle tuber viroid.

■ 10. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, "Microorganisms" and "Toxins," ECCN 1C360 is removed.

■ 11. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, "Microorganisms" and "Toxins," ECCN 1C991 is amended under the List of Items Controlled section by revising the fourth sentence in the "Related Definitions" paragraph and by revising paragraph a. in the "Items" paragraph to read as follows:

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

* * * * *

List of Items Controlled
Unit: * * *
Related Controls: * * *
Related Definitions: * * * Biological toxins in any other configuration, including bulk shipments, or for any other end-uses are controlled by ECCN 1C351. * * *

Items:
a. Vaccines against items controlled by ECCN 1C351, 1C352, 1C353 or 1C354.
* * * * *

■ 12. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, "Microorganisms" and "Toxins," ECCN 1E001 is amended by revising the ECCN heading and by revising the "Control(s)" language for "Country Chart—CB Column 1" in the License Requirements section to read as follows:

1E001 "Technology" according to the General Technology Note for the "Development" or "Production" of items controlled by 1A001.b, 1A001.c, 1A002, 1A003, 1A004, 1A005, 1A006.b, 1A007, 1A008, 1A101, 1B (except 1B999), or 1C (except 1C355, 1C980 to 1C984, 1C988, 1C990, 1C991, 1C995 to 1C999).

License Requirements

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

Table with 2 columns: Control(s), Country chart. Row 1: CB applies to "technology" for items controlled by 1C351, 1C352, 1C353, or 1C354. Row 2: License Requirements Note: * * *

■ 13. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Special Materials and Related Equipment, Chemicals, "Microorganisms" and "Toxins," ECCN 1E351 is amended by revising the ECCN heading and by revising the "Control(s)" language for "Country Chart—CB Column 1" in the License Requirements section to read as follows:

1E351 "Technology" according to the General Technology Note for the disposal of chemicals or microbiological materials controlled by 1C350, 1C351, 1C352, 1C353, or 1C354.

License Requirements

Reason for Control: CB, AT

Table with 2 columns: Control(s), Country chart. Row 1: CB applies to "technology" for the disposal of items controlled by 1C351, 1C352, 1C353, or 1C354. Row 2: License Requirements Note: * * *

■ 14. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2—Materials Processing, ECCN 2B352 is amended under the "Items" paragraph in the List of Items Controlled section by redesignating paragraphs f. through h. as paragraphs g. through i.,

respectively, and adding a new paragraph f. to read as follows:

2B352 Equipment capable of use in handling biological materials, as follows (see List of Items Controlled).

* * * * *
List of Items Controlled
Unit: * * *
Related Controls: * * *
Related Definitions: * * *
Items:

* * * * *
f. Spray-drying equipment capable of drying toxins or pathogenic microorganisms having all of the following characteristics:
f.1. A water evaporation capacity of ≥ 0.4 kg/h and ≤ 400 kg/h;
f.2. The ability to generate a typical mean product particle size of ≤ 10 micrometers with existing fittings or by minimal modification of the spray-dryer with atomization nozzles enabling generation of the required particle size; and
f.3. Capable of being sterilized or disinfected in situ.
* * * * *

Dated: May 29, 2013.
Kevin J. Wolf,
Assistant Secretary for Export Administration.

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BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Dexmedetomidine; Lasalocid; Melengestrol; Monensin; and Tylosin; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Correcting amendments.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document amending the animal drug regulations to reflect approval actions for new animal drug applications and abbreviated new animal drug applications during March 2013 that appeared in the Federal Register of April 30, 2013. FDA is correcting the approved strengths of dexmedetomidine hydrochloride injectable solution. This correction is being made to improve the accuracy of the animal drug regulations.

DATES: This rule is effective June 5, 2013.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug