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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 738, 740, 745 and 774

[Docket No. 170306234-7234-01]

RIN 0694-AH37

Implementation of the February 2017 Australia Group (AG) Intersessional Decisions and the June 2017 AG Plenary Understandings; Addition of India to the AG

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 recommendations presented at the February 2017 Australia Group (AG) Intersessional Implementation Meeting, and later adopted

pursuant to the AG silent approval procedure, and the recommendations made at the June 2017 AG Plenary Implementation Meeting and adopted by the AG Plenary. This rule amends the following Export Control Classification Numbers (ECCNs) on the Commerce Control List (CCL) to reflect the February 2017 Intersessional Implementation Meeting recommendations that were adopted by the AG: ECCN 2B350 (by adding certain prefabricated repair assemblies, and specially designed components therefor, that are designed for attachment to glass-lined reaction vessels, reactors, storage tanks, containers or receivers controlled by this entry); ECCN 2B351 (by clarifying that toxic gas monitoring equipment includes toxic gas monitors and monitoring systems, as well as their dedicated detecting components); and ECCN 2B352 (by adding certain nucleic acid assemblers and synthesizers to this entry and clarifying how the capacity of certain fermenters should be measured for purposes of determining whether they are controlled under this entry).

Consistent with the June 2017 AG Plenary Implementation Meeting recommendations that were adopted by the AG, this rule amends the following ECCNs on the CCL: ECCN 1C353 (to clarify that genetically modified organisms include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation and that inactivated organisms containing recoverable nucleic acids are considered to be genetic elements) and ECCN 1C350 (by adding N,N-Diisopropylaminoethanethiol hydrochloride). This rule also corrects several typographical errors in a note to ECCN 1C351 and updates the advance notification requirements in the EAR that apply to certain exports of saxitoxin. Finally, this rule amends the EAR to reflect the addition of India as a participating country in the AG.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the recommendations presented at the Australia Group (AG) Intersessional Implementation Meeting held in Buenos Aires, Argentina, on February 15, 2017, and adopted pursuant to the AG silent approval procedure in April 2017, and the recommendations presented at the Implementation Meeting of the 2017 AG Plenary held in Paris, France, from June 26-30, 2017, and adopted by the AG Plenary. This rule also amends the EAR to reflect the addition of India as a participating country in the AG, as of January 19, 2018. 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.

Amendments to the CCL based on the February 2017 AG Intersessional Recommendations

ECCN 2B350 (chemical manufacturing facilities and equipment)

This final rule amends ECCN 2B350 on the CCL to reflect changes to the AG “Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology and Software” based on the February 2017 Intersessional Implementation Meeting recommendations that were adopted by the AG pursuant to its silent approval procedure. Specifically, this rule amends ECCN 2B350 to control prefabricated repair assemblies, and their specially designed components, that: (1) are designed for mechanical attachment to glass-lined reaction vessels and reactors controlled under 2B350.a or glass-lined storage tanks, containers and receivers controlled under 2B350.c; and (2) have metallic surfaces that are made from tantalum or tantalum alloys and come in direct contact with the chemical(s) being processed. These assemblies and components were added to the AG chemical manufacturing facilities and equipment common control list, because they are capable of being used to prolong the life, or even allow the recommissioning, of glass-lined reactors and storage tanks that are suitable for use in the production of chemical weapons (CW) agents or AG-listed precursor chemicals.

All items controlled under ECCN 2B350 continue to require a license for chemical/biological (CB) reasons to destinations indicated in CB Column 2 on the Commerce Country Chart (see

Supplement No. 1 to part 738 of the EAR) and for anti-terrorism (AT) reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

ECCN 2B351 (toxic gas monitors and monitoring systems)

This final rule amends ECCN 2B351 on the CCL to reflect changes to the AG “Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology and Software” based on the February 2017 Intersessional Implementation Meeting recommendations that were adopted by the AG pursuant to its silent approval procedure. Specifically, this rule amends ECCN 2B351 to clarify that this entry controls toxic gas monitors and monitoring systems, and their dedicated detecting components (i.e., detectors, sensor devices, and replaceable sensor cartridges), having either of the following characteristics: (1) designed for continuous operation and usable for the detection of chemical warfare agents or precursor chemicals controlled by ECCN 1C350 at concentrations of less than 0.3 mg/m³; or (2) designed for the detection of cholinesterase-inhibiting activity. The decision to specifically identify toxic gas monitors, in addition to toxic gas monitoring systems, on the AG chemical manufacturing facilities and equipment common control list is based on the fact that certain portable toxic gas monitors (e.g., small handheld detectors) are capable of satisfying the technical control criteria applicable to toxic gas monitoring systems and, as such, may also be suitable for use in a CW production or storage facility. This rule also amends related “software” controls in ECCN 2D351 to reflect the updates to ECCN 2B351 described above.

All items controlled under ECCN 2B351 continue to require a license for CB reasons to destinations indicated in CB Column 2 on the Commerce Country Chart and for AT reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

ECCN 2B352 (equipment capable of use in handling biological materials)

This final rule amends ECCN 2B352 on the CCL to reflect changes to the AG “Control List of Dual-Use Biological Equipment and Related Technology and Software” based on the February 2017 Intersessional Implementation Meeting recommendations that were adopted by the AG pursuant to its silent approval procedure. Specifically, this rule amends ECCN 2B352 to indicate that the “total internal volume” of a fermenter must be measured to determine whether its capacity meets the control level of “20 liters or greater” specified in 2B352.b.1. This clarification was made to ensure that all AG participating countries apply the same criterion to measure capacity for purposes of determining whether a fermenter is subject to control.

This rule also amends ECCN 2B352 by adding a new paragraph .j to control nucleic acid assemblers and synthesizers that are both: (1) partly or entirely automated; and (2) designed to generate continuous nucleic acids greater than 1.5 kilobases in length with error rates less than 5% in a single run. These items were added to the AG dual-use biological equipment common control list because they are capable of being used to generate pathogens and toxins without the need to acquire controlled genetic elements and organisms.

All items controlled under ECCN 2B352 continue to require a license for CB reasons to destinations indicated in CB Column 2 on the Commerce Country Chart and for AT reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

Amendments to the CCL based on the June 2017 AG Plenary Understandings

ECCN 1C350 (precursor chemicals)

This final rule amends ECCN 1C350 to reflect updates to the AG “Chemical Weapons Precursors” control list adopted at the June 2017 AG Plenary meeting. Specifically, this rule amends ECCN 1C350.b by adding the precursor chemical hydrochloride salt (C.A.S. #41480-75-5) N,N-Diisopropylaminoethanethiol hydrochloride. This rule also alphabetically reorders the precursor chemicals listed in ECCN 1C350.b, .c, and .d to facilitate the identification of these chemicals. The precursor chemicals affected by these amendments to ECCN 1C350 are indicated in the following table.

| AG-Controlled Precursor Chemicals | Previous CCL Designation | Current CCL Designation |
|--|---------------------------------|--------------------------------|
| (C.A.S. #683-08-9) Diethyl methylphosphonate | ECCN 1C350.b.22 | ECCN 1C350.b.4 |
| (C.A.S. #15715-41-0) Diethyl methylphosphonite | ECCN 1C350.b.4 | ECCN 1C350.b.5 |

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| (C.A.S. #2404-03-7) Diethyl-N,N-dimethylphosphoramidate | ECCN 1C350.b.5 | ECCN 1C350.b.6 |
| (C.A.S. #41480-75-5) N,N-Diisopropylaminoethanethiol hydrochloride | NONE – EAR 99 | ECCN 1C350.b.7 |
| (C.A.S. #5842-07-9) N,N-Diisopropyl-beta-aminoethane thiol | ECCN 1C350.b.6 | ECCN 1C350.b.8 |
| (C.A.S. #96-80-0) N,N-Diisopropyl-beta-aminoethanol | ECCN 1C350.b.8 | ECCN 1C350.b.9 |
| (C.A.S. #96-79-7), N,N-Diisopropyl-beta-aminoethyl chloride | ECCN 1C350.b.9 | ECCN 1C350.b.10 |
| (C.A.S. #4261-68-1) N,N-Diisopropyl-beta-aminoethyl chloride hydrochloride | ECCN 1C350.b.7 | ECCN 1C350.b.11 |
| (C.A.S. #6163-75-3) Dimethyl ethylphosphonate | ECCN 1C350.b.10 | ECCN 1C350.b.12 |
| (C.A.S. #756-79-6) Dimethyl methylphosphonate | ECCN 1C350.b.11 | ECCN 1C350.b.13 |
| (C.A.S. #677-43-0) N,N-Dimethylamino-phosphoryl dichloride | ECCN 1C350.b.23 | ECCN 1C350.b.14 |
| (C.A.S. #1498-40-4) Ethyl phosphonous dichloride [Ethyl phosphinyl dichloride] | ECCN 1C350.b.12 | ECCN 1C350.b.15 |

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|---|-----------------|-----------------|
| (C.A.S. #430-78-4) Ethyl phosphorus difluoride [Ethyl phosphinyl difluoride] | ECCN 1C350.b.13 | ECCN 1C350.b.16 |
| (C.A.S. #1066-50-8) Ethyl phosphonyl dichloride | ECCN 1C350.b.14 | ECCN 1C350.b.17 |
| (C.A.S. #993-13-5) Methylphosphonic acid | ECCN 1C350.b.21 | ECCN 1C350.b.18 |
| (C.A.S. #676-98-2) Methylphosphonothioic dichloride | ECCN 1C350.b.24 | ECCN 1C350.b.19 |
| (C.A.S. #464-07-3) Pinacolyl alcohol | ECCN 1C350.b.18 | ECCN 1C350.b.20 |
| (C.A.S. #1619-34-7) 3-Quinuclidinol | ECCN 1C350.b.19 | ECCN 1C350.b.21 |
| (C.A.S. #111-48-8) Thiodiglycol | ECCN 1C350.b.20 | ECCN 1C350.b.22 |
| (C.A.S. #139-87-7) Ethyldiethanolamine | ECCN 1C350.c.12 | ECCN 1C350.c.3 |
| (C.A.S. #10025-87-3) Phosphorus oxychloride | ECCN 1C350.c.3 | ECCN 1C350.c.4 |
| (C.A.S. #10026-13-8) Phosphorus pentachloride | ECCN 1C350.c.4 | ECCN 1C350.c.5 |
| (C.A.S. #7719-12-2) Phosphorus trichloride | ECCN 1C350.c.5 | ECCN 1C350.c.6 |
| (C.A.S. #10025-67-9) Sulfur monochloride | ECCN 1C350.c.6 | ECCN 1C350.c.8 |
| (C.A.S. #7719-09-7) Thionyl chloride | ECCN 1C350.c.8 | ECCN 1C350.c.9 |
| (C.A.S. #102-71-6) Triethanolamine | ECCN 1C350.c.9 | ECCN 1C350.c.10 |

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| (C.A.S. #122-52-1) Triethyl phosphite | ECCN 1C350.c.10 | ECCN 1C350.c.11 |
| (C.A.S. #121-45-9) Trimethyl phosphite | ECCN 1C350.c.11 | ECCN 1C350.c.12 |
| (C.A.S. #109-89-7) Diethylamine | ECCN 1C350.d.25 | ECCN 1C350.d.3 |
| (C.A.S. #100-37-8) N,N-Diethylaminoethanol | ECCN 1C350.d.3 | ECCN 1C350.d.4 |
| (C.A.S. #298-06-6) O,O-Diethyl phosphorodithioate | ECCN 1C350.d.23 | ECCN 1C350.d.5 |
| (C.A.S. #2465-65-8) O,O-Diethyl phosphorothioate | ECCN 1C350.d.22 | ECCN 1C350.d.6 |
| (C.A.S. #108-18-9) Di-isopropylamine | ECCN 1C350.d.4 | ECCN 1C350.d.7 |
| (C.A.S. #124-40-3) Dimethylamine | ECCN 1C350.d.5 | ECCN 1C350.d.8 |
| (C.A.S. #506-59-2) Dimethylamine hydrochloride | ECCN 1C350.d.6 | ECCN 1C350.d.9 |
| (C.A.S. #7664-39-3) Hydrogen fluoride | ECCN 1C350.d.7 | ECCN 1C350.d.10 |
| (C.A.S. #3554-74-3) 3-Hydroxyl-1-methylpiperidine | ECCN 1C350.d.8 | ECCN 1C350.d.11 |
| (C.A.S. #76-89-1) Methyl benzilate | ECCN 1C350.d.9 | ECCN 1C350.d.12 |
| (C.A.S. #1314-80-3) Phosphorus pentasulfide | ECCN 1C350.d.10 | ECCN 1C350.d.13 |
| (C.A.S. #75-97-8) Pinacolone | ECCN 1C350.d.11 | ECCN 1C350.d.14 |
| (C.A.S. #7789-29-9) Potassium bifluoride | ECCN 1C350.d.14 | ECCN 1C350.d.15 |
| (C.A.S. #151-50-8) Potassium cyanide | ECCN 1C350.d.12 | ECCN 1C350.d.16 |

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| (C.A.S. #7789-23-3) Potassium fluoride | ECCN 1C350.d.13 | ECCN 1C350.d.17 |
| (C.A.S. #3731-38-2) 3-Quinuclidone | ECCN 1C350.d.15 | ECCN 1C350.d.18 |
| (C.A.S. #1333-83-1) Sodium bifluoride | ECCN 1C350.d.16 | ECCN 1C350.d.19 |
| (C.A.S. #143-33-9) Sodium cyanide | ECCN 1C350.d.17 | ECCN 1C350.d.20 |
| (C.A.S. #7681-49-4) Sodium fluoride | ECCN 1C350.d.18 | ECCN 1C350.d.21 |
| (C.A.S. #16893-85-9) Sodium hexafluorosilicate | ECCN 1C350.d.24 | ECCN 1C350.d.22 |
| (C.A.S. #1313-82-2) Sodium sulfide | ECCN 1C350.d.19 | ECCN 1C350.d.23 |
| (C.A.S. #637-39-8) Triethanolamine hydrochloride | ECCN 1C350.d.20 | ECCN 1C350.d.24 |
| (C.A.S. #116-17-6) Tri-isopropyl phosphite | ECCN 1C350.d.21 | ECCN 1C350.d.25 |

All items controlled under ECCN 1C350 continue to require a license for CB reasons to destinations indicated in CB Column 2 on the Commerce Country Chart and for AT reasons to countries listed in Country Group E:1 (see Supplement No. 1 to part 740 of the EAR). In addition, items controlled under 1C350.b or .c require a license to certain destinations for chemical weapons (CW) reasons, as described in the License Requirements section of ECCN 1C350 and in Section 742.18 of the EAR.

ECCN 1C353 (genetic elements and genetically modified organisms)

This final rule amends ECCN 1C353 on the CCL to reflect updates to the AG controls on certain genetic elements and genetically modified organisms adopted at the June 2017 AG Plenary meeting. Specifically, this rule amends ECCN 1C353 to control any genetically modified organism that contains, or any genetic element that codes for: (1) any gene or genes specific to any virus controlled by ECCN 1C351.a or .b or 1C354.c; (2) any gene or genes specific to any bacterium controlled by ECCN 1C351.c or 1C354.a, or any fungus controlled by ECCN 1C351.e or 1C354.b, and which in itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health or could endow or enhance pathogenicity; or (3) any toxins, or their subunits, controlled by ECCN 1C351.d.

In addition, this rule amends the Technical Notes to ECCN 1C353 to clarify that “genetically modified organisms include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation” (see Technical Note 1 to ECCN 1C353, as amended by this rule) and that inactivated organisms containing recoverable nucleic acids are considered to be genetic elements, whether genetically modified or unmodified, or chemically synthesized in whole or in part (see Technical Note 2 to ECCN 1C353, as amended by this rule). Technical Note 3 to ECCN 1C353, as amended by this rule, states that this ECCN does not control nucleic acid sequences of shiga toxin producing *Escherichia coli* of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups, other than those genetic elements coding for shiga toxin, or for its subunits.

This rule also defines the term “endow or enhance pathogenicity,” for purposes of the controls in ECCN 1C353 (see Technical Note 4 to ECCN 1C353, as amended by this rule), as when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism’s ability to be used to deliberately cause disease or death. This might include alterations to, inter alia: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability.

All items controlled under ECCN 1C353 continue to require a license for CB reasons to destinations indicated in CB Column 1 on the Commerce Country Chart and for AT reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

Amendments to the EAR to reflect the addition of India to the AG

This rule makes conforming amendments to the EAR to reflect the addition of India to the AG, as of January 19, 2018. Specifically, this rule amends the entry for India in the Commerce Country Chart (Supplement No. 1 to part 738 of the EAR) by removing the “X” from this entry under the column CB 2. In addition, this rule amends the Country Groups chart (Supplement No. 1 to part 740 of the EAR) by adding an “X” to the entry for India under column A:3, Australia Group.

Corrections to ECCN 1C351 (human and animal pathogens and “toxins”)

This final rule amends ECCN 1C351 on the CCL by removing several outdated references to former ECCN 1C352 in the Note that follows 1C351.a.4, which describes avian influenza (AI) viruses subject to control under this ECCN, and adding in their place references to the relevant AI controls described in 1C351.a.4. These corrections do not affect the scope of the items subject to control under this ECCN or the license requirements applicable to these items.

Correction to Advance Notification Requirements for Certain Exports of Saxitoxin

This final rule also corrects the Chemical Weapons Convention (CWC) Schedule 1 chemical advance notification requirements in Section 745.1 of the EAR to reflect the April 27, 2006 (71 FR 24918), amendments to the Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710-722) that, inter alia, amended the definition of *advance notification* in Section 710.1 of the CWCR, as well as the advance notification requirements in Section 712.6(a) of the CWCR, to indicate that the 45-day advance notification requirement for exports or imports of Schedule 1 chemicals does not apply to the export or import of 5 milligrams or less of saxitoxin (see ECCN 1C351.d.12) for medical or diagnostic purposes only – the latter requires only a 3-day advance notification. Specifically, this final rule amends the first sentence in Section 745.1(a) of the EAR to read as follows: “You must notify BIS at least 45 calendar days prior to exporting any quantity of a Schedule 1 chemical listed in Supplement No. 1 to this part to another State Party, except that notifications for exports of 5 milligrams or less of saxitoxin (for medical or diagnostic purposes only) must be submitted to BIS at least 3 calendar days prior to the date of

export (see 15 CFR 712.6(a)).” The advance notification requirements in Section 745.1 of the EAR refer only to exports, because imports are outside the scope of these EAR requirements. However, as indicated above, the advance notification requirements described in Section 712.6(a) of the CWCR apply to imports, as well as exports. The exemption from the 45-day advance notification requirement, for certain exports and imports of saxitoxin (as described above), was approved and entered into force for all CWC States Parties on October 31, 1999.

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 chemical weapons precursors, human and animal pathogens/toxins, chemical manufacturing equipment, and equipment capable of use in handling biological materials.

The scope of the CCL-based CB controls on human and animal pathogens and toxins was not affected by the correction to ECCN 1C351 in which outdated references to former ECCN 1C352 were removed from the Note that follows 1C351.a.4 and references to the relevant avian influenza (AI) controls described in 1C351.a.4 were added in their place. In addition, the updates to the controls on genetic elements and genetically modified organisms described in ECCN 1C353 clarified the scope of these controls, but did not actually expand them. In short, neither of these changes is expected to result in an increase in the number of license applications that will have to be submitted to BIS for exports, reexports, or transfers (in-country) of these items.

However, the changes made by this final rule to the CCL entries controlling chemical weapons precursors, chemical manufacturing equipment, and equipment capable of use in handling biological materials are expected to result in a slight increase in the number of license applications that will have to be submitted for these items. Specifically, the addition of the precursor chemical hydrochloride salt N,N-Diisopropylaminoethanethiol hydrochloride (C.A.S. #41480-75-5) to ECCN 1C350.b is expected to result in the submission of one or two additional license applications per year. The addition of controls on certain prefabricated repair assemblies, and their specially designed components, to ECCN 2B350 is expected to result in the submission of four or five additional license applications per year. Specifically listing toxic gas monitors in ECCN 2B351 (to clarify that this entry controls, inter alia, certain portable gas monitors as well as toxic gas monitoring systems) is expected to result in the submission of two or three additional license applications per year. The addition of controls on nucleic acid assemblers and synthesizers to ECCN 2B352 is expected to result in the submission of four or five additional license applications per year.

Therefore, the number of additional license applications that would have to be submitted per year, as a result of the amendments to ECCNs 1C350, 2B350, 2B351 and 2B352 described above, is not expected to exceed fifteen license applications. This total represents a relatively insignificant portion of the overall trade in such items and is well within the scope of the information collection approved by the Office of Management and Budget (OMB) under control number 0694-0088 (see Rulemaking Requirements #2, below).

Saving Clause

Shipments of items removed from eligibility for export or reexport 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], pursuant to actual orders for export or reexport 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 or reexported before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Any such items not actually exported or reexported before midnight, on [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], 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 [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Beginning at midnight on [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], 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 Administration Act

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, 2017 (82 FR 39005 (August 16, 2017)), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*). BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

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.

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 AG agreements 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 of mass destruction. The first meeting of what subsequently became known as the Australia Group (AG) took place in Brussels in June 1985. At that meeting, the 15 participating countries and the European Commission agreed to explore how existing export controls might be made more effective to prevent the spread of chemical weapons. The AG has met regularly since then, and annual meetings are now held in Paris. The scope of the export controls addressed by the AG has evolved to address emerging threats and challenges. Evidence of the diversion of dual-use materials to biological weapons programs in the early 1990s led to participants' adoption of export controls on specific biological agents. The common control lists developed by the AG have also expanded to include technology and equipment that can be used in the manufacturing or disposal of chemical and biological weapons. The number of countries participating in the AG has grown from 15 in 1985 to 42, plus the European Union. 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 (CBW) 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. The AG's activities are especially important 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, Commerce 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 AG-related 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. Furthermore, this rule qualifies for a good cause exception under 5 U.S.C. 553(b)(B) 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 – this finding, and a brief statement of the reasons therefor, are described under Rulemaking Requirements #4, below. Accordingly, this rule meets the requirements set forth in the April 5, 2017, OMB guidance implementing E.O. 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 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, Simplified Network Application Processing System. This collection 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. Although this final rule makes important changes to the EAR for items controlled for chemical/biological (CB) reasons, Commerce believes the overall increase in costs and burdens due to this rule will be minimal. Specifically, BIS expects the burden hours associated with this collection to increase, slightly, by 7 hours and 24 minutes (i.e., 15 applications \times 29.6 minutes per response) for an estimated cost increase of \$222 (i.e., 7 hours and 24 minutes \times \$30 per hour). This increase is not expected to exceed the existing estimates currently associated with OMB control number 0694–0088. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget, 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, N.W., 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. 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 42 member countries that act on a consensus basis and the amendments set forth in this rule implement changes made to the AG common control lists (as a result of the adoption of the recommendations made at the February 2017 AG Intersessional Implementation Meeting and the understandings reached at the June 2017 AG Plenary Implementation Meeting) and other changes that are necessary to ensure consistency with the controls maintained by the AG. Because 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.

Although the APA requirements in section 553 are not applicable to this action under the provisions of paragraph (a)(1), this action also falls within two other exceptions in the section. The subsection (b) requirement that agencies publish a notice of proposed rulemaking, which includes information on the public proceedings, does not apply when an agency for good cause finds that the notice and public procedures are impracticable, unnecessary, or contrary to the public interest, and the agency incorporates the finding (and the reasons therefor) in the rule that

is issued (5 U.S.C. 553(b)(B)). In addition, the section 553(d) requirement that publication of a rule shall be made not less than 30 days before its effective date can be waived if an agency finds there is good cause to do so.

The section 553 requirements for notice and public procedures and for a delay in the date of effectiveness do not apply to this rule, as there is good cause to waive such practices. 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 manner. Delaying this rulemaking would prevent the United States from fulfilling its commitment to the AG in a timely manner, would injure the credibility of the United States in this and other multilateral regimes, and may impair the international community's ability to effectively control the export of certain potentially national- and international security-threatening items. Therefore, this regulation is issued in final form, and is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects

15 CFR Part 738

Administrative practice and procedure, Exports, Foreign trade.

15 CFR Part 740

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

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, parts 738, 740, 745 and 774 of the Export Administration

Regulations (15 CFR parts 730-774) are amended as follows:

PART 738 – [AMENDED]

1. The authority citation for part 738 continues to read as follows:

Authority: 50 U.S.C. 4601 *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; 42 U.S.C. 2139a; 15 U.S.C. 1824a; 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; Notice of August 15, 2017, 82 FR 39005 (August 16, 2017).

2. Supplement No. 1 to Part 738 is amended by revising the entry for “India” to read as follows:

Supplement No. 1 to Part 738--COMMERCE COUNTRY CHART

[Reason for control]

| Countries | Chemical and biological weapons | | | Nuclear nonproliferation | | National security | | Missile tech | Regional stability | | Firearms convention | Crime control | | | Anti-terrorism | |
|--------------------|---------------------------------|------|------|--------------------------|------|-------------------|------|--------------|--------------------|------|---------------------|---------------|------|------|----------------|------|
| | CB 1 | CB 2 | CB 3 | NP 1 | NP 2 | NS 1 | NS 2 | MT 1 | RS 1 | RS 2 | FC 1 | CC 1 | CC 2 | CC 3 | AT 1 | AT 2 |
| * * * * * | | | | | | | | | | | | | | | | |
| India ⁷ | X | | | X | | X | X | X | X | | | | | | | |

* * * * *

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⁷See §758.1(b)(9) for an AES filing requirement for exports of CC column 1 or 3, or RS column 2 items to India. Also note that a license is still required for items controlled under ECCNs 6A003.b.4.b and 9A515.e for RS column 2 reasons when destined to India.

* * * * *

PART 740 – [AMENDED]

3. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4601 *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, 2017, 82 FR 39005 (August 16, 2017).

4. In Supplement No. 1 to Part 740, Country Groups, Country Group A is amended by revising the entry for “India” to read as follows:

Supplement No. 1 to Part 740—Country Groups

Country Group A

| Country | [A:1] Wassenaar participating states¹ | [A:2] Missile technology control regime | [A:3] Australia group | [A:4] Nuclear suppliers group² | [A:5] | [A:6] |
|----------------|---|--|--------------------------------------|--|--------------|--------------|
| | | * * * * * | | | | |
| India | | X | X | | | X |
| | | * * * * * | | | | |

¹Country Group A:1 is a list of the Wassenaar Arrangement Participating States, except for Malta, Russia and Ukraine.

²Country Group A:4 is a list of the Nuclear Suppliers Group countries, except for the People's Republic of China (PRC).

* * * * *

PART 745 - [AMENDED]

5. The authority citation for part 745 continues to read as follows:

Authority: 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of November 8, 2016, 81 FR 79379 (November 10, 2016).

6. In § 745.1, the first sentence in paragraph (a) is revised to read as follows:

§ 745.1 Advance notification and annual report of all exports of Schedule 1 chemicals to other States Parties.

* * * * *

(a) *Advance notification of exports.* You must notify BIS at least 45 calendar days prior to exporting any quantity of a Schedule 1 chemical listed in Supplement No. 1 to this part to another State Party, except that notifications for exports of 5 milligrams or less of saxitoxin (for medical or diagnostic purposes only) must be submitted to BIS at least 3 calendar days prior to the date of export (see 15 CFR 712.6(a)). * * *

* * * * *

PART 774 - [AMENDED]

7. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. 4601 *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; 43 U.S.C. 1354; 15 U.S.C. 1824a; 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; Notice of August 15, 2017, 82 FR 39005 (August 16, 2017).

8. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, ECCN 1C350 is revised to read as follows:

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

1C350 Chemicals that may be used as precursors for toxic chemical agents (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 2 |

CW applies to 1C350 .b, and .c. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons. A license is required, for CW reasons, to export or reexport Schedule 2 chemicals and mixtures identified in 1C350.b to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR). A license is required, for CW reasons, to export Schedule 3 chemicals and mixtures identified in 1C350.c to States not Party to the CWC, unless an End-Use Certificate issued by the government of the importing country has been obtained by the exporter prior to export. A license is required, for CW reasons, to reexport Schedule 3 chemicals and mixtures identified in 1C350.c from a State not Party to the CWC to any other State not Party to the CWC. (See §742.18 of the EAR for license requirements and policies for toxic and precursor chemicals controlled for CW reasons. See §745.2 of the EAR for End-Use Certificate requirements that apply to exports of Schedule 3 chemicals to countries not listed in Supplement No. 2 to part 745 of the EAR.)

AT applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for AT reasons in 1C350. A license is required, for AT reasons, to export or reexport items controlled by 1C350 to a country in Country Group E:1 of Supplement No. 1 to part 740 of the EAR. (See part 742 of the EAR for additional information on the AT controls that apply to Iran, North Korea, Sudan, and Syria. See part 746 of the EAR for additional information on sanctions that apply to Iran, North Korea, and Syria.)

License Requirement Notes:

1. Sample Shipments: *Subject to the following requirements and restrictions, a license is not required for sample shipments when the cumulative total of these shipments does not exceed a 55-gallon container or 200 kg of a single chemical to any one consignee during a calendar year. A consignee that receives a sample shipment under this exclusion may not resell, transfer, or reexport the sample shipment, but may use the sample shipment for any other legal purpose unrelated to chemical weapons.*

a. Chemicals Not Eligible:

A. *[Reserved]*

B. *CWC Schedule 2 chemicals (States not Party to the CWC). No CWC Schedule 2 chemical or mixture identified in 1C350.b is eligible for sample shipment to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR) without a license.*

b. Countries Not Eligible: *Countries in Country Group E:1 of Supplement No. 1 to part 740 of the EAR are not eligible to receive sample shipments of any chemicals controlled by this ECCN without a license.*

c. Sample shipments that require an End-Use Certificate for CW reasons: *No CWC Schedule 3 chemical or mixture identified in 1C350.c is eligible for sample shipment to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR) without a license, unless an End-Use Certificate issued by the government of the importing country is obtained by the exporter prior to export (see §745.2 of the EAR for End-Use Certificate requirements).*

d. Sample shipments that require a license for reasons set forth elsewhere in the EAR: Sample shipments, as described in this Note 1, may require a license for reasons set forth elsewhere in the EAR. See, in particular, the end-use/end-user restrictions in part 744 of the EAR, and the restrictions that apply to embargoed countries in part 746 of the EAR.

e. Annual report requirement. The exporter is required to submit an annual written report for shipments of samples made under this Note 1. The report must be on company letterhead stationery (titled "Report of Sample Shipments of Chemical Precursors" at the top of the first page) and identify the chemical(s), Chemical Abstract Service Registry (C.A.S.) number(s), quantity(ies), the ultimate consignee's name and address, and the date of export for all sample shipments that were made during the previous calendar year. The report must be submitted no later than February 28 of the year following the calendar year in which the sample shipments were made, to: U.S. Department of Commerce, Bureau of Industry and Security, 14th Street and Pennsylvania Ave. NW., Room 2099B, Washington, DC 20230, Attn: "Report of Sample Shipments of Chemical Precursors."

2. Mixtures:

a. Mixtures that contain precursor chemicals identified in ECCN 1C350, in concentrations that are below the levels indicated in 1C350.b through .d, are controlled

by ECCN 1C395 or 1C995 and are subject to the licensing requirements specified in those ECCNs.

b. A license is not required under this ECCN for a mixture, when the controlled chemical in the mixture is a normal ingredient in consumer goods packaged for retail sale for personal use. Such consumer goods are designated EAR99. However, a license may be required for reasons set forth elsewhere in the EAR.

Note to mixtures: Calculation of concentrations of AG-controlled chemicals:

a. Exclusion. No chemical may be added to the mixture (solution) for the sole purpose of circumventing the Export Administration Regulations;

b. Percent Weight Calculation. When calculating the percentage, by weight, of ingredients in a chemical mixture, include all ingredients of the mixture, including those that act as solvents.

3. Compounds. *Compounds created with any chemicals identified in this ECCN 1C350 may be shipped NLR (No License Required), without obtaining an End-Use Certificate, unless those compounds are also identified in this entry or require a license for reasons set forth elsewhere in the EAR.*

4. Testing Kits: *Certain medical, analytical, diagnostic, and food testing kits containing small quantities of chemicals identified in this ECCN 1C350, are excluded from the scope of this ECCN and are controlled under ECCN 1C395 or 1C995. (Note that replacement reagents for*

such kits are controlled by this ECCN 1C350 if the reagents contain one or more of the precursor chemicals identified in 1C350 in concentrations equal to or greater than the control levels for mixtures indicated in 1C350.)

Technical Notes: *1. For purposes of this entry, a “mixture” is defined as a solid, liquid or gaseous product made up of two or more ingredients that do not react together under normal storage conditions.*

2. The scope of this control applicable to Hydrogen Fluoride (see 1C350.d.7 in the List of Items Controlled) includes its liquid, gaseous, and aqueous phases, and hydrates.

3. Precursor chemicals in ECCN 1C350 are listed by name, Chemical Abstract Service (CAS) number and CWC Schedule (where applicable). Precursor chemicals of the same structural formula (e.g., hydrates) are controlled by ECCN 1C350, regardless of name or CAS number. CAS numbers are shown to assist in identifying whether a particular precursor chemical or mixture is controlled under ECCN 1C350, irrespective of nomenclature. However, CAS numbers cannot be used as unique identifiers in all situations because some forms of the listed precursor chemical have different CAS numbers, and mixtures containing a precursor chemical listed in ECCN 1C350 may also have different CAS numbers.

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

LVS: N/A

GBS: N/A

CIV: N/A

List of Items Controlled

Related Controls: See USML Category XIV(c) for related chemicals “subject to the ITAR” (see 22 CFR parts 120 through 130).

Related Definitions: See §770.2(k) of the EAR for synonyms for the chemicals listed in this entry.

Items:

a. [Reserved]

b. Australia Group-controlled precursor chemicals also identified as Schedule 2 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

b.1. (C.A.S. #7784-34-1) Arsenic trichloride;

b.2. (C.A.S. #76-93-7) Benzilic acid;

b.3. (C.A.S. #78-38-6) Diethyl ethylphosphonate;

b.4. (C.A.S. #683-08-9) Diethyl methylphosphonate;

- b.5. (C.A.S. #15715-41-0) Diethyl methylphosphonite;
- b.6. (C.A.S. #2404-03-7) Diethyl-N,N-dimethylphosphoroamidate;
- b.7. (C.A.S. #41480-75-5) N,N-Diisopropylaminoethanethiol hydrochloride;
- b.8. (C.A.S. #5842-07-9) N,N-Diisopropyl-beta-aminoethane thiol;
- b.9. (C.A.S. #96-80-0) N,N-Diisopropyl-beta-aminoethanol;
- b.10. (C.A.S. #96-79-7), N,N-Diisopropyl-beta-aminoethyl chloride;
- b.11. (C.A.S. #4261-68-1) N,N-Diisopropyl-beta-aminoethyl chloride hydrochloride;
- b.12. (C.A.S. #6163-75-3) Dimethyl ethylphosphonate;
- b.13. (C.A.S. #756-79-6) Dimethyl methylphosphonate;
- b.14. (C.A.S. #677-43-0) N,N-Dimethylamino-phosphoryl dichloride;
- b.15. (C.A.S. #1498-40-4) Ethyl phosphonous dichloride [Ethyl phosphinyl dichloride];
- b.16. (C.A.S. #430-78-4) Ethyl phosphonus difluoride [Ethyl phosphinyl difluoride];
- b.17. (C.A.S. #1066-50-8) Ethyl phosphonyl dichloride;
- b.18. (C.A.S. #993-13-5) Methylphosphonic acid;
- b.19. (C.A.S. #676-98-2) Methylphos-phonothioic dichloride;
- b.20. (C.A.S. #464-07-3) Pinacolyl alcohol;
- b.21. (C.A.S. #1619-34-7) 3-Quinuclidinol;

b.22. (C.A.S. #111-48-8) Thiodiglycol.

c. Australia Group-controlled precursor chemicals also identified as Schedule 3 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

c.1. (C.A.S. #762-04-9) Diethyl phosphite;

c.2. (C.A.S. #868-85-9) Dimethyl phosphite (dimethyl hydrogen phosphite);

c.3. (C.A.S. #139-87-7) Ethyldiethanolamine;

c.4. (C.A.S. #10025-87-3) Phosphorus oxychloride;

c.5. (C.A.S. #10026-13-8) Phosphorus pentachloride;

c.6. (C.A.S. #7719-12-2) Phosphorus trichloride;

c.7. (C.A.S. #10545-99-0) Sulfur dichloride;

c.8. (C.A.S. #10025-67-9) Sulfur monochloride;

c.9. (C.A.S. #7719-09-7) Thionyl chloride;

c.10. (C.A.S. #102-71-6) Triethanolamine;

c.11. (C.A.S. #122-52-1) Triethyl phosphite;

c.12. (C.A.S. #121-45-9) Trimethyl phosphite.

d. Other Australia Group-controlled precursor chemicals not also identified as Schedule 1, 2, or 3 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

- d.1. (C.A.S. #1341-49-7) Ammonium hydrogen fluoride;
- d.2. (C.A.S. #107-07-3) 2-Chloroethanol;
- d.3. (C.A.S. #109-89-7) Diethylamine;
- d.4. (C.A.S. #100-37-8) N,N-Diethylaminoethanol;
- d.5. (C.A.S. #298-06-6) O,O-Diethyl phosphorodithioate;
- d.6. (C.A.S. #2465-65-8) O,O-Diethyl phosphorothioate;
- d.7. (C.A.S. #108-18-9) Di-isopropylamine;
- d.8. (C.A.S. #124-40-3) Dimethylamine;
- d.9. (C.A.S. #506-59-2) Dimethylamine hydrochloride;
- d.10. (C.A.S. #7664-39-3) Hydrogen fluoride;
- d.11. (C.A.S. #3554-74-3) 3-Hydroxyl-1-methylpiperidine;
- d.12. (C.A.S. #76-89-1) Methyl benzilate;
- d.13. (C.A.S. #1314-80-3) Phosphorus pentasulfide;
- d.14. (C.A.S. #75-97-8) Pinacolone;
- d.15. (C.A.S. #7789-29-9) Potassium bifluoride;

- d.16. (C.A.S. #151-50-8) Potassium cyanide;
- d.17. (C.A.S. #7789-23-3) Potassium fluoride;
- d.18. (C.A.S. #3731-38-2) 3-Quinuclidone;
- d.19. (C.A.S. #1333-83-1) Sodium bifluoride;
- d.20. (C.A.S. #143-33-9) Sodium cyanide;
- d.21. (C.A.S. #7681-49-4) Sodium fluoride;
- d.22. (C.A.S. #16893-85-9) Sodium hexafluorosilicate;
- d.23. (C.A.S. #1313-82-2) Sodium sulfide;
- d.24. (C.A.S. #637-39-8) Triethanolamine hydrochloride;
- d.25. (C.A.S. #116-17-6) Tri-isopropyl phosphite.

9. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, ECCN 1C351 is revised to read as follows:

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, 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.

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

CIV: 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.19. 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: **(1)** For the purposes of this entry “immunotoxin” is defined as an antibody-toxin conjugate intended to destroy specific target cells (e.g., tumor cells) that bear antigens homologous to the antibody. **(2)** For the purposes of this entry “subunit” is defined as a portion of the “toxin”.

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. Monkeypox virus;
- a.31. Murray Valley encephalitis virus;
- a.32. Newcastle disease virus;
- a.33. Nipah virus;
- a.34. Omsk hemorrhagic fever virus;
- a.35. Oropouche virus;
- a.36. Peste-des-petits ruminants virus;
- a.37. Porcine Teschovirus;
- a.38. Powassan virus;
- a.39. Rabies virus and all other members of the Lyssavirus genus;
- a.40. Reconstructed 1918 influenza virus;

Technical Note: 1C351.a.40 includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.

- a.41. Rift Valley fever virus;
- a.42. Rinderpest virus;
- a.43. Rocio virus;
- a.44. Sabia virus;
- a.45. Seoul virus;
- a.46. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);
- a.47. Sheeppox virus;
- a.48. Sin Nombre virus;
- a.49. St. Louis encephalitis virus;
- a.50. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);
- a.51. Swine vesicular disease virus;
- a.52. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus—see 1C351.b.3 for Siberian subtype);
- a.53. Variola virus;

a.54. Venezuelan equine encephalitis virus;

a.55. Vesicular stomatitis virus;

a.56. Western equine encephalitis virus; *or*

a.57. 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.52 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. *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. *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, and “subunits” thereof:

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*.

10. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, ECCN 1C353 is revised to read as follows:

1C353 Genetic elements and genetically modified organisms, 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 entire entry | CB Column 1 |
| AT applies to entire entry | AT Column 1 |

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

LVS: N/A

GBS: N/A

CIV: N/A

List of Items Controlled

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 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: N/A

Items:

a. Any genetically modified organism that contains, or any genetic element that codes for, any of the following:

a.1. Any gene or genes specific to any virus controlled by 1C351.a or .b or 1C354.c;

a.2. Any gene or genes specific to any bacterium controlled by 1C351.c or 1C354.a, or any fungus controlled by 1C351.e or 1C354.b, and which;

a.2.a. In itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health; *or*

a.2.b. Could endow or enhance pathogenicity; *or*

a.3. Any toxins, or their subunits, controlled by 1C351.d.

b. [Reserved].

Technical Notes: 1. *Genetically modified organisms include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation.*

2. *“Genetic elements” include, inter alia, chromosomes, genomes, plasmids, transposons, vectors, and inactivated organisms containing recoverable nucleic acid fragments, whether genetically modified or unmodified, or chemically synthesized in whole or in part. For the purposes of this ECCN 1C353, nucleic acids from an inactivated organism, virus, or sample are considered to be ‘recoverable’ if the inactivation and preparation of the material is intended or known to facilitate isolation, purification, amplification, detection, or identification of nucleic acids.*

3. *This ECCN does not control nucleic acid sequences of shiga toxin producing Escherichia coli of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups, other than those genetic elements coding for shiga toxin, or for its subunits.*

4. *‘Endow or enhance pathogenicity’ is defined as when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism’s ability to be used to deliberately cause disease or death. This might include alterations to, inter alia: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability.*

11. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2, ECCN 2B350 is revised to read as follows:

2B350 Chemical manufacturing facilities and equipment, except valves controlled by 2A226, 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 entire entry | CB Column 2 |
| AT applies to entire entry | AT Column 1 |

License Requirement Note: *This ECCN does not control equipment that is both:*

(1) “Specially Designed” for use in civil applications (e.g., food processing, pulp and paper processing, or water purification) and (2) inappropriate, by the nature of its design, for use in storing, processing, producing or conducting and controlling the flow of the chemical weapons precursors controlled by 1C350.

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

LVS: \$2,000 for all Country Group B destinations, except those also listed under Country

Group D:3 (see Supplement No. 1 to part 740 of the EAR).

GBS: N/A

CIV: N/A

List of Items Controlled

Related Controls: See also ECCNs 2A226, 2A992, 2A993, 2B231, and 2B999.

Related Definitions: For purposes of this entry the term ‘chemical warfare agents’ includes those agents “subject to the ITAR” (see 22 CFR parts 120 through 130).

Items:

a. Reaction vessels, reactors and prefabricated repair assemblies therefor, as follows:

a.1. Reaction vessels or reactors, with or without agitators, with total internal (geometric) volume greater than 0.1 m³ (100 liters) and less than 20 m³ (20,000 liters), where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

a.1.a Alloys with more than 25% nickel and 20% chromium by weight;

a.1.b. Nickel or alloys with more than 40% nickel by weight;

a.1.c. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

a.1.d. Glass (including vitrified or enameled coating or glass lining);

a.1.e. Tantalum or tantalum alloys;

a.1.f. Titanium or titanium alloys;

a.1.g. Zirconium or zirconium alloys; *or*

a.1.h. Niobium (columbium) or niobium alloys;

a.2. Prefabricated repair assemblies, and their specially designed components, that:

a.2.a. Are designed for mechanical attachment to glass-lined reaction vessels or reactors described in 2B350.a.1; *and*

a.2.b. Have metallic surfaces that are made from tantalum or tantalum alloys and come in direct contact with the chemical(s) being processed.

b. Agitators designed for use in reaction vessels or reactors described in 2B350.a.1, and impellers, blades or shafts designed for such agitators, where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

b.1. Alloys with more than 25% nickel and 20% chromium by weight;

b.2. Nickel or alloys with more than 40% nickel by weight;

b.3. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

- b.4. Glass (including vitrified or enameled coatings or glass lining);
 - b.5. Tantalum or tantalum alloys;
 - b.6. Titanium or titanium alloys;
 - b.7. Zirconium or zirconium alloys; *or*
 - b.8. Niobium (columbium) or niobium alloys.
- c. Storage tanks, containers, receivers and prefabricated repair assemblies therefor, as follows:
- c.1. Storage tanks, containers or receivers with a total internal (geometric) volume greater than 0.1 m³ (100 liters) where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:
 - c.1.a. Alloys with more than 25% nickel and 20% chromium by weight;
 - c.1.b. Nickel or alloys with more than 40% nickel by weight;
 - c.1.c. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);
 - c.1.d. Glass (including vitrified or enameled coatings or glass lining);
 - c.1.e. Tantalum or tantalum alloys;
 - c.1.f. Titanium or titanium alloys;
 - c.1.g. Zirconium or zirconium alloys; *or*

c.1.h. Niobium (columbium) or niobium alloys;

c.2. Prefabricated repair assemblies, and their specially designed components, that:

c.2.a. Are designed for mechanical attachment to glass-lined storage tanks, containers or receivers described in 2B350.c.1; *and*

c.2.b. Have metallic surfaces that are made from tantalum or tantalum alloys and come in direct contact with the chemical(s) being processed.

d. Heat exchangers or condensers with a heat transfer surface area of less than 20 m^2 , but greater than 0.15 m^2 , and tubes, plates, coils or blocks (cores) designed for such heat exchangers or condensers, where all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:

d.1. Alloys with more than 25% nickel and 20% chromium by weight;

d.2. Nickel or alloys with more than 40% nickel by weight;

d.3. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

d.4. Glass (including vitrified or enameled coatings or glass lining);

d.5. Tantalum or tantalum alloys;

d.6. Titanium or titanium alloys;

d.7. Zirconium or zirconium alloys;

d.8. Niobium (columbium) or niobium alloys;

d.9. Graphite or carbon-graphite;

d.10. Silicon carbide; *or*

d.11. Titanium carbide.

e. Distillation or absorption columns of internal diameter greater than 0.1 m, and liquid distributors, vapor distributors or liquid collectors designed for such distillation or absorption columns, where all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:

e.1. Alloys with more than 25% nickel and 20% chromium by weight;

e.2. Nickel or alloys with more than 40% nickel by weight;

e.3. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

e.4. Glass (including vitrified or enameled coatings or glass lining);

e.5. Tantalum or tantalum alloys;

e.6. Titanium or titanium alloys;

e.7. Zirconium or zirconium alloys;

e.8. Niobium (columbium) or niobium alloys; *or*

e.9. Graphite or carbon-graphite.

f. Remotely operated filling equipment in which all surfaces that come in direct contact with the chemical(s) being processed are made from any of the following materials:

f.1. Alloys with more than 25% nickel and 20% chromium by weight; *or*

f.2. Nickel or alloys with more than 40% nickel by weight.

g. Valves, as follows:

g.1. Valves having both of the following characteristics:

g.1.a. A nominal size greater than 1.0 cm (3/8 in.); *and*

g.1.b. All surfaces that come in direct contact with the chemical(s) being produced, processed, or contained are made from materials identified in Technical Note 1 to 2B350.g.

g.2. Valves, except for valves controlled by 2B350.g.1, having all of the following characteristics:

g.2.a. A nominal size equal to or greater than 2.54 cm (1 inch) and equal to or less than 10.16 cm (4 inches);

g.2.b. Casings (valve bodies) or preformed casing liners controlled by 2B350.g.3, in which all surfaces that come in direct contact with the chemical(s) being produced,

processed, or contained are made from materials identified in Technical Note 1 to 2B350.g; *and*

g.2.c. A closure element designed to be interchangeable.

g.3. Casings (valve bodies) and preformed casing liners having both of the following characteristics:

g.3.a. Designed for valves in 2B350.g.1 or .g.2; *and*

g.3.b. All surfaces that come in direct contact with the chemical(s) being produced, processed, or contained are made from materials identified in Technical Note 1 to 2B350.g.

Technical Note 1 to 2B350.g: *All surfaces of the valves controlled by 2B350.g.1, and the casings (valve bodies) and preformed casing liners controlled by 2B350.g.3, that come in direct contact with the chemical(s) being produced, processed, or contained are made from the following materials:*

- a. Alloys with more than 25% nickel and 20% chromium by weight;*
- b. Nickel or alloys with more than 40% nickel by weight;*
- c. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);*
- d. Glass (including vitrified or enameled coating or glass lining);*

e. Tantalum or tantalum alloys;

f. Titanium or titanium alloys;

g. Zirconium or zirconium alloys;

h. Niobium (columbium) or niobium alloys; or

i. Ceramic materials, as follows:

i.1. Silicon carbide with a purity of 80% or more by weight;

i.2. Aluminum oxide (alumina) with a purity of 99.9% or more by weight; or

i.3. Zirconium oxide (zirconia).

Technical Note 2 to 2B350.g: *The ‘nominal size’ is defined as the smaller of the inlet and outlet port diameters.*

h. Multi-walled piping incorporating a leak detection port, in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

h.1. Alloys with more than 25% nickel and 20% chromium by weight;

h.2. Nickel or alloys with more than 40% nickel by weight;

h.3. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);

h.4. Glass (including vitrified or enameled coatings or glass lining);

h.5. Tantalum or tantalum alloys;

h.6. Titanium or titanium alloys;

h.7. Zirconium or zirconium alloys;

h.8. Niobium (columbium) or niobium alloys; *or*

h.9. Graphite or carbon-graphite.

i. Multiple-seal and seal-less pumps with manufacturer's specified maximum flow-rate greater than 0.6 m³/hour (600 liters/hour), or vacuum pumps with manufacturer's specified maximum flow-rate greater than 5 m³/hour (5,000 liters/hour) (under standard temperature (273 K (0 °C)) and pressure (101.3 kPa) conditions), and casings (pump bodies), preformed casing liners, impellers, rotors or jet pump nozzles designed for such pumps, in which all surfaces that come into direct contact with the chemical(s) being processed are made from any of the following materials:

i.1. Alloys with more than 25% nickel and 20% chromium by weight;

i.2. Nickel or alloys with more than 40% nickel by weight;

- i.3. Fluoropolymers (polymeric or elastomeric materials with more than 35% fluorine by weight);
- i.4. Glass (including vitrified or enameled coatings or glass lining);
- i.5. Tantalum or tantalum alloys;
- i.6. Titanium or titanium alloys;
- i.7. Zirconium or zirconium alloys;
- i.8. Niobium (columbium) or niobium alloys.
- i.9. Graphite or carbon-graphite;
- i.10. Ceramics; *or*
- i.11. Ferrosilicon (high silicon iron alloys).

Technical Note to 2B350.i: *The seals referred to in 2B350.i come into direct contact with the chemical(s) being processed (or are designed to do so), and provide a sealing function where a rotary or reciprocating drive shaft passes through a pump body.*

- j. Incinerators designed to destroy chemical warfare agents, chemical weapons precursors controlled by 1C350, or chemical munitions having “specially designed” waste supply systems, special handling facilities and an average combustion chamber temperature greater than 1000 °C

in which all surfaces in the waste supply system that come into direct contact with the waste products are made from or lined with any of the following materials:

- j.1. Alloys with more than 25% nickel and 20% chromium by weight;
- j.2. Nickel or alloys with more than 40% nickel by weight; *or*
- j.3. Ceramics.

Technical Note 1: *Carbon-graphite is a composition consisting primarily of graphite and amorphous carbon, in which the graphite is 8 percent or more by weight of the composition.*

Technical Note 2: *For the items listed in 2B350, the term ‘alloy,’ when not accompanied by a specific elemental concentration, is understood as identifying those alloys where the identified metal is present in a higher percentage by weight than any other element.*

Technical Note 3: *The materials used for gaskets, packing, seals, screws or washers, or other materials performing a sealing function, do not determine the control status of the items in this ECCN, provided that such components are designed to be interchangeable.*

Note: *See Categories V and XIV of the United States Munitions List for all chemicals that are “subject to the ITAR” (see 22 CFR parts 120 through 130).*

12. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2, ECCN 2B351 is revised to read as follows:

2B351 Toxic gas monitors and monitoring systems, and their dedicated detecting “parts” and “components” (i.e., detectors, sensor devices, and replaceable sensor cartridges), as follows, except those systems and detectors controlled by ECCN 1A004.c (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 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)

LVS: N/A

GBS: N/A

CIV: N/A

List of Items Controlled

Related Controls: See ECCN 2D351 for “software” for toxic gas monitors and monitoring systems, and their dedicated detecting “parts” and “components,” controlled by this ECCN. Also see ECCN 1A004, which controls chemical detection systems and “specially designed” “parts” and “components” therefor that are “specially designed” or modified for detection or identification of chemical warfare agents, but not “specially designed” for military use, and ECCN 1A995, which controls certain detection equipment, “parts” and “components” not controlled by ECCN 1A004 or by this ECCN.

Related Definitions: (1) For the purposes of this entry, the term “dedicated” means committed entirely to a single purpose or device. (2) For the purposes of this entry, the term “continuous operation” describes the capability of the equipment to operate on line without human intervention. The intent of this entry is to control toxic gas monitors and monitoring systems capable of collection and detection of samples in environments such as chemical plants, rather than those used for batch-mode operation in laboratories.

Items:

- a. Designed for continuous operation and usable for the detection of chemical warfare agents or precursor chemicals controlled by 1C350 at concentrations of less than 0.3 mg/m^3 ; *or*
- b. Designed for the detection of cholinesterase-inhibiting activity.

13. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2 --
Materials Processing, ECCN 2B352 is revised to read as follows:

2B352 Equipment capable of use in handling biological materials, 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 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)

LVS: N/A

GBS: N/A

CIV: N/A

List of Items Controlled

Related Controls: See ECCNs 1A004 and 1A995 for protective equipment that is not covered by this entry. Also see ECCN 9A120 for controls on certain “UAV” systems designed or modified to dispense an aerosol and capable of carrying elements of a payload in the form of a particulate or liquid, other than fuel “parts” or “components” of such vehicles, of a volume greater than 20 liters.

Related Definitions: (1) “Lighter than air vehicles”—balloons and airships that rely on hot air or on lighter-than-air gases, such as helium or hydrogen, for their lift. (2) “UAVs”—Unmanned Aerial Vehicles. (3) “VMD”—Volume Median Diameter.

Items:

a. Containment facilities and related equipment, as follows:

a.1. Complete containment facilities at P3 or P4 containment level.

Technical Note: P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the *WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004)*.

a.2. Equipment designed for fixed installation in containment facilities specified in paragraph a.1 of this ECCN, as follows:

- a.2.a. Double-door pass-through decontamination autoclaves;
- a.2.b. Breathing air suit decontamination showers;
- a.2.c. Mechanical-seal or inflatable-seal walkthrough doors.

b. Fermenters and components as follows:

b.1. Fermenters capable of cultivation of micro-organisms or of live cells for the production of viruses or toxins, without the propagation of aerosols, having a total internal volume of 20 liters or greater.

b.2. Components designed for such fermenters, as follows:

b.2.a. Cultivation chambers designed to be sterilized or disinfected in situ;

b.2.b. Cultivation chamber holding devices; *or*

b.2.c. Process control units capable of simultaneously monitoring and controlling two or more fermentation system parameters (e.g., temperature, pH, nutrients, agitation, dissolved oxygen, air flow, foam control).

Technical Note: Fermenters include bioreactors (including single-use (disposable) bioreactors), chemostats and continuous-flow systems.

c. Centrifugal separators capable of the continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all of the following characteristics:

- c.1. One or more sealing joints within the steam containment area;
- c.2. A flow rate greater than 100 liters per hour;
- c.3. “Parts” or “components” of polished stainless steel or titanium; *and*
- c.4. Capable of in-situ steam sterilization in a closed state.

Technical Note: Centrifugal separators include decanters.

d. Cross (tangential) flow filtration equipment and “accessories”, as follows:

d.1. Cross (tangential) flow filtration equipment capable of separation of microorganisms, viruses, toxins or cell cultures having all of the following characteristics:

d.1.a. A total filtration area equal to or greater than 1 square meter (1 m²); *and*

d.1.b. Having any of the following characteristics:

d.1.b.1. Capable of being sterilized or disinfected in-situ; *or*

d.1.b.2. Using disposable or single-use filtration “parts” or “components”.

N.B.: 2B352.d.1 does not control reverse osmosis and hemodialysis equipment, as specified by the manufacturer.

d.2. Cross (tangential) flow filtration “parts” or “components” (e.g., modules, elements, cassettes, cartridges, units or plates) with filtration area equal to or greater than 0.2 square meters (0.2 m²) for each “part” or “component” and designed for use in cross (tangential) flow filtration equipment controlled by 2B352.d.1.

***Technical Note:** In this ECCN, “sterilized” denotes the elimination of all viable microbes from the equipment through the use of either physical (e.g., steam) or chemical agents. “Disinfected” denotes the destruction of potential microbial infectivity in the equipment through the use of chemical agents with a germicidal effect. “Disinfection” and “sterilization” are distinct from “sanitization”, the latter referring to cleaning procedures designed to lower the microbial content of equipment without necessarily achieving elimination of all microbial infectivity or viability.*

e. Steam, gas or vapor sterilizable freeze-drying equipment with a condenser capacity of 10 kg of ice or greater in 24 hours (10 liters of water or greater in 24 hours) and less than 1000 kg of ice in 24 hours (less than 1,000 liters of water in 24 hours).

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.

g. Protective and containment equipment, as follows:

g.1. Protective full or half suits, or hoods dependant upon a tethered external air supply and operating under positive pressure.

Technical Note: *This entry does not control suits designed to be worn with self-contained breathing apparatus.*

g.2. Biocontainment chambers, isolators, or biological safety cabinets having all of the following characteristics, for normal operation:

g.2.a. Fully enclosed workspace where the operator is separated from the work by a physical barrier;

g.2.b. Able to operate at negative pressure;

g.2.c. Means to safely manipulate items in the workspace; *and*

g.2.d. Supply and exhaust air to and from the workspace is high-efficiency particulate air (HEPA) filtered.

Note 1 to 2B352.g.2: 2B352.g.2 controls class III biosafety cabinets, as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004) or constructed in accordance with national standards, regulations or guidance.

Note 2 to 2B352.g.2: 2B352.g.2 does not control isolators “specially designed” for barrier nursing or transportation of infected patients.

h. Aerosol inhalation equipment designed for aerosol challenge testing with microorganisms, viruses or toxins, as follows:

h.1. Whole-body exposure chambers having a capacity of 1 cubic meter or greater;

h.2. Nose-only exposure apparatus utilizing directed aerosol flow and having a capacity for the exposure of 12 or more rodents, or two or more animals other than rodents, and closed animal restraint tubes designed for use with such apparatus.

i. Spraying or fogging systems and “parts” and “components” therefor, as follows:

i.1. Complete spraying or fogging systems, “specially designed” or modified for fitting to aircraft, “lighter than air vehicles,” or “UAVs,” capable of delivering, from a liquid suspension, an initial droplet “VMD” of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.2. Spray booms or arrays of aerosol generating units, “specially designed” or modified for fitting to aircraft, “lighter than air vehicles,” or “UAVs,” capable of delivering, from a liquid suspension, an initial droplet “VMD” of less than 50 microns at a flow rate of greater than 2 liters per minute;

i.3. Aerosol generating units “specially designed” for fitting to the systems as specified in paragraphs i.1 and i.2 of this ECCN.

Technical Notes: 1. *Aerosol generating units are devices “specially designed” or modified for fitting to aircraft and include nozzles, rotary drum atomizers and similar devices.*

2. *This ECCN does not control spraying or fogging systems, “parts” and “components,” as specified in 2B352.i, that are demonstrated not to be capable of delivering biological agents in the form of infectious aerosols.*

3. Droplet size for spray equipment or nozzles “specially designed” for use on aircraft or “UAVs” should be measured using either of the following methods (pending the adoption of internationally accepted standards):

a. Doppler laser method,

b. Forward laser diffraction method.

j. Nucleic acid assemblers and synthesizers that are both:

j.1 Partly or entirely automated; *and*

j.2. Designed to generate continuous nucleic acids greater than 1.5 kilobases in length with error rates less than 5% in a single run.

14. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2, ECCN 2D351 is revised to read as follows:

2D351 Dedicated “software” for toxic gas monitors and monitoring systems, and their dedicated detecting “parts” and “components,” controlled by ECCN 2B351.

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)

CIV: N/A

TSR: N/A

List of Items Controlled

Related Controls: N/A

Related Definitions: (1) For the purposes of this entry, the term “dedicated” means committed entirely to a single purpose or device. (2) 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.

DATED: March 27, 2018

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Deputy Assistant Secretary

for Export Administration

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