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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 748 and 774

[Docket No. 200521-0143]

RIN 0694-AH60

Implementation of the February 2020 Australia Group Intersessional Decisions: Addition of Certain Rigid-Walled, Single-Use Cultivation Chambers and Precursor Chemicals to the Commerce Control List

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 decisions made at the February 2020 Australia Group (AG) Intersessional Implementation Meeting, and those later adopted pursuant

to the AG's silence procedure. Specifically, this rule amends Export Control Classification Numbers (ECCNs) 1C350, 1C351 and 2B352 on the Commerce Control List (CCL) to reflect these AG changes. ECCN 1C350 is amended by adding twenty-four precursor chemicals, as well as mixtures in which at least one of these chemicals constitutes 30 percent or more of the weight of the mixture, to ECCN 1C350.d. ECCN 1C351 is amended to add Middle East respiratory syndrome-related coronavirus (MERS-related coronavirus). ECCN 2B352 is amended by adding a *Technical Note* to indicate that cultivation chamber holding devices controlled in 2B352.b.2.b include single-use cultivation chambers with rigid walls. The items addressed by this final rule were not previously listed on the CCL or controlled multilaterally. BIS, consistent with the interagency process described in the Export Control Reform Act of 2018 (ECRA), identified the precursor chemicals and single-use cultivation chambers addressed by this final rule as emerging technologies that are essential to U.S. national security and for which effective controls can be implemented. The inclusion of such items in this final rule is consistent with the requirements of ECRA and the decision of the AG to add such items to its common control lists, thereby making exports of such items subject to multilateral control (following the implementation of these changes by individual AG participating countries, including the United States).

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

FOR FURTHER INFORMATION CONTACT: Dr. Wesley Johnson, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of

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SUPPLEMENTARY INFORMATION:

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the decisions made at the Australia Group (AG) Intersessional Implementation Meeting held in Bratislava, Slovak Republic, on February 5 through 6, 2020, and those subsequently made pursuant to the AG silence procedure which ended on February 28, 2020 (the AG silence procedure provides for the adoption of a measure, subsequent to its provisional acceptance at an AG plenary or intersessional meeting, provided that no participating country submits an objection on or before a specified date). 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 2020 AG Intersessional Recommendations

ECCN 1C350 (chemical weapons precursors)

This final rule amends Export Control Classification Number (ECCN) 1C350 on the Commerce Control List (CCL) (Supplement No. 1 to part 774 of the EAR) to reflect changes to the AG

"Chemical Weapons Precursors" common control list based on the February 2020 Intersessional Implementation Meeting recommendations that were approved by the AG pursuant to a silence procedure which ended on February 28, 2020. Specifically, this rule amends ECCN 1C350 by adding the following twenty-four precursor chemicals under ECCN 1C350.d:

(C.A.S. #589-57-1) Diethyl chlorophosphite;

(C.A.S. #762-77-6) Ethyl chlorofluorophosphate;

(C.A.S. #1498-51-7) Ethyl dichlorophosphate;

(C.A.S. #460-52-6) Ethyl difluorophosphate;

(C.A.S. #754-01-8) Methyl chlorofluorophosphate;

(C.A.S. #677-24-7) Methyl dichlorophosphate;

(C.A.S. #22382-13-4) Methyl difluorophosphate;

(C.A.S. #14277-06-6) N,N-Diethylacetamidine;

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

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

(C.A.S. #1342789-47-2) N,N-Diethylisobutanamidine;

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

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

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

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

(C.A.S. #1340437-35-5) N,N-Dimethylbutanamidine;

(C.A.S. #44205-42-7) N,N-Dimethylformamidine;

(C.A.S. #321881-25-8) N,N-Dimethylisobutanamidine;

(C.A.S. #56776-14-8) N,N-Dimethylpropanamidine;

(C.A.S. #1339586-99-0) N,N-Dipropylacetamidine;

(C.A.S. #1342422-35-8) N,N-Dipropylbutanamidine;

(C.A.S. #48044-20-8) N,N-Dipropylformamidine;

(C.A.S. #1342700-45-1) N,N-Dipropylisobutanamidine; and

(C.A.S. #1341496-89-6) N,N-Dipropylpropanamidine.

Note that mixtures in which at least one of the chemicals listed in ECCN 1C350.d (which now includes the twenty-four precursor chemicals listed above) constitutes 30 percent or more of the weight of the mixture are also controlled under this ECCN.

In addition, although this rule does not amend ECCN 1D390 ("software" for chemical production process control), ECCN 1E001 ("technology" for the "development" or "production" of, *inter alia*, precursor chemicals controlled by ECCN 1C350), ECCN 1E350 ("technology" for chemical production facilities) or ECCN 1E351 ("technology" for the disposal of, *inter alia*, precursor chemicals), these ECCNs cross-reference items controlled by ECCN 1C350 and, consequently, "software" or "technology" that is related to any of the twenty-four precursor chemicals added by this rule to ECCN 1C350.d is now subject to control under ECCN 1D390, 1E001, 1E350 or 1E351 if such "software" or "technology" falls within the parameters of the controls described therein.

Prior to the addition of these twenty-four precursor chemicals to the AG chemical weapons precursors common control list, BIS, consistent with the interagency process described in the Export Control Reform Act of 2018 (ECRA) (50 U.S.C. 4801-4852) under Section 1758

(codified at 50 U.S.C. 4817), identified these items as emerging technologies that are essential to U.S. national security and for which effective controls can be implemented. This interagency process resulted in a finding that the absence of export controls on these precursor chemicals could be exploited for chemical weapons purposes. The inclusion of these precursor chemicals in this final rule is consistent with the requirements of ECRA and the decision of the AG to add these items to their common control lists, thereby making exports of such items subject to multilateral control.

This rule alphabetically reorders the precursor chemicals listed in ECCN 1C350.d to reflect the addition of the twenty-four precursor chemicals identified above. To assist in identifying the precursor chemicals that are now controlled under ECCN 1C350.d, the following table lists each chemical now found in ECCN 1C350.d, as well as the previous ECCN 1C350.d listing (if any) for these chemicals.

AG-Controlled Precursor Chemicals	**Previous CCL Designation**	**Current CCL Designation**
(C.A.S. #1341-49-7) Ammonium hydrogen fluoride	ECCN 1C350.d.1	ECCN 1C350.d.1
(C.A.S. #107-07-3) 2-Chloroethanol	ECCN 1C350.d.2	ECCN 1C350.d.2
(C.A.S. #109-89-7) Diethylamine	ECCN 1C350.d.3	ECCN 1C350.d.3
(C.A.S. #100-37-8) N,N-Diethylaminoethanol	ECCN 1C350.d.4	ECCN 1C350.d.4
(C.A.S. #589-57-1) Diethyl chlorophosphite	Not listed	ECCN 1C350.d.5

(C.A.S. #298-06-6) O,O-Diethyl phosphorodithioate	ECCN 1C350.d.5	ECCN 1C350.d.6
(C.A.S. #2465-65-8) O,O-Diethyl phosphorothioate	ECCN 1C350.d.6	ECCN 1C350.d.7
(C.A.S. #108-18-9) Di-isopropylamine	ECCN 1C350.d.7	ECCN 1C350.d.8
(C.A.S. #124-40-3) Dimethylamine	ECCN 1C350.d.8	ECCN 1C350.d.9
(C.A.S. #506-59-2) Dimethylamine hydrochloride	ECCN 1C350.d.9	ECCN 1C350.d.10
(C.A.S. #762-77-6) Ethyl chlorofluorophosphate	Not listed	ECCN 1C350.d.11
(C.A.S. #1498-51-7) Ethyl dichlorophosphate	Not listed	ECCN 1C350.d.12
(C.A.S. #460-52-6) Ethyl difluorophosphate	Not listed	ECCN 1C350.d.13
(C.A.S. #7664-39-3) Hydrogen fluoride	ECCN 1C350.d.10	ECCN 1C350.d.14
(C.A.S. #3554-74-3) 3-Hydroxyl-1-methylpiperidine	ECCN 1C350.d.11	ECCN 1C350.d.15
(C.A.S. #76-89-1) Methyl benzilate	ECCN 1C350.d.12	ECCN 1C350.d.16
(C.A.S. #754-01-8) Methyl chlorofluorophosphate	Not listed	ECCN 1C350.d.17
(C.A.S. #677-24-7) Methyl dichlorophosphate	Not listed	ECCN 1C350.d.18
(C.A.S. #22382-13-4) Methyl difluorophosphate	Not listed	ECCN 1C350.d.19
(C.A.S. #14277-06-6) N,N Diethylacetamidine	Not listed	ECCN 1C350.d.20

(C.A.S. #53510-30-8) N,N-Diethylbutanamidine	Not listed	ECCN 1C350.d.21
(C.A.S. #90324-67-7) N,N-Diethylformamidine	Not listed	ECCN 1C350.d.22
(C.A.S. #1342789-47-2) N,N Diethylisobutanamidine	Not listed	ECCN 1C350.d.23
(C.A.S. #84764-73-8) N,N-Diethylpropanamidine	Not listed	ECCN 1C350.d.24
(C.A.S. #1315467-17-4) N,N-Diisopropylbutanamidine	Not listed	ECCN 1C350.d.25
(C.A.S. #857522-08-8) N,N-Diisopropylformamidine	Not listed	ECCN 1C350.d.26
(C.A.S. #2909-14-0) N,N-Dimethylacetamidine	Not listed	ECCN 1C350.d.27
(C.A.S. #1340437-35-5) N,N-Dimethylbutanamidine	Not listed	ECCN 1C350.d.28
(C.A.S. #44205-42-7) N,N-Dimethylformamidine	Not listed	ECCN 1C350.d.29
(C.A.S. #321881-25-8) N,N-Dimethylisobutanamidine	Not listed	ECCN 1C350.d.30
(C.A.S. #56776-14-8) N,N-Dimethylpropanamidine	Not listed	ECCN 1C350.d.31
(C.A.S. #1339586-99-0) N,N-Dipropylacetamidine	Not listed	ECCN 1C350.d.32
C.A.S. #1342422-35-8) N,N-Dipropylbutanamidine	Not listed	ECCN 1C350.d.33
(C.A.S. #48044-20-8) N,N-Dipropylformamidine	Not listed	ECCN 1C350.d.34
(C.A.S. #1342700-45-1) N,N-Dipropylisobutanamidine	Not listed	ECCN 1C350.d.35
(C.A.S. #1341496-89-6) N,N-Dipropylpropanamidine	Not listed	ECCN 1C350.d.36

(C.A.S. #1314-80-3) Phosphorus pentasulfide	ECCN 1C350.d.13	ECCN 1C350.d.37
(C.A.S. #75-97-8) Pinacolone	ECCN 1C350.d.14	ECCN 1C350.d.38
(C.A.S. #7789-29-9) Potassium bifluoride	ECCN 1C350.d.15	ECCN 1C350.d.39
(C.A.S. #151-50-8) Potassium cyanide	ECCN 1C350.d.16	ECCN 1C350.d.40
(C.A.S. #7789-23-3) Potassium fluoride	ECCN 1C350.d.17	ECCN 1C350.d.41
(C.A.S. #3731-38-2) 3-Quinuclidone	ECCN 1C350.d.18	ECCN 1C350.d.42
(C.A.S. #1333-83-1) Sodium bifluoride	ECCN 1C350.d.19	ECCN 1C350.d.43
(C.A.S. #143-33-9) Sodium cyanide	ECCN 1C350.d.20	ECCN 1C350.d.44
(C.A.S. #7681-49-4) Sodium fluoride	ECCN 1C350.d.21	ECCN 1C350.d.45
(C.A.S. #16893-85-9) Sodium hexafluorosilicate	ECCN 1C350.d.22	ECCN 1C350.d.46
(C.A.S. #1313-82-2) Sodium sulfide	ECCN 1C350.d.23	ECCN 1C350.d.47

(C.A.S. #637-39-8) Triethanolamine hydrochloride	ECCN 1C350.d.24	ECCN 1C350.d.48
(C.A.S. #116-17-6) Tri-isopropyl phosphite	ECCN 1C350.d.25	ECCN 1C350.d.49

Note that all items controlled under ECCN 1C350.d, including the newly added precursor chemicals described above, are controlled for chemical/biological (CB) reasons and anti-terrorism (AT) reasons (see CB Column 2 of the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR and the AT license requirements described in part 742 of the EAR that apply to Iran, North Korea, Sudan and Syria). A license also is required to certain destinations in accordance with the embargoes and other special controls described in part 746 of the EAR.

ECCN 1C351 (human and animal pathogen and toxins)

This final rule amends ECCN 1C351 on the CCL to reflect changes to the AG "Control List of Human and Animal Pathogens and Toxins" based on the February 2020 Intersessional Implementation Meeting recommendations that were adopted by AG. Specifically, this rule adds the Middle East respiratory syndrome-related coronavirus (MERS-related coronavirus) to ECCN 1C351.a.30 due to its homology with severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus) and its potential use in biological weapons activities. The viruses in ECCN 1C351.a that were previously numbered, in alphabetical order, as .a.30 through .a.57 have

been renumbered as .a.31 through .a.58, respectively, and relevant cross-references adjusted as necessary.

In addition, although this rule does not amend ECCN 1E001 ("technology" for the "development" or "production" of, *inter alia*, pathogens or "toxins" controlled by ECCN 1C351) or ECCN 1E351 ("technology" for the disposal of, *inter alia*, microbiological materials), these ECCNs cross-reference items controlled by ECCN 1C351 and, consequently, "technology" that is related to the MERS-related coronavirus added by this rule to ECCN 1C351.a.30 is now subject to control under ECCN 1E001 or 1E351 if such "technology" falls within the parameters of the controls described therein.

Note that all items controlled under ECCN 1C351.d, including the newly added MERS-related coronavirus, require a license for CB reasons and AT reasons to the destinations indicated under CB Column 1 and AT Column 1, respectively, on the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR (also see the AT license requirements described in part 742 of the EAR that apply to Iran, North Korea, Sudan and Syria). In addition, a license is required to certain destinations in accordance with the embargoes and other special controls described in part 746 of the EAR. Also note that, in addition to the license requirements described above, items controlled under ECCN 1C351.d.11 or .d.12 require a license to certain destinations for chemical weapons (CW) reasons, as described in the License Requirements section of ECCN 1C351 and in Section 742.18 of the EAR.

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 2020 Intersessional Implementation Meeting recommendations that were adopted by the AG. Specifically, this rule adds a *Technical Note* to ECCN 2B352.b to indicate that cultivation chamber holding devices controlled in 2B352.b.2.b include single-use cultivation chambers with rigid walls. Consequently, such single-use cultivation chambers require a license for CB reasons and AT reasons to the destinations indicated under CB Column 2 and AT Column 1, respectively, on the Commerce Country Chart in Supplement No. 1 to part 738 of the EAR (also see the AT license requirements described in part 742 that apply to Iran, North Korea, Sudan and Syria). A license also is required to certain destinations in accordance with the embargoes and other special controls described in part 746 of the EAR.

In addition, although this rule does not amend ECCNs 2E001, 2E002 and 2E301 (which control, respectively, "technology" for the "development," "production" or "use" of, *inter alia*, ECCN 2B352 equipment), these ECCNs cross-reference items controlled by ECCN 2B352 and, consequently, "technology" that is related to rigid-walled, single-use cultivation chambers added by this rule to ECCN 2B352.b.2.b is now subject to control under ECCN 2E001, 2E002 or 2E301 if such "technology" falls within the parameters of the controls described therein.

Prior to the addition of these cultivation chambers to the AG biological equipment common control list, BIS, consistent with the interagency process described in Section 1758 of ECRA, identified these items as emerging technologies that are essential to U.S. national security and for

which effective controls can be implemented. This interagency process resulted in a finding that disposable cultivation chambers that do not require the use of a holding device have recently gained significant market share in the single-use biological equipment market (both within and outside the United States) and, furthermore, that they are capable of functioning as cultivation chamber holding devices controlled under ECCN 2B352.b.2.b. Consequently, the absence of export controls on these single-use cultivation chambers could be exploited for chemical and biological weapons (CBW) purposes. Among the items of concern, in this regard, are impeller-mixed liquid culture chambers, as well as novel packed-bed and hollow-fiber models. The inclusion of these cultivation chambers in this final rule is consistent with the requirements of ECRA and the decision of the AG to add these items to their common control lists, thereby making exports of such items subject to multilateral control.

Conforming Changes to Supplement No. 7 to Part 748

This final rule also amends Supplement No. 7 to part 748 to update the ECCN reference to hydrogen fluoride (C.A.S. #7664-39-3) in the eligible item descriptions for the following validated end-users: (1) "Samsung China Semiconductor Co. Ltd." and (2) "Shanghai Huahong Grace Semiconductor Manufacturing Corporation." As described above, hydrogen fluoride was previously classified under ECCN 1C350.d.10, but is now classified under ECCN 1C350.d.14 with the publication of this rule. These conforming amendments do not change the scope of eligible items for either of the two validated end-users indicated above – they merely update the ECCN references in Supplement No. 7 to part 748 to correctly identify which ECCN 1C350.d items are eligible for each of these validated end-users. Because this rule does not add or remove

any validated end-users or revise the scope of eligible items, the citation for this rule is not indicated in the "Federal Register Citation" column of Supplement No. 7.

Saving Clause

Shipments of items removed from eligibility for export, reexport or transfer (in-country) under a license exception or without a license (i.e., under the designator "NLR") as a result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], pursuant to actual orders for export, reexport or transfer (in-country) to a foreign destination, may proceed to that destination under the previously applicable license exception or without a license (NLR) so long as they are exported, reexported or transferred (in-country) before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Any such items not actually exported, reexported or transferred (in-country) before midnight, on [INSERT DATE 60 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 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Beginning at midnight on [INSERT DATE 60 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 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. Sections 4801-4852. ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. As set forth in section 1768 of ECRA, all delegations, rules, regulations, orders, determinations, licenses, or other forms of administrative action that were made, issued, conducted, or allowed to become effective under the Export Administration Act of 1979 (previously, 50 U.S.C. 4601 *et seq*.) (as in effect prior to August 13, 2018, and as continued in effect pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq*.)) or the Export Administration Regulations, and were in effect as of August 13, 2018, shall continue in effect according to their terms until modified, superseded, set aside, or revoked under the authority of ECRA.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including: potential economic, environmental, public health and

safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits and of reducing costs, harmonizing rules, and promoting flexibility. This rule has been designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

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

In calculating the costs that will be imposed by this rule, BIS estimates that no more than 25 additional license applications will have to be submitted to BIS, annually, as a result of the

implementation of the amendments described in this rule (see Rulemaking Requirements #2, below). Application of the cost-benefit analysis required under Executive Orders 13563 and 12866 to this rule, as described above, indicates that this rule is intended to improve the national security of the United States as its primary direct benefit. Accordingly, consistent with the stated purpose of the proposed amendments to ECCNs 1C350, 1C351 and 2B352, this rule meets the requirements set forth in the April 5, 2017, OMB guidance implementing Executive Order 13771 (82 FR 9339, February 3, 2017), regarding what constitutes a regulation issued "with respect to a national security function of the United States," and 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 the following collections of information subject to the requirements of the PRA. These collections have been approved by OMB under control numbers 0694–0088 (Simplified Network Application Processing System) and 0694-0096 (Five Year Records Retention Period). The approved information collection under OMB control number 0694-0088 includes license applications, among other things, and carries a burden estimate of 29.6 minutes per manual or electronic submission for a total burden estimate of 31,833 hours. The approved information collection under OMB control number 0694-0096 includes recordkeeping requirements and carries a burden estimate of less than 1 minute per response for a total burden estimate of 248 hours.

Although this rule contains important changes to the EAR for items controlled for chemical/biological (CB) reasons, BIS believes the overall increase in costs and burdens due to the implementation of these changes will be minimal. Specifically, BIS expects the burden hours associated with these collections will increase, slightly, by 12 hours and 45 minutes (i.e., 25 applications × 30.6 minutes per response) for a total estimated cost increase of $382.50 (i.e., 12 hours and 45 minutes × $30 per hour). The $30 per hour cost estimate for OMB control numbers 0694-0088 and 0694-0096 is consistent with the salary data for export compliance specialists currently available through glassdoor.com (glassdoor.com estimates that an export compliance specialist makes $55,280 annually, which computes to roughly $26.58 per hour). This increase is not expected to exceed the existing estimates currently associated with OMB control numbers 0694–0088 and 0694-0096. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet 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. Pursuant to Section 1762 of the Export Control Reform Act of 2018 (50 U.S.C. Sec. 4821), this action is exempt from the Administrative Procedure Act (APA) (5 U.S.C. 553)

requirements for notice of proposed rulemaking, opportunity for public participation and delay in effective date.

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by the APA or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq*.) are not applicable. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

List of Subjects

15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, parts 748 and 774 of the Export Administration Regulations (15 CFR parts 730-774) are amended as follows:

PART 748 - [AMENDED]

1. The authority citation for 15 CFR part 748 continues to read as follows:

Authority: 50 U.S.C. 4801-4582; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *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 14, 2019, 84 FR 41881 (August 15, 2019).

2. Supplement 7 to part 748 is amended by revising the validated end-user entries for "Samsung China Semiconductor Co. Ltd." and "Shanghai Huahong Grace Semiconductor Manufacturing Corporation," listed under the country "China (People's Republic of)" to read as follows:

SUPPLEMENT NO. 7 TO PART 748—AUTHORIZATION VALIDATED END-USER (VEU): LIST OF VALIDATED END-USERS, RESPECTIVE ITEMS ELIGIBLE FOR EXPORT, REEXPORT AND TRANSFER, AND ELIGIBLE DESTINATIONS

Country	Validated end-user	Eligible items (by ECCN)	Eligible destination	FEDERAL REGISTER citation
Nothing in this Supplement shall be deemed to supersede other provisions in the EAR, including but not limited to §748.15(c).				
China (People's Republic of)	* * * * * * *			
	Samsung China Semiconductor Co. Ltd.	1C350.c.4, 1C350.d.14, 2B006.a, 2B006.b.1.d, 2B230, 2B350.d.2, 2B350.g.3, 2B350.i.3, 3A233, 3B001.a.1, 3B001.b, 3B001.e, 3B001.f, 3B001.h, 3C002, 3C004, 3D002, and 3E001 (limited to "technology" for items classified under 3C002 and 3C004 and "technology" for	Samsung China Semiconductor Co., Ltd., No. 1999, North Xiaohe Road, Xi'an, China 710119	78 FR 41291, 7/10/13. 78 FR 69535, 11/20/13. 79 FR 30713, 5/29/14. 80 FR 11863, 3/5/15.

		use consistent with the International Technology Roadmap for Semiconductors process for items classified under ECCNs 3B001 and 3B002)		
	Shanghai Huahong Grace Semiconductor Manufacturing Corporation	1C350.c.4, 1C350.d.14, 2B230, 2B350.d.2, 2B350.g.3, 2B350.i.4, 3B001.a.1, 3B001.b, 3B001.e, 3B001.f, 3B001.h, 3C002, 3C004, 5B002, and 5E002 (controlled by ECCNs 5A002, 5A004, or 5A992 that have been successfully reviewed under the encryption review process specified in Sections 740.17(b)(2) or 740.17(b)(3) of the EAR)	Shanghai Huahong Grace Semiconductor Manufacturing Corporation—HFab 2, 668 Guoshoujing Road, Zhangjiang Hi-Tech Park, Shanghai 201203 China Shanghai Huahong Grace Semiconductor Manufacturing Corporation—HFab 1, 1188 Chuanqiao Road, Pudong, Shanghai 201206 China Shanghai Huahong Grace Semiconductor Manufacturing Corporation—GFab1, 1399 Zuchongzhi Road, Zhangjiang Hi-Tech Park, Shanghai 201203 China	78 FR 32981, 6/3/13.
* * * * * * *				

PART 774 - [AMENDED]

3. The authority citation for 15 CFR part 774 continues to read as follows:

Authority: 50 U.S.C. 4801-4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42

U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

4. Supplement 1 to part 774 is amended in category 1 by revising ECCN 1C350 and ECCN 1C351 and in category 2 by revising ECCN 2B352 to read as follows:

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

* * * * *

Category 1−Special Materials and Related Equipment, Chemicals, "Microorganisms," and "Toxins"

* * * * *

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.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) 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. #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. #762-77-6) Ethyl chlorofluorophosphate;

d.12. (C.A.S. #1498-51-7) Ethyl dichlorophosphate;

d.13. (C.A.S. #460-52-6) Ethyl difluorophosphate;

d.14. (C.A.S. #7664-39-3) Hydrogen fluoride;

d.15. (C.A.S. #3554-74-3) 3-Hydroxyl-1-methylpiperidine;

d.16. (C.A.S. #76-89-1) Methyl benzilate;

d.17. (C.A.S. #754-01-8) Methyl chlorofluorophosphate;

d.18. (C.A.S. #677-24-7) Methyl dichlorophosphate;

d.19. (C.A.S. #22382-13-4) Methyl difluorophosphate;

d.20. (C.A.S. #14277-06-6) N,N Diethylacetamidine;

d.21. (C.A.S. #53510-30-8) N,N-Diethylbutanamidine;

d.22. (C.A.S. #90324-67-7) N,N-Diethylformamidine;

d.23. (C.A.S. #1342789-47-2) N,N Diethylisobutanamidine;

d.24. (C.A.S. #84764-73-8) N,N-Diethylpropanamidine;

d.25. (C.A.S. #1315467-17-4) N,N-Diisopropylbutanamidine;

d.26. (C.A.S. #857522-08-8) N,N-Diisopropylformamidine;

d.27. (C.A.S. #2909-14-0) N,N-Dimethylacetamidine;

d.28. (C.A.S. #1340437-35-5) N,N-Dimethylbutanamidine;

d.29. (C.A.S. #44205-42-7) N,N-Dimethylformamidine;

d.30. (C.A.S. #321881-25-8) N,N-Dimethylisobutanamidine;

d.31. (C.A.S. #56776-14-8) N,N-Dimethylpropanamidine;

d.32. (C.A.S. #1339586-99-0) N,N-Dipropylacetamidine;

d.33. C.A.S. #1342422-35-8) N,N-Dipropylbutanamidine;

d.34. (C.A.S. #48044-20-8) N,N-Dipropylformamidine;

d.35. (C.A.S. #1342700-45-1) N,N-Dipropylisobutanamidine;

d.36. (C.A.S. #1341496-89-6) N,N-Dipropylpropanamidine;

d.37. (C.A.S. #1314-80-3) Phosphorus pentasulfide;

d.38. (C.A.S. #75-97-8) Pinacolone;

d.39. (C.A.S. #7789-29-9) Potassium bifluoride;

d.40. (C.A.S. #151-50-8) Potassium cyanide;

d.41. (C.A.S. #7789-23-3) Potassium fluoride;

d.42. (C.A.S. #3731-38-2) 3-Quinuclidone;

d.43. (C.A.S. #1333-83-1) Sodium bifluoride;

d.44. (C.A.S. #143-33-9) Sodium cyanide;

d.45. (C.A.S. #7681-49-4) Sodium fluoride;

d.46. (C.A.S. #16893-85-9) Sodium hexafluorosilicate;

d.47. (C.A.S. #1313-82-2) Sodium sulfide;

d.48. (C.A.S. #637-39-8) Triethanolamine hydrochloride;

d.49. (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 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. 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, 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.

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Category 2—Materials Processing

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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 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 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 to 2B352.c: *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 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 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 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 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.

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Richard E. Ashooh

Assistant Secretary

for Export Administration

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