**Authority:** 49 U.S.C. 106(f), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

*Paragraph 5000 Class D Airspace.*

* * * * *

**ANM CO D Denver, CO [Amended]**

Centennial Airport, CO
(Lat. 39°34′12″ N, long. 104°50′57″ W)

That airspace extending upward from the surface to but not including 8,000 feet MSL within 3.9 miles northwest and 4.6 miles southeast of the airport's 038° bearing extending to 4.6 miles northeast, within a 6.4-mile radius from the airport's 083° bearing clockwise to the 201° bearing, and within a 4.9-mile radius from the airport's 201° bearing clockwise to the 347° bearing.

* * * * *

*Paragraph 6004 Class E Airspace Designated as an Extension to a Class D or Class E Surface Area.*

* * * * *

**ANM CO E4 Englewood, CO [Removed]**

* * * * *

Issued in Des Moines, Washington, on December 17, 2024.

**B.G. Chew,**

*Group Manager, Operations Support Group, Western Service Center.*

[FR Doc. 2024–30530 Filed 12–20–24; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF COMMERCE

## Bureau of Industry and Security

## 15 CFR Parts 742 and 774

**[Docket No. 241212–0324]**

**RIN 0694–AJ83**

## Implementation of Certain Australia Group Decisions

**AGENCY:** Bureau of Industry and Security, Department of Commerce.

**ACTION:** Final rule.

**SUMMARY:** The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement changes agreed to by Australia Group (AG) member countries at recent meetings. These include controlling: instruments for the automated chemical synthesis of peptides (automated peptide synthesizers), dipropylamine, and neosaxitoxin; and revising the controls for botulinum toxins, toxic gas monitors, and centrifugal separators. This rule also makes minor conforming changes for the new controls and revisions to existing controls.

**DATES:** This rule is effective December 23, 2024.

**FOR FURTHER INFORMATION CONTACT:**

For questions on pathogens and toxins discussed in this rule, contact Dr. Lauren Reynolds, Chemical and Biological Controls Division, Office of Nonproliferation and Foreign Policy Controls, Bureau of Industry and Security, Telephone: (202) 482–2794, Email: *Lauren.Reynolds@bis.doc.gov.*

For all other questions pertaining to this rule, contact Logan Norton, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482–1762, Email: *RPD2@bis.doc.gov.*

**SUPPLEMENTARY INFORMATION:**

### The Australia Group

BIS is amending the Export Administration Regulations (EAR) (15 CFR parts 730–774) to reflect the decisions made at the 2023 Intersessional Meeting in Rome, Italy, the 2023 Plenary Meeting in Paris, France, the 2024 Intersessional Meeting in Berlin, Germany and the 2024 Plenary Meeting in Paris, France. The Australia Group (AG) is a multilateral forum consisting of 42 participating countries and the European Union. These participants maintain export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

### Regulatory Changes

As stated above, this rule implements changes agreed upon at the 2023 and 2024 Intersessional and Plenary Meetings of the AG. The changes made at each meeting are described below in chronological order.

*2023 Intersessional*

The AG meeting of the 2023 Intersessional determined that not all AG members assess gas detection systems with the same criteria. Prior to this rule, the control text only referred to the ability to detect chemical warfare agents or AG controlled precursors at a concentration of less than 0.3 mg/m$^3$. This made it unclear if a gas detection system with a noise level near 0.3 mg/m$^3$ was controlled, without taking into account the instrument detection limit. As a result, the AG agreed to a uniform way of applying the control language on toxic gas monitors and monitoring systems. To clarify the text, the AG agreed to the new term called 'minimum detection limit' and a corresponding definition, both detailed below, to the control text.

The AG agreed to two changes to ECCN 2B351. First, in item paragraph .a, ''at concentrations of less than'' is replaced with '''minimum detection limit' of'', which is still followed by the 0.3 mg/m$^3$ concentration measurement. Second, it adds a technical note defining 'minimum detection limit' as the lowest detectable concentration of the analyte required to produce a signal greater than three times the standard deviation of the toxic gas monitor's or monitoring system's signal when measuring a blank sample; alternatively, in the case of toxic gas monitors or monitoring systems having a deadband or programmed zero suppression, the 'minimum detection limit' is the lowest detectable concentration required to produce a reading.

*2023 Plenary*

In the 2023 Plenary Meeting, the AG reached consensus on three primary revisions, mostly impacting ECCNs 1C350.d and 1C351.d.

ECCN 1C350.d had multiple changes. In February 2020 the AG added a number of precursors to the chemical weapons precursors control list. However, dipropylamine, which is also useful for the synthesis of the corresponding AG-controlled precursors, was not yet controlled. The AG determined that it was important to address this issue by controlling dipropylamine. Under ECCN 1C350, (C.A.S. #142–84–7) Dipropylamine was added as .d.11. The items that had been listed in item paragraphs .d.11 through .d.49 remain, with their item paragraphs shifting up by a factor of one.

Botulinum toxins can be neurotoxins or non-neurotoxins. Previously, the AG had not specifically stated if only botulinum neurotoxins should be captured by ECCN 1C351.d.3 or if all botulinum toxins are included. The AG agreed to update the language to ''botulinum neurotoxins'' noting the greater risk of their use in chemical and biological weapons activities relative to other botulinum toxins. Under ECCN 1C351, item paragraph .d.3 was revised to read as ''botulinum neurotoxins'' as opposed to previously reading ''botulinum toxins.'' Conforming

changes were made in ECCN 1C991.c.1, .c.2, .d.1, and .d.3.

Neosaxitoxin is a potent neurotoxin causing similar symptoms to saxitoxin and gonyautoxins, both of which were controlled at the 2022 Plenary Meeting, in humans and animals. The AG found that the high toxicity of neosaxitoxin has been demonstrated in scientific models, as well as its resistance to heat; these factors make this toxin a potential threat as it could be used as a biological weapon like saxitoxin. Therefore, the AG agreed to control neosaxitoxin under the ''List of Human and Animal Pathogens and Toxins for Export Control.'' BIS details the toxins on this list under ECCN 1C351.d. To facilitate this addition, item paragraph .d.12 was redesignated to control neosaxitoxin (NEO), which shifted what had been in item paragraphs .d.12 through .d.21 up by a factor of one. Given this new control, license requirement note 2 to ECCN 1C351, which discussed neosaxitoxin, is removed, shifting notes 3 through 5 down by a factor of one. Additionally, multiple references to the item paragraphs for ricin and saxitoxin (now item paragraphs .d.15 and .d.16, respectively), had to be updated; these conforming changes occurred in: § 742.2(a)(1)(i), (a)(2)(ii), and (a)(2)(vi)(B); § 742.18(a)(1), (b)(1)(i), (b)(1)(ii), and (b)(1)(iii); ECCNs 1C351, 1C353, 1C991, 1E001, and 1E351.

*2024 Intersessional*

Prior to the publication of this rule, centrifugal separators were already controlled under ECCN 2B352.c. Since these controls were put into place, the technology and characteristics of newly available single-use centrifugal separators shows a potential for abuse comparable to that of the listed centrifugal separators. Single-use centrifugal separators are new to market and are increasingly used in the biopharmaceutical industry. Single-use centrifugal separators are mainly designed for the separation of protein expressing cell cultures. Available single-use centrifugal separators create new ways of processing cell culture-based fermentations with a yield of 98% or more. Most single-use centrifugal separators systems are flexible in usage and simple for scaling. Therefore, the AG felt it necessary to revise the control text for these items, accounting for single-use centrifugal separators.

To best facilitate these revisions, structural changes were made to the existing ECCN 2B352.c. Prior to this rule, item paragraph .c comprised of c.1 through c.4, controlling multiple-use centrifugal separators. These parameters are now combined into a single .c.1, with new item paragraphs .c.1.a through .c; one parameter, what was .c.2 (a flow rate greater than 100 liters per hour), has been shifted up into the introductory text of .c, such that it applies to both single-use and multiple-use centrifugal separators. Now, item paragraph .c.2 will detail control text for single-use centrifugal separators, in which all components that come in direct contact with the substances being processed are disposable or single-use. As a conforming change, the technical note to item paragraph .c is revised to include single-use centrifugal separators.

*2024 Plenary*

At the 2024 Plenary Meeting, the AG reached consensus on controlling instruments for automated peptide synthesizers. Recent advances in peptide synthesis technology and instrumentation have increased both the speed of peptide synthesis and the length of peptide products, including peptides and proteins greater than 100 amino acids in length.[1] Most protein toxins that are controlled under ECCN 1C351 are over 100 amino acids in length and have an average length of 300 amino acids (with the notable exception of conotoxins, which range between 10–100 amino acids in length). Consequently, absent the imposition of additional controls on the export, reexport or transfer (in-country) of certain peptide synthesis technology and instrumentation (*e.g.,* automated peptide synthesizers), there would be an increased risk that such technology and instrumentation could be used to produce controlled toxins for biological weapons purposes.

Automated peptide synthesizers are controlled under new item paragraph .k in ECCN 2B352. Item paragraph .k, contains two subparagraphs, .k.1 and .k.2. Item paragraph .k controls peptide synthesizers that are both: partly or entirely automated (.k.1) and capable of generating peptides at a 'system synthesis scale' of 1 mmol or greater (.k.2). Item paragraph .k includes a technical note, providing a definition of a 'system synthesis scale' as follows: denotes the maximum amount of peptide (mmol) that can be produced by the instrument using the largest compatible reaction vessels (L). For multiple peptides produced in parallel, this is the sum of the largest compatible reaction vessels (L). The new controls also include a nota bene referring readers to ECCN 2B350 for other chemical reaction vessels or reactors.

[1] Sameer S. Kulkarni et al., *Rapid and Efficient Protein Synthesis Through Expansion of the Native Chemical Ligation Concept,* Nature Revs. Chemistry, Mar. 29, 2018, page 1.

**RIN History**

On April 20, 2023, BIS published *Section 1758 Technology Export Controls on Instruments for the Automated Chemical Synthesis of Peptides* (88 FR 24341) (Peptide Synthesizers Proposed Rule), seeking comments on proposed additional controls of peptide synthesizers. That rule, published under RIN 0694–AI84, which is its U.S. Government regulatory identification number, proposed identifying automated peptide synthesizers as emerging and foundational technologies consistent with Section 1758 of the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. 4801–4852. Section 1758 provides that BIS identify emerging and foundational technologies that are essential to U.S. national security and are not critical technologies, as that term is defined in the Defense Production Act of 1950, as amended. This final rule finalizes those proposed changes; however, this rule includes additional changes outside of the scope of the Peptide Synthesizers Proposed Rule and includes items that are not Section 1758 technologies. Those changes are consistent with the authorities described in Section 1753 of ECRA (50 U.S.C. 4812) to regulate the export, reexport, and transfer (in-country) of items subject to U.S. jurisdiction as well as the mandate to seek multilateral controls. Pursuant to Section 1762(a) of ECRA (50 U.S.C. 4821(a)), these changes can be imposed in a final rule without prior notice and comment. To avoid public confusion, BIS created a new RIN for this rule, RIN 0694–AJ83, to encompass the finalized version of the proposed Section 1758 technologies and the additional changes.

**Public Comments in Response to Peptide Synthesizers Proposed Rule**

BIS published two actions, an Advanced Notice of Proposed Rulemaking (87 FR 55930 (Sept. 13, 2022)) and the Peptide Synthesizers Proposed Rule to better inform the AG process through public comments. BIS received five comments from the public on the 2022 advanced notice of proposed rulemaking, to which BIS responded in the Peptide Synthesizers Proposed Rule, but received no comments on the Peptide Synthesizers Proposed Rule itself.

**Export Control Reform Act of 2018**

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for

Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. 4801–4852. ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. In particular, and as noted elsewhere, Section 1753 of ECRA (50 U.S.C. 4812) authorizes the regulation of exports, reexports, and transfers (in-country) of items subject to U.S. jurisdiction as well as the mandate to ''seek to secure the cooperation of other governments and multilateral organizations to impose control systems that are consistent, to the extent possible, with the controls imposed under'' the EAR. Further, ECRA notes that the ''national security and foreign policy of the United States require that the export, reexport, and in-country transfer of items . . . be controlled . . . [t]o carry out obligations and commitments under international agreements and arrangements, including multilateral export control regimes.'' 50 U.S.C. 4811(2)(E). Further, Section 1754(a)(1) through (16) of ECRA (50 U.S.C. 4813(a)(1) through (16)) authorizes, *inter alia:* (1) the establishment of a list of controlled items; (2) the prohibition of unauthorized exports, reexports, and transfers (in-country); (3) the requirement of licenses or other authorizations for exports, reexports, and transfers (in-country) of controlled items; (4) the apprising of the public of changes in policy, regulations, and procedures; and (5) any other action necessary to carry out ECRA that is not otherwise prohibited by law. Pursuant to Section 1762(a) of ECRA (50 U.S.C. 4821(a)), these changes can be imposed in a final rule without prior notice and comment.

**Rulemaking Requirements**

1. This rule has been determined to be a significant regulatory action for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or 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 regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and commodity classifications, and carries a burden estimate of 29.4 minutes for a manual or electronic submission for a total burden estimate of 35,739 hours. BIS estimates an increase of 40 new licenses each year, which would be an increase of 25 burden hours. This minimal burden hour increase is within existing estimates for this collection. Additional information regarding these collections of information—including all background materials—can be found at *https://www.reginfo.gov/public/do/PRAMain* by using the search function to enter either the title of the collection or the OMB Control Number.

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

4. As stated in the preamble of this final rule, the amendments contained in this rule reflect decisions made by the AG. Therefore, pursuant to Section 1762 of ECRA (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation and delay in effective date. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this final rule by the APA or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*), are not applicable. However, specifically on the changes related to the Peptide Synthesizers Proposed Rule, the following applies: Consistent with the emerging and foundational technologies notice and comment requirements in Section 1758(a)(2)(C) of ECRA (50 U.S.C. 4817(a)(2)(C)), BIS published Peptide Synthesizers Proposed Rule to provide the public with notice and the opportunity to comment on its proposal to amend ECCN 2B352 as detailed above, the synthesis and collection of which BIS had identified for evaluation according to the criteria in Section 1758 of ECRA pertaining to emerging and foundational technologies. No public comments were made on the proposed rule.

Consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*), BIS has prepared the following final regulatory flexibility analysis (FRFA) of the impact that this final rule will have on small businesses. This only applies to the portions of the rule that finalize changes to Peptide Synthesizers Proposed Rule; the other changes in this rule are exempt under ECRA from this requirement.

*Description of the Reasons Why Action Is Being Considered*

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

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

The objective of the Section 1758 portions of this final rule, and all other Section 1758 technology proposed rules published by BIS, is to control emerging and foundational technologies identified by BIS and its interagency partners as being essential to U.S. national security.

Other than the discussions above about the regulatory history of these items, no other Federal rules duplicate, overlap, or conflict with this final rule.

*Number and Description of Small Entities Regulated by the Final Action*

This final rule will apply to all persons engaged in the export, reexport or transfer (in-country) of the automated peptide synthesizers proposed for control under ECCN 2B352 and the related ''technology'' subject to the EAR. Presently, these instruments and related ''technology'' are used in research and development activities in the biotechnology field (*e.g.,* U.S. university, military and industrial laboratories). Therefore, BIS anticipates that the final controls will result in 'deemed' export license applications (for the release of ''technology'' to foreign nationals located within the United States) to allow access to this ''technology'' by foreign students and faculty at U.S. universities, as well as by non-U.S. employees of U.S. biochemical firms. There will most likely also be 'deemed' reexport license applications for the release of this ''technology'' to third-country foreign nationals located in foreign countries who are engaged in research and development activities involving this ''technology.''

BIS does not collect or maintain the data necessary to determine how many of the affected persons are small entities as that term is used by the Small Business Administration. However, in the Peptide Synthesizers Proposed Rule, BIS was able to estimate the number of license applications that the agency anticipates receiving as a result of this proposed rule and is using that estimate as a means of assessing the impact on

small businesses. Using the North American Industry Classification System Codes (NAICS) 541714 (Research and Technology in Biotechnology (except Nanobiotechnology)), BIS determined that the standard small business size in this industry is 1,000 employees. Using Table 1a of the Census Bureau's 2019 Exports by Company Type and Employment Size and extrapolating to 1,000 employees, BIS then estimated that approximately 40% of all identified companies that export in this industry are small businesses. BIS also estimates that it will receive 40 license applications per year for the items described in this proposed rule (see the PRA estimates described in Rulemaking Requirements #2, above). Based on that information, BIS estimates that the agency will receive approximately 16 license applications per year from small businesses, or roughly 40% of the 40 estimated license applications.

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

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

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

The changes in this rule and the corresponding reporting, recordkeeping, and other compliance requirements are discussed in the background section of the preamble of this document and, consequently, are not repeated here. To the extent that compliance with the changes in this rule would impose a burden on persons, including small businesses, BIS believes the burden will be minimal.

*Significant Alternatives and Underlying Analysis*

As noted above, BIS does not believe that this rule will have a significant economic impact on small businesses. Nevertheless, consistent with 5 U.S.C. 603(c), BIS considered significant alternatives as outlined in the Peptide Synthesizers Proposed Rule. However, those options would have had a greater impact not only on small businesses, but also on research and development laboratories (both academic and corporate), which are involved in advancing these technologies. BIS has determined that finalizing focused controls on the items detailed above is the least disruptive alternative for implementing export controls in a manner consistent with controlling technology that has been determined, through the Section 1758 technology interagency process authorized under ECRA, to be essential to U.S. national security.

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

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

This final rule does not contain an exemption for small businesses from this license requirement because BIS and its interagency partners had to assess whether these controls are essential to U.S. national security. Specifically, items controlled could be used for nefarious purposes and, as such, controlling these items on the CCL may be determined to be essential to U.S. national security pursuant to the interagency process for identifying emerging and foundational technologies that is described in Section 1758(a) of ECRA (50 U.S.C. 4817(a)). An exemption for small businesses would undermine the effectiveness of these controls.

*Conclusion*

The FRFA prepared by BIS requested comments on the analyses and conclusions contained therein, including the overall conclusion that the amendments in the Peptide Synthesizers Proposed Rule would not have a significant economic impact on a substantial number of small entities. BIS did not receive any comments in response to the analyses and conclusions contained in the IRFA for the Peptide Synthesizers Proposed Rule.

**List of Subjects**

*15 CFR Part 742*

Exports and Terrorism.

*15 CFR Part 774*

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, parts 742, and 774 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

## PART 742—CONTROL POLICY—CCL BASED CONTROLS

■ 1. The authority citation for part 742 continues to read as follows:

**Authority:** 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 1, 2023, 88 FR 75475 (November 3, 2023).

■ 2. Amend § 742.2 by revising paragraphs (a)(1)(i), (a)(2)(ii), and (a)(2)(vi) to read as follows:

**§ 742.2 Proliferation of chemical and biological weapons.**

(a) * * *

(1) * * *

(i) Toxins identified in ECCNs 1C351.d.15 and .16;

* * * * *

(2) * * *

(ii) Human pathogens, zoonoses, toxins, animal pathogens, genetically modified microorganisms and plant pathogens identified in ECCNs 1C351 (except .d.15 and .16), 1C353 (except genetic elements of toxins in ECCN 1C351.d.15 and .16), and 1C354; and

* * * * *

(vi) Technology (ECCNs 1E001 and 1E351) for:

(A) Production and/or disposal of chemical precursors described in ECCN 1C350; and

(B) Production and/or disposal of microbiological commodities described in paragraph (a)(2)(ii) of this section (except toxins and genetic elements of those toxins in ECCN 1C351.d.15 and .16). * * *

* * * * *

■ 3. Amend § 742.18 by revising paragraphs (a)(1), (b)(1)(i) introductory text, (b)(1)(ii), and (b)(1)(iii) to read as follows:

**§ 742.18 Chemical Weapons Convention (CWC or Convention).**

* * * * *

(a) *License requirements*—(1) *Schedule 1 chemicals and mixtures controlled under ECCN 1C351.* A license is required for CW reasons to export or reexport Schedule 1 chemicals controlled under ECCN 1C351.d.15 or .d.16 to all destinations including Australia, Canada, and the United Kingdom. CW applies to 1C351.d.15 for ricin in the form of Ricinus Communis AgglutininII ($RCA_{II}$), which is also known as ricin D or Ricinus Communis LectinIII ($RCL_{III}$), and Ricinus Communis LectinIV ($RCL_{IV}$), which is also known as ricin E. CW applies to 1C351.d.16 for saxitoxin identified by C.A.S. #35523–89–8. (Note that the advance notification procedures and annual reporting requirements described in § 745.1 of the EAR also apply to exports of Schedule 1 chemicals.)

(b) * * *

(1) * * *

(i) *Exports to States Parties to the CWC.* Applications to export Schedule 1 Chemicals controlled under ECCN 1C351.d.15 or .d.16 to States Parties to the CWC (destinations listed in supplement no. 2 to part 745 of the EAR) generally will be denied, unless all of the following conditions are met:

* * * * *

(ii) *Exports to States not party to the CWC.* Applications to export Schedule 1 chemicals controlled under ECCN 1C351.d.15 or .d.16 to States not Party to the CWC (destinations not listed in supplement no. 2 to part 745 of the EAR) generally will be denied, consistent with U.S. obligations under the CWC to prohibit exports of these chemicals to States not Party to the CWC.

(iii) *Reexports.* Applications to reexport Schedule 1 chemicals controlled under ECCN 1C351.d.15 or .d.16 generally will be denied to all destinations (including both States Parties to the CWC and States not Party to the CWC).

* * * * *

## PART 774—THE COMMERCE CONTROL LIST

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

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

### Supplement No. 1 to part 774—The Commerce Control List

■ 5. Supplement no.1 to part 774 is revised as follows:

■ a. In Category 1 revise ECCNs 1C350, 1C351, 1C353, 1C991, 1E001, and 1E351; and

■ b. Under Category 2 revise ECCNs 2B351 and 2B352.

The revisions read as follows:

**Category 1—Materials, Chemicals, Microorganisms and Toxins**

**C. ''MATERIALS''**

* * * * *

**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, 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.14 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, isotopically-labeled forms or all possible stereoisomers) 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

**List of Items Controlled**

*Related Controls:* See USML Category XIV for related chemical agent binary precursors and key precursors ''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) Methylphosphonothioic 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. #589–57–1) Diethyl chlorophosphite;

d.6. (C.A.S. #298–06–6) O,O-Diethyl phosphorodithioate;

d.7. (C.A.S. #2465–65–8) O,O-Diethyl phosphorothioate;

d.8. (C.A.S. #108–18–9) Di-isopropylamine;

d.9. (C.A.S. #124–40–3) Dimethylamine;

d.10. (C.A.S. #506–59–2) Dimethylamine hydrochloride;

d.11. (C.A.S. #142–84–7) Dipropylamine

d.12. (C.A.S. #762–77–6) Ethyl chlorofluorophosphate;

d.13. (C.A.S. #1498–51–7) Ethyl dichlorophosphate;

d.14. (C.A.S. #460–52–6) Ethyl difluorophosphate;

d.15. (C.A.S. #7664–39–3) Hydrogen fluoride;

d.16. (C.A.S. #3554–74–3) 3-Hydroxyl-1-methylpiperidine;

d.17. (C.A.S. #76–89–1) Methyl benzilate;

d.18. (C.A.S. #754–01–8) Methyl chlorofluorophosphate;

d.19. (C.A.S. #677–24–7) Methyl dichlorophosphate;

d.20. (C.A.S. #22382–13–4) Methyl difluorophosphate;

d.21. (C.A.S. #14277–06–6) N,N Diethylacetamidine;

d.22. (C.A.S. #53510–30–8) N,N-Diethylbutanamidine;

d.23. (C.A.S. #90324–67–7) N,N-Diethylformamidine;

d.24. (C.A.S. #1342789–47–2) N,N Diethylisobutanamidine;

d.25. (C.A.S. #84764–73–8) N,N-Diethylpropanamidine;

d.26. (C.A.S. #1315467–17–4) N,N-Diisopropylbutanamidine;

d.27. (C.A.S. #857522–08–8) N,N-Diisopropylformamidine;

d.28. (C.A.S. #2909–14–0) N,N-Dimethylacetamidine;

d.29. (C.A.S. #1340437–35–5) N,N-Dimethylbutanamidine;
d.30. (C.A.S. #44205–42–7) N,N-Dimethylformamidine;
d.31. (C.A.S. #321881–25–8) N,N-Dimethylisobutanamidine;
d.32. (C.A.S. #56776–14–8) N,N-Dimethylpropanamidine;
d.33. (C.A.S. #1339586–99–0) N,N-Dipropylacetamidine;
d.34. C.A.S. #1342422–35–8) N,N-Dipropylbutanamidine;
d.35. (C.A.S. #48044–20–8) N,N-Dipropylformamidine;
d.36. (C.A.S. #1342700–45–1) N,N-Dipropylisobutanamidine;
d.37. (C.A.S. #1341496–89–6) N,N-Dipropylpropanamidine;
d.38. (C.A.S. #1314–80–3) Phosphorus pentasulfide;
d.39. (C.A.S. #75–97–8) Pinacolone;
d.40. (C.A.S. #7789–29–9) Potassium bifluoride;
d.41. (C.A.S. #151–50–8) Potassium cyanide;
d.42. (C.A.S. #7789–23–3) Potassium fluoride;
d.43. (C.A.S. #3731–38–2) 3-Quinuclidone;
d.44. (C.A.S. #1333–83–1) Sodium bifluoride;
d.45. (C.A.S. #143–33–9) Sodium cyanide;
d.46. (C.A.S. #7681–49–4) Sodium fluoride;
d.47. (C.A.S. #16893–85–9) Sodium hexafluorosilicate;
d.48. (C.A.S. #1313–82–2) Sodium sulfide;
d.49. (C.A.S. #637–39–8) Triethanolamine hydrochloride;
d.50. (C.A.S. #116–17–6) Tri-isopropyl phosphite.

**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 items controlled by 1C351.d.15 and .16. | CB Column 1. |
| CB applies to entire entry. | CB Column 2. |

CW applies to 1C351.d.15 and .d.16 and a license is required for CW reasons for all destinations, including Australia, Canada, and the United Kingdom, as follows: CW applies to 1C351.d.15 for ricin in the form of (1) Ricinus communis AgglutininII ($RCA_{II}$), also known as ricin D or Ricinus Communis LectinIII ($RCL_{III}$) and (2) Ricinus communis LectinIV ($RCL_{IV}$), also known as ricin E. CW applies to 1C351.d.16 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 | 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 1C351.d, with the exception of toxins controlled for CW reasons under 1C351.d.15 or .d.16, 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. Clostridium perfringens strains, other than the epsilon toxin-producing strains of Clostridium perfringens described in 1C351.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.*

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

*4. 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

**List of Items Controlled**

*Related Controls:* (1) Certain forms of ricin and saxitoxin in 1C351.d.15 and .d.16 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 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 USML Category XIV for modified biological agents and biologically derived substances that are ''subject to the ITAR'' (see 22 CFR parts 120 through 130).
*Related Definitions:* For the purposes of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact.
*Items:*

a. Viruses identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:
a.1. African horse sickness virus;
a.2. African swine fever virus;
a.3. Andes virus;
a.4. Avian influenza (AI) viruses identified as having high pathogenicity (HP), as follows:
a.4.a. AI viruses that have an intravenous pathogenicity index (IVPI) in 6-week-old chickens greater than 1.2; *or*
a.4.b. AI viruses that cause at least 75% mortality in 4- to 8-week-old chickens infected intravenously.
*Note:*
*Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in 1C351.a.4 (specifically, 1C351.a.4.a or .a.4.b) should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is controlled under 1C351.a.4.*
a.5. Bluetongue virus;
a.6. Chapare virus;
a.7. Chikungunya virus;
a.8. Choclo virus;
a.9. Classical swine fever virus (Hog cholera virus);
a.10. Crimean-Congo hemorrhagic fever virus;
a.11. Dobrava-Belgrade virus;
a.12. Eastern equine encephalitis virus;
a.13. Ebolavirus (includes all members of the Ebolavirus genus);
a.14. Foot-and-mouth disease virus;
a.15. Goatpox virus;
a.16. Guanarito virus;
a.17. Hantaan virus;
a.18. Hendra virus (Equine morbillivirus);
a.19. Japanese encephalitis virus;
a.20. Junin virus;
a.21. Kyasanur Forest disease virus;
a.22. Laguna Negra virus;
a.23. Lassa virus;
a.24. Louping ill virus;
a.25. Lujo virus;
a.26. Lumpy skin disease virus;
a.27. Lymphocytic choriomeningitis virus;
a.28. Machupo virus;
a.29. Marburgvirus (includes all members of the Marburgvirus genus);
a.30. Middle East respiratory syndrome-related coronavirus (MERS-related coronavirus);
a.31. Monkeypox virus;
a.32. Murray Valley encephalitis virus;
a.33. Newcastle disease virus;
a.34. Nipah virus;
a.35. Omsk hemorrhagic fever virus;

a.36. Oropouche virus;
a.37. Peste-des-petits ruminants virus;
a.38. Porcine Teschovirus;
a.39. Powassan virus;
a.40. Rabies virus and all other members of the Lyssavirus genus;
a.41. Reconstructed 1918 influenza virus;
*Technical Note:*
*1C351.a.41 includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.*
a.42. Rift Valley fever virus;
a.43. Rinderpest virus;
a.44. Rocio virus;
a.45. Sabia virus;
a.46. Seoul virus;
a.47. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);
a.48. Sheeppox virus;
a.49. Sin Nombre virus;
a.50. St. Louis encephalitis virus;
a.51. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);
a.52. Swine vesicular disease virus;
a.53. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus—see 1C351.b.3 for Siberian subtype);
a.54. Variola virus;
a.55. Venezuelan equine encephalitis virus;
a.56. Vesicular stomatitis virus;
a.57. Western equine encephalitis virus; *or*
a.58. Yellow fever virus.
b. Viruses identified on the APHIS/CDC ''select agents'' lists (see Related Controls paragraph #2 for this ECCN), but not identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:
b.1. [Reserved];
b.2. [Reserved]; *or*
b.3. Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus—see 1C351.a.53 for Far Eastern subtype).
c. Bacteria identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows:
c.1. Bacillus anthracis;
c.2. Brucella abortus;
c.3. Brucella melitensis;
c.4. Brucella suis;
c.5. Burkholderia mallei (Pseudomonas mallei);
c.6. Burkholderia pseudomallei (Pseudomonas pseudomallei);
c.7. Chlamydia psittaci (Chlamydophila psittaci);
c.8. Clostriduim argentinense (formerly known as Clostridium botulinum Type G), botulinum neurotoxin producing strains;
c.9. Clostridium baratii, botulinum neurotoxin producing strains;
c.10. Clostridium botulinum;
c.11. Clostridium butyricum, botulinum neurotoxin producing strains;
c.12. Clostridium perfringens, epsilon toxin producing types;
c.13. Coxiella burnetii;
c.14. Francisella tularensis;
c.15. Mycoplasma capricolum subspecies capripneumoniae (''strain F38'');
c.16. Mycoplasma mycoides subspecies mycoides SC (small colony) (a.k.a. contagious bovine pleuropneumonia);
c.17. Rickettsia prowazekii;
c.18. Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi);
c.19. Shiga toxin producing Escherichia coli (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups;
*Note:*
*Shiga toxin producing Escherichia coli (STEC) includes, inter alia, enterohaemorrhagic E. coli (EHEC), verotoxin producing E. coli (VTEC) or verocytotoxin producing E. coli (VTEC).*
c.20. Shigella dysenteriae;
c.21. Vibrio cholerae; *or*
c.22. Yersinia pestis.
d. ''Toxins'' identified on the Australia Group (AG) ''List of Human and Animal Pathogens and Toxins for Export Control,'' as follows, or their subunits:
d.1. Abrin;
d.2. Aflatoxins;
d.3. Botulinum neurotoxins;
d.4. Brevetoxins;
d.5. Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins;
d.6. Conotoxins;
d.7. Diacetoxyscirpenol;
d.8. Gonyautoxins;
d.9. HT–2 toxin;
d.10. Microcystins (Cyanginosins);
d.11. Modeccin;
d.12. Neosaxitoxin (NEO);
d.13. Nodularins;
d.14. Palytoxin;
d.15. Ricin;
d.16. Saxitoxin;
d.17. Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);
d.18. Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F);
d.19. T–2 toxin;
d.20. Tetrodotoxin;
d.21. Viscumin (Viscum album lectin 1); *or*
d.22. Volkensin.
e. ''Fungi'', as follows:
e.1. Coccidioides immitis; *or*
e.2. Coccidioides posadasii.

* * * * *

**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 genetic elements of items controlled by 1C351.d.15 and .16. | CB Column 1. |
| CB applies to entire entry. | CB Column 2. |
| 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

**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 USML Category XIV for modified biological agents and biologically derived substances that are ''subject to the ITAR'' (see 22 CFR parts 120 through 130).
*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, genes, translated product or translated products 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.*

* * * * *

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

**License Requirements**

*Reason for Control:* CB, AT

| *Control(s)* | *Country chart (See Supp. No. 1 to part 738)* |
|---|---|
| CB applies to 1C991.c ... | CB Column 3. |
| AT applies to entire entry | AT Column 1. |

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

*LVS:* N/A
*GBS:* N/A

**List of Items Controlled**

*Related Controls:* (1) Medical products containing ricin or saxitoxin, as follows, are controlled for CW reasons under ECCN 1C351:
(a) Ricinus communis AgglutininII ($RCA_{II}$), also known as ricin D, or Ricinus Communis LectinIII ($RCL_{III}$);
(b) Ricinus communis LectinIV ($RCL_{IV}$), also known as ricin E; *or*
(c) Saxitoxin identified by C.A.S. #35523–89–8.
(2) The export of a ''medical product'' that is an ''Investigational New Drug'' (IND), as defined in 21 CFR 312.3, is subject to certain U.S. Food and Drug Administration (FDA) requirements that are independent of the export requirements specified in this ECCN or elsewhere in the EAR. These FDA requirements are described in 21 CFR 312.110 and must be satisfied in addition to any requirements specified in the EAR.
(3) Also see 21 CFR 314.410 for FDA requirements concerning exports of new drugs and new drug substances.
*Related Definitions:* For the purpose of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact. For the purpose of this entry, 'medical products' are: (1) Pharmaceutical formulations designed for testing and human (or veterinary) administration in the treatment of medical conditions; (2) prepackaged for distribution as clinical or medical products; and (3) approved by the U.S. Food and Drug Administration either to be marketed as clinical or medical products or for use as an ''Investigational New Drug'' (IND) (see 21 CFR part 312). For the purpose of this entry, 'diagnostic and food testing kits' are specifically developed, packaged and marketed for diagnostic or public health purposes. Biological toxins in any other configuration, including bulk shipments, or for any other end-uses are controlled by ECCN 1C351. For the purpose of this entry, 'vaccine' is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.
*Items:*

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

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

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

c. Medical products that contain any of the following:

c.1. Toxins controlled by ECCN 1C351.d (except for botulinum neurotoxins controlled by ECCN 1C351.d.3, conotoxins controlled by ECCN 1C351.d.6, or items controlled for CW reasons under ECCN 1C351.d.15 or .d.16); *or*

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

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

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

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

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

e. Diagnostic and food testing kits containing toxins controlled by ECCN 1C351.d (except for items controlled for CW reasons under ECCN 1C351.d.15 or .d.16).

* * * * *

**E. ''Technology''**

**1E001 ''Technology'' according to the General Technology Note for the ''development'' or ''production'' of items controlled by 1A002, 1A003, 1A004, 1A005, 1A006.b, 1A007, 1A008 1A101, 1A231, 1B (except 1B608, 1B613 or 1B999), or 1C (except 1C355, 1C608, 1C980 to 1C984, 1C988, 1C990, 1C991, 1C995 to 1C999).**

**License Requirements**

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

| *Control(s)* | *Country chart (see Supp. No. 1 to part 738)* |
|---|---|
| NS applies to ''technology'' for items controlled by 1A002, 1A003, 1A005, 1A006.b, 1A007, 1B001 to 1B003, 1B018, 1C001 to 1C011, or 1C018. | NS Column 1. |
| NS applies to ''technology'' for items controlled by 1A004. | NS Column 2. |
| MT applies to ''technology'' for items controlled by 1A101, 1B001, 1B101, 1B102, 1B115 to 1B119, 1C001, 1C007, 1C011, 1C101, 1C102, 1C107, 1C111, 1C116, 1C117, or 1C118 for MT reasons. | MT Column 1. |
| NP applies to ''technology'' for items controlled by 1A002, 1A007, 1A231, 1B001, 1B101, 1B201, 1B225, 1B226, 1B228 to 1B234, 1C002, 1C010, 1C111, 1C116, 1C202, 1C210, 1C216, 1C225 to 1C237, or 1C239 to 1C241 for NP reasons. | NP Column 1. |
| CB applies to ''technology'' for items controlled by 1C351.d.15 and .16 and the 1C353 genetic elements of toxins in ECCN 1C351.d.15 and .16. | CB Column 1. |
| CB applies to ''technology'' for items controlled by 1C351, 1C353, or 1C354; and CB applies to ''technology'' for materials controlled by 1C350 and for chemical detection systems and dedicated detectors therefor, in 1A004.c, that also have the technical characteristics described in 2B351.a. | CB Column 2. |
| RS applies to technology for equipment controlled in 1A004.d. | RS Column 2. |
| AT applies to entire entry | AT Column 1. |

**Reporting Requirements**

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

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

*TSR:* Yes, except for the following:
(1) Items controlled for MT reasons; or
(2) Exports and reexports to destinations outside of those countries listed in Country Group A:5 (See Supplement No. 1 to part

740 of the EAR) of ''technology'' for the ''development'' or production'' of the following:

(a) Items controlled by 1C001; or

(b) Items controlled by 1A002.a which are composite structures or laminates having an organic ''matrix'' and being made from materials listed under 1C010.c or 1C010.d.

**Special Conditions for STA**

*STA:* License Exception STA may not be used to ship or transmit ''technology'' according to the General Technology Note for the ''development'' or ''production'' of equipment and materials specified by ECCNs 1A002, 1C001, 1C007.c, 1C010.c or d or 1C012 to any of the destinations listed in Country Group A:6 (See Supplement No. 1 to part 740 of the EAR).

**List of Items Controlled**

*Related Controls* (1) Also see ECCNs 1E101, 1E201, and 1E202. (2) See ECCN 1E608 for ''technology'' for items classified under ECCN 1B608 or 1C608 that, immediately prior to July 1, 2014, were classified under ECCN 1B018.a or 1C018.b through .m (note that ECCN 1E001 controls ''development'' and ''production'' ''technology'' for chlorine trifluoride controlled by ECCN 1C111.a.3.f—see ECCN 1E101 for controls on ''use'' ''technology'' for chlorine trifluoride). (3) See ECCN 1E002.g for control libraries (parametric technical databases) ''specially designed'' or modified to enable equipment to perform the functions of equipment controlled under ECCN 1A004.c (Nuclear, biological and chemical (NBC) detection systems) or ECCN 1A004.d (Equipment for detecting or identifying explosives residues). (4) ''Technology'' for lithium isotope separation (see related ECCN 1B233) and ''technology'' for items described in ECCN 1C012 are subject to the export licensing authority of the Department of Energy (see 10 CFR part 810). (5) ''Technology'' for items described in ECCN 1A102 is ''subject to the ITAR'' (see 22 CFR parts 120 through 130).

*Related Definitions:* N/A

*Items:*

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

* * * * *

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

**License Requirements**

*Reason for Control:* CB, AT

| *Control(s)* | *Country chart (see Supp. No. 1 to part 738)* |
|---|---|
| CB applies to ''technology'' for the disposal of items controlled by 1C351.d.15 and .16 and the 1C353 genetic elements of toxins in ECCN 1C351.d.15 and .16. | CB Column 1. |
| CB applies to ''technology'' for the disposal of items controlled by 1C351, 1C353, or 1C354; and CB applies to ''technology'' for the disposal of items controlled by 1C350. | CB Column 2. |
| AT applies to entire entry | AT Column 1. |

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

TSR: N/A

**List of Items Controlled**

*Related Controls:* N/A

*Related Definitions:* N/A

*Items:*

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

* * * * *

**Category 2—Materials Processing**

**B. ''Test'', ''Inspection'' and ''Production Equipment''**

* * * * *

**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

**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 'minimum detection limit' of 0.3 mg/m$^3$; *or*

b. Designed for the detection of cholinesterase-inhibiting activity.

**Technical note:** *The 'minimum detection limit' of toxic gas monitors or monitoring systems is the lowest detectable concentration of the analyte required to produce a signal greater than three times the standard deviation of the toxic gas monitor's or monitoring system's signal when measuring a blank sample.*

*In the case of toxic gas monitors or monitoring systems having a deadband or programmed zero suppression, the 'minimum detection limit' is the lowest detectable concentration required to produce a reading.*

**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

**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 to 2B352.a.1:** *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 Notes to 2B352.b:**

*1. Fermenters include bioreactors (including single-use (disposable) bioreactors), chemostats and continuous-flow systems.*

*2. Cultivation chamber holding devices controlled by 2B352.b.2.b include single-use cultivation chambers with rigid walls.*

c. Centrifugal separators capable of continuous separation, without the propagation of aerosols, having a flow rate greater than 100 liters per hour, as follows:

c.1. Centrifugal separators having all of the following characteristics:

c.1.a. One or more sealing joints within the steam containment area;

c.1.b. Components of polished stainless steel or titanium; *and*

c.1.c. Capable of in-situ steam sterilization in a closed state.

c.2. Single-use centrifugal separators, in which all components that come in direct contact with the substances being processed are disposable or single-use.

*Technical Note to 2B352.c: Centrifugal separators and single-use 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 $m^2$); *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 $m^2$) 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 a process to reduce the number of microorganisms, but not usually of bacterial spores, through the use of chemical agents, without necessarily killing or removing all organisms.*

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 dependent upon a tethered external air supply and operating under positive pressure.

**Technical Note to 2B352.g.1:** *2B352.g.1 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 controls any isolator having all of the characteristics described in 2B352.g.2.a through g.2.d, regardless of its intended use and its designation, except for medical 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 to 2B352.i:**

*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.

k. Peptide synthesizers that are both:

k.1 Partly or entirely automated; *and*

k.2 Capable of generating peptides at a 'system synthesis scale' of 1 mmol or greater.

**Technical Note to 2B352.k:** *'System synthesis scale' denotes the maximum amount of peptide (mmol) that can be produced by the instrument using the largest compatible reaction vessels (L). For multiple peptides produced in parallel, this is the sum of the largest compatible reaction vessels (L).*

*N.B. to paragraph .k: See ECCN 2B350 for other chemical reaction vessels or reactors.*

* * * * *

**Matthew S. Borman,**

*Principal Deputy Assistant Secretary for Export Administration.*

[FR Doc. 2024–30425 Filed 12–20–24; 8:45 am]

**BILLING CODE 3510–33–P**