Billing Code: 3510-33-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No. 160922876-6876-01]

RIN 0694-AH14

Implementation of the February 2016 Australia Group (AG) Intersessional Decisions and the June 2016 AG Plenary Understandings

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) publishes this final rule to amend the Export Administration Regulations (EAR) to implement the recommendations presented at the February 2016 Australia Group (AG) Intersessional Implementation Meeting, and later adopted pursuant to the AG silent approval procedure, and the understandings reached at the June 2016

AG Plenary Implementation Meeting. This rule amends two Commerce Control List (CCL) entries to reflect the February 2016 Intersessional Implementation Meeting recommendations that were adopted by the AG. Specifically, this rule amends the CCL entry that controls certain human and zoonotic pathogens and toxins to reflect the AG updates to the nomenclature for certain bacteria and toxins identified on the AG "List of Human and Animal Pathogens and Toxins for Export Control." In addition, this rule amends the CCL entry that controls equipment capable of handling biological materials to reflect the AG updates to the controls on cross (tangential) flow filtration equipment described on the AG "Control List of Dual-Use Biological Equipment and Related Technology and Software."

Consistent with the understandings adopted at the June 2016 AG Plenary Implementation Meeting that updated the AG "List of Human and Animal Pathogens and Toxins for Export Control," this rule amends the CCL entry that controls certain human and zoonotic pathogens and toxins by removing dengue fever virus, updating the nomenclature of the listing for conotoxin, and consolidating the controls for Shiga toxin and Verotoxin (and other Shiga-like ribosome inactivating proteins) under a single listing. This rule also amends the CCL entry that controls equipment capable of handling biological materials by updating the controls on biological containment facilities and related equipment and the controls on fermenters, consistent with the AG Plenary Implementation Meeting updates to the AG "Control List of Dual-Use Biological Equipment and Related Technology and Software."

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

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SUPPLEMENTARY INFORMATION: The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the recommendations presented at the Australia Group (AG) Intersessional Implementation Meeting held in Brussels, Belgium, on February 2, 2016, and adopted pursuant to the AG silent approval procedure in April 2016, and the understandings reached at the Implementation Meeting of the 2016 AG Plenary held in Paris, France, from June 6-10, 2016. The AG is a multilateral forum consisting of 41 participating countries that maintain export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

Amendments to the CCL based on the February 2016 AG Intersessional Recommendations

ECCN 1C351 (human and animal pathogens and "toxins")

This final rule amends Export Control Classification Number (ECCN) 1C351 on the CCL to update the nomenclature for two bacteria and five toxins, consistent with the AG Intersessional

Implementation Meeting updates to the AG "List of Human and Animal Pathogens and Toxins for Export Control." Specifically, this rule updates the nomenclature for the bacteria "Chlamydia pscittaci" and "Salmonella typhi" and the toxin "Viscum Album Lectin 1" to reflect current scientific usage. This rule also removes the word "toxin" from the listings for "Diacetoxyscirpenol toxin," "Modeccin toxin," and "Volkensin toxin," because it was deemed to be redundant (i.e., the abbreviated nomenclature, absent the word "toxin," adequately identifies these particular toxins). In addition, this rule revises the description for "Microcystin" by making it plural, thereby clarifying that ECCN 1C351.d.9 controls all variants of this toxin. Finally, this rule renumbers the listings for "Viscumin" and "Volkensin" to control these toxins under ECCN 1C351.d.17 and .d.18, respectively, to conform with the June 2016 AG Plenary Implementation Meeting change in which the Shiga toxin and Verotoxin listings (ECCN 1C351.d.13 and .d.17, respectively) were merged into a single listing (ECCN 1C351.d.13). These amendments to ECCN 1C351 are summarized in the following table.

Previous Names of AG-Controlled Bacteria and Toxins	**Current Names of AG-Controlled Bacteria and Toxins**	**Previous CCL Designation**	**Current CCL Designation**
Chlamydophila psittaci (formerly known as Chlamydia psittaci)	Chlamydia psittaci (Chlamydophila psittaci)	ECCN 1C351.c.7	NO CHANGE
Salmonella typhi	Salmonella enterica	ECCN 1C351.c.18	NO CHANGE

	subspecies enterica serovar Typhi (Salmonella typhi)		
Diacetoxyscirpenol toxin	Diacetoxyscirpenol	ECCN 1C351.d.7	NO CHANGE
Microcystin (Cyanginosin)	Microcystins (Cyanginosins)	ECCN 1C351.d.9	NO CHANGE
Modeccin toxin	Modeccin	ECCN 1C351.d.10	NO CHANGE
Viscum Album Lectin 1 (Viscumin)	Viscumin (Viscum album lectin 1)	ECCN 1C351.d.18	ECCN 1C351.d.17
Volkensin toxin	Volkensin	ECCN 1C351.d.19	ECCN 1C351.d.18

The license requirements applicable to the bacteria and toxins affected by these amendments to ECCN 1C351 remain unchanged. Specifically, all of these items continue to require a license for chemical/biological (CB) reasons to destinations indicated under CB Column 1 on the Commerce Country Chart and for anti-terrorism (AT) reasons to destinations indicated in AT Column 1 on the Commerce Country Chart.

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

This final rule amends ECCN 2B352 on the CCL to reflect changes to the AG "Control List of

Dual-Use Biological Equipment and Related Technology and Software" based on the February 2016 Intersessional Implementation Meeting recommendations that were adopted by the AG pursuant to its silent approval procedure. Specifically, this rule amends the controls on cross (tangential) flow filtration equipment described in 2B352.d.1 by removing the word "pathogenic" from the description of this equipment. This change is made because there is no distinction, with respect to either the technical characteristics or the use of this equipment, between pathogenic and non-pathogenic micro-organisms.

This rule also amends ECCN 2B352, consistent with the AG intersessional recommendations, by revising the Nota Bene to 2B352.d.1 to clarify that the exclusion from the controls on cross (tangential) flow filtration equipment listed in 2B352.d.1 applies to hemodialysis equipment, as specified by the manufacturer, as well as reverse osmosis equipment (i.e., both hemodialysis equipment and reverse osmosis equipment, as specified by the manufacturer, are excluded from control under ECCN 2B252.d.1).

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

Amendments to the CCL based on the June 2016 AG Plenary Understandings

ECCN 1C351 (human and animal pathogens and "toxins")

This final rule amends ECCN 1C351 on the CCL to remove the listing for "dengue fever virus," revise the listing for "Conotoxin," and merge the listings for "Shiga toxin" and Verotoxin" consistent with the AG Plenary Implementation Meeting updates to the AG "List of Human and Animal Pathogens and Toxins for Export Control."

The removal of "dengue fever virus" from control under ECCN 1C351 is designed to reduce barriers to the export of clinical samples, materials, and "technology" required for vaccine development, production, and distribution. To reflect the removal of the ECCN 1C351 controls on "dengue fever virus," which was controlled under ECCN 1C351.a.11 prior to the publication of this final rule, this rule also makes conforming changes to ECCN 1C351.a by renumbering those items previously designated as 1C351.a.12 through .a.58 as 1C351.a.11 through .a 57. Consistent with this renumbering, this rule revises the Technical Note to newly redesignated ECCN 1C351.a.40 ("reconstructed 1918 influenza virus") to reference the new designation for this listing. In addition, the listing for "tick-borne encephalitis virus (Siberian subtype)" in ECCN 1C351.b.3 is amended by revising the parenthetical reference therein to "tick-borne encephalitis virus (Far Eastern subtype)" to reflect the new designation for the latter (i.e., ECCN 1C351.a.52).

This rule also revises the description for "Conotoxin" by making it plural to clarify that ECCN 1C351.d.6 controls all variants of this toxin.

In addition, the listings for "Shiga toxin" and "Verotoxin" which, prior to the publication of this final rule, were controlled under ECCN 1C351.d.13 and d.17, respectively, are merged into a

single listing under ECCN 1C351.d.13 that also includes some changes in nomenclature to clarify the scope of these controls. The revised listing reads as follows: "Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins)."

This rule also makes certain conforming changes to other listings in ECCN 1C351 to reflect the merger of the "Shiga toxin" and "Verotoxin" listings and the related nomenclature changes described above. First, the Note to ECCN 1C351.c.19 (Shiga-toxin producing Escherichia coli) is revised to read: "Shiga toxin producing Escherichia coli (STEC) includes, inter alia, enterohaemorrhagic E. coli (EHEC), verotoxin producing E. coli (VTEC) or verocytotoxin producing E. coli (VTEC)." Specifically, this Note is revised by adding the "Verotoxin" nomenclature and by replacing the phrase "also known as" with the phrase "inter alia," thereby clarifying that this Note does not exclude other relevant shiga-toxin producing strains from the scope of ECCN 1C351.c.19. Second (as referenced in the description of the AG intersessional changes, above), this rule renumbers the listings for "Viscumin" and "Volkensin" to control these toxins under ECCN 1C351.d.17 and .d.18, respectively, to reflect the merger of the Shiga toxin and Verotoxin listings (which were previously designated as ECCN 1C351.d.13 and .d.17, respectively) into a single listing (ECCN 1C351.d.13).

Except for the dengue fever virus, the license requirements applicable to the viruses, bacteria and toxins affected by these amendments to ECCN 1C351 remain unchanged. Specifically, all of these items, except the dengue fever virus, continue to require a license for CB reasons to destinations indicated under CB Column 1 on the Commerce Country Chart and for AT reasons to destinations indicated in AT Column 1 on the Commerce Country Chart. The dengue fever

virus is now designated as EAR99 and, as such, no longer requires a license for CB or AT reasons. However, any item that is subject to the EAR, whether or not it is listed on the CCL, may require a license for reasons described elsewhere in the EAR (e.g., the end-user/end-use controls described in part 744 of the EAR or the embargoes and other special controls described in part 746 of the EAR).

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

This final rule also 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 understandings reached at the June 2016 AG Plenary Implementation Meeting. Specifically, this rule amends ECCN 2B352.a by expanding the controls on biological containment facilities and related equipment to include the following equipment designed for fixed installation in complete containment facilities at the P3 or P4 containment level: (1) double-door pass-through decontamination autoclaves; (2) breathing air suit decontamination showers; and (3) mechanical-seal or inflatable-seal walkthrough doors. This change is made in recognition of the fact that such equipment could be acquired, individually, and subsequently assembled into a functional containment facility that would be subject to the controls described in ECCN 2B352.a.

In addition, this rule amends ECCN 2B352.b.1 (fermenters) by removing the word "pathogenic" from the description of this equipment. This change is made, because there is no distinction, with respect to either the technical characteristics or the use of this equipment, between pathogenic and non-pathogenic micro-organisms. As revised, ECCN 2B352.b.1 reads:

"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 capacity of 20 liters or greater." This clarification to ECCN 2B352.b.1 was adopted by the AG, subsequent to the June 2016 AG Plenary Implementation Meeting, pursuant to their silent approval procedure.

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

Effect of this rule on the scope of the CB controls in the EAR

The changes made by this rule only marginally affect the scope of the EAR controls on human and animal pathogens/toxins and equipment capable of use in handling biological materials.

The scope of the CCL-based CB controls on human and animal pathogens and toxins was not affected by the nomenclature changes involving the following items in ECCN 1C351: the bacteria listed under ECCN 1C351.c.7 (Chlamydia psittaci) or .c.18 (Salmonella); the toxins listed under ECCN 1C351.d.6 (Conotoxins), .d.7 (Diacetoxyscirpenol), .d.9 (Microcystins), or .d.10 (Modeccin); and the toxins Viscumin and Volkensin (renumbered as ECCN 1C351.d.17 and .d.18, respectively). In addition, the merger of the listings for Shiga toxin and Verotoxin (previously controlled under ECCN 1C351.d.13 and .d.17, respectively) under a single listing (ECCN 1C351.d.13), and the related nomenclature changes involving these toxins, clarified the controls applicable to these toxins, but did not affect the scope of these controls. Furthermore,

the removal of the dengue fever virus from ECCN 1C351 is not expected to significantly reduce the number of license applications that will have to be submitted for items controlled under this ECCN. Consequently, none of the changes made by this rule to ECCN 1C351 are expected to have a significant impact on the number of license applications that will have to be submitted for the items controlled under this ECCN.

The updates in this rule to the ECCN 2B352.a controls on biological containment facilities represent an expansion in the number of items that require a license under this ECCN. However, the expanded controls apply to only a relatively small percentage of these types of items that were not controlled under ECCN 2B352 prior to the publication of this rule (i.e., only those double-door pass-through decontamination autoclaves, breathing air suit decontamination showers, and mechanical-seal or inflatable-seal walkthrough doors that are designed for fixed installation in P3 or P4 biological containment facilities). Consequently, any increase in the number of license applications resulting from this change is not expected to be significant, when considered as a percentage of these types of items.

The scope of the CCL-based CB controls on equipment capable of use in handling biological materials was not affected by the clarifications involving fermenters controlled under ECCN 2B352.b or cross (tangential) flow filtration equipment controlled under ECCN 2B352.d. Consequently, none of these changes to ECCN 2B352 are expected to have a significant impact on the number of license applications that will have to be submitted for the items controlled under this ECCN.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 4, 2016 (81 FR 52587 (August 8, 2016)), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*). BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

2. Notwithstanding any other provision of law, no person is required to respond to,

nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule contains a collection of information subject to the requirements of the PRA. This collection has been approved by OMB under Control Number 0694-0088 (Multi-Purpose Application), which carries a burden hour estimate of 58 minutes to prepare and submit form BIS-748. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget, by email to Jasmeet_K._Seehra@omb.eop.gov or by fax to (202) 395–7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th Street & Pennsylvania Avenue, N.W., Room 2705, Washington, DC 20230 or by email to RPD2@bis.doc.gov.

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

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Immediate implementation of these amendments is non-discretionary and fulfills the United States' international obligation to the Australia Group (AG). The AG contributes to international security and regional stability through the

harmonization of export controls and seeks to ensure that exports do not contribute to the development of chemical and biological weapons. The AG consists of 41 member countries that act on a consensus basis and the amendments set forth in this rule implement changes made to the AG common control lists (as a result of the adoption of the recommendations made at the February 2016 AG Intersessional Implementation Meeting and the understandings reached at the June 2016 AG Plenary Implementation Meeting) and other changes that are necessary to ensure consistency with the controls maintained by the AG. Because the United States is a significant exporter of the items in this rule, immediate implementation of this provision is necessary for the AG to achieve its purpose. Any delay in implementation will create a disruption in the movement of affected items globally because of disharmony between export control measures implemented by AG members, resulting in tension between member countries. Export controls work best when all countries implement the same export controls in a timely manner.

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

List of Subjects in 15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

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

PART 774 - [AMENDED]

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

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. 4305; 22 U.S.C. 7201 et seq.; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 4, 2016, 81 FR 52587 (August 8, 2016).

Supplement No. 1 to Part 774 - [Amended]

2. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1--Special Materials and Related Equipment, Chemicals, "Microorganisms" and "Toxins," ECCN 1C351 is amended in the "Items" paragraph under the "List of Items Controlled" section:

a. By removing paragraph a.11 and redesignating paragraphs a.12 through a.58 as paragraphs a.11 through a.57;

b. By revising the Technical Note to newly designated paragraph a.40;

c. By revising paragraph b.3;

d. By revising paragraphs c.7 and c.18;

e. By revising the Note immediately following paragraph c.19;

f. By revising paragraphs d.6, d.7, d.9, d.10 and d.13;

g. By removing paragraph d.17 and redesignating paragraphs d.18 and d.19 as paragraphs d.17 and d.18, respectively; and

h. By revising newly designated paragraphs d.17 and d.18.

The revisions read as follows:

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

* * * * *

List of Items Controlled

* * * * *

Items:

a. * * *

a.11. Dobrava-Belgrade virus;

a.12. Eastern equine encephalitis virus;

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

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

a.15. Goatpox virus;

a.16. Guanarito virus;

a.17. Hantaan virus;

a.18. Hendra virus (Equine morbillivirus);

a.19. Japanese encephalitis virus;

a.20. Junin virus;

a.21. Kyasanur Forest disease virus;

a.22. Laguna Negra virus;

a.23. Lassa virus;

a.24. Louping ill virus;

a.25. Lujo virus;

a.26. Lumpy skin disease virus;

a.27. Lymphocytic choriomeningitis virus;

a.28. Machupo virus;

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

a.30. Monkeypox virus;

a.31. Murray Valley encephalitis virus;

a.32. Newcastle disease virus;

a.33. Nipah virus;

a.34. Omsk hemorrhagic fever virus;

a.35. Oropouche virus;

a.36. Peste-des-petits ruminants virus;

a.37. Porcine Teschovirus;

a.38. Powassan virus;

a.39. Rabies virus and all other members of the Lyssavirus genus;

a.40. Reconstructed 1918 influenza virus;

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

a.41. Rift Valley fever virus;

a.42. Rinderpest virus;

a.43. Rocio virus;

a.44. Sabia virus;

a.45. Seoul virus;

a.46. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);

a.47. Sheeppox virus;

a.48. Sin Nombre virus;

a.49. St. Louis encephalitis virus;

a.50. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);

a.51. Swine vesicular disease virus;

a.52. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus—see 1C351.b.3 for Siberian subtype);

a.53. Variola virus;

a.54. Venezuelan equine encephalitis virus;

a.55. Vesicular stomatitis virus;

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

a.57. Yellow fever virus.

b. * * *

b.3. Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus—see 1C351.a.52 for Far Eastern subtype).

c. * * *

c.7. Chlamydia psittaci (Chlamydophila psittaci);

* * * * *

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

c.19. * * *

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).*

* * * * *

d. * * *

d.6. Conotoxins;

d.7. Diacetoxyscirpenol;

d.8. * * *

d.9. Microcystins (Cyanginosins);

d.10. Modeccin;

* * * * *

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

* * * * *

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

d.18. Volkensin.

* * * * *

3. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2 -- Materials Processing, ECCN 2B352 is amended in the "Items" paragraph, under the List of Items Controlled section, by revising paragraph a, by revising paragraph b.1, by revising the introductory text of paragraph d.1, and by revising the nota bene to paragraph d.1, to read as follows:

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

* * * * *

List of Items Controlled

Related Controls: * * *

Related Definition: * * *

Items:

a. Containment facilities and related equipment, as follows:

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

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

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

a.2.a. Double-door pass-through decontamination autoclaves;

a.2.b. Breathing air suit decontamination showers;

a.2.c. Mechanical-seal or inflatable-seal walkthrough doors.

b. * * *

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 capacity of 20 liters or greater.

* * * * *

d. * * *

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

* * * * *

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

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DATED: December 7, 2016

Kevin J. Wolf

Assistant Secretary

for Export Administration

[FR Doc. 2016-30099 Filed: 12/15/2016 8:45 am; Publication Date: 12/16/2016]