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DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR 774 and 799A

[Docket No. 960723206-6206-0]

RIN 0694-AB37

Biological Warfare Experts Group Meeting: Implementation of Changes to Export Administration Regulations; ECCNs 1C991, 1C61B, 1B71E, and 1C91F.

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Export Administration (BXA) maintains the Commerce Control List (CCL) as part of the Export Administration Regulations (EAR). This rule amends the CCL by revising Export Control Classification Numbers (ECCNs) 1C991, 1C61B, 1B71E, and 1C91F. The changes made by this rule are based on discussions in

the Biological Warfare Experts Group (a subgroup of the Australia Group (AG)).

This rule will minimally increase the number of validated export licenses required for items classified under ECCN 1C61B and 1B71E.

The EAR have been completely amended by an interim rule published on March 25, 1996 (61 FR 12714) that provides for a transition period within which exporters can take advantage of both the old rules and the new rules until November 1, 1996. Therefore, this rule and all other amendments to the EAR during the transition period will amend both the new EAR and the old EAR, which are now designated with the letter "A" following the part number. This rule consists primarily of changes to the old EAR to conform to the new EAR, except changes to ECCNs 1C991 and 1C91F.

DATE: This rule is effective (DATE OF PUBLICATION).

FOR FURTHER INFORMATION CONTACT:

For questions on foreign policy controls, call Patricia Sefcik, Bureau of Export Administration, Telephone:

(202) 482-0707.

For questions of a technical nature on chemical weapon precursors, biological agents, and equipment that can be used to produce chemical and biological weapons agents, call James Seevaratnam, Bureau of Export Administration, Telephone: (202) 482-3343.

For questions of a general nature, call Hillary Hess, Bureau Export Administration, Telephone: (202) 482-2440.

SUPPLEMENTARY INFORMATION:

Background

Consultations of the Biological Warfare Experts Group were held October 16-19, 1995 in conjunction with the Australia Group plenary meeting. The consultations resulted in changes to the list of controlled items, including the following revisions to the names of certain microorganisms: changing Rickettsia quintana to Bartonella quintana (Rochalimea quintana, Rickettsia quintana), Pseudomonas mallei to Burkholderia mallei (Pseudomonas

mallei), and Pseudomonas pseudomallei to Burkholderia pseudomallei (Pseudomonas pseudomallei). It was also agreed to place the former name in parentheses following the new name on the list in order to assist in appropriate identification for export control purposes.

This rule revises the note in the requirement section of ECCN 1C61B to exclude immunotoxins. A technical note added to ECCN 1C61B provides the definitions of "immunotoxin" and "subunit". Immunotoxins are therapeutics with no biological warfare application. Immunotoxins have been added to ECCN 1C91F and are eligible for export under the provisions of General License G-DEST to all destinations but those listed in Country Groups S, Z, and Iran. In addition, a technical note that adds the definition of "immunotoxin" has been added to ECCN 1C91F. This rule makes parallel changes to ECCN 1C991.

This rule also implements changes in the area of dual-use biological equipment. In ECCN 1B71E, "Equipment that can be used in the production of biological weapons", the capacity parameter for fermenters, within paragraph (b), is decreased from "equal to or greater than 300 liters" to "equal to or greater than 100 liters". This is done to expand export controls to capture

smaller fermenters that can be used for biological warfare purposes.

Prior to this final rule, fermenters of the designated size were controlled only if they either contained "double or multiple sealing joints within the steam containment area" or were "capable of in-situ sterilization in a closed state." These two modifiers or limiting descriptors have been removed by this final rule.

This rule also makes a clarification to cross-flow filtration equipment (ECCN 1B71E paragraph (d)). Where the control language formerly stated "cross-flow filtration equipment designed for continuous separation...", this final rule controls "Cross-flow filtration equipment capable of continuous separation...".

Lastly, this rule expands controls on aerosol chambers within ECCN 1B71E paragraph (g). Where the control language used to state "Chambers designed for aerosol challenge testing with pathogenic microorganisms ...", it will now state "Chambers designed for aerosol challenge testing with microorganisms ...". The word "pathogenic" is removed to expand export controls to

aerosol chambers not specifically designed for pathogenic microorganisms.

Although the Export Administration Act (EAA) expired on August 20, 1994, the President invoked the International Emergency Economic Powers Act and continued in effect, to the extent permitted by law, the provisions of the EAA and the EAR in Executive Order 12924 of August 19, 1994, as extended by the President's notice of August 15, 1995 (60 FR 42767).

Saving Clause

Shipments of items removed from general license authorizations 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 pursuant to actual orders for export before (DATE OF PUBLICATION) may be exported under the previous general license provisions up to and including (4 WEEKS AFTER DATE OF PUBLICATION). Any such items not actually exported before midnight (4 WEEKS AFTER DATE OF PUBLICATION),

require a validated export license in accordance with this regulation.

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These collections have been approved by the Office of Management and Budget under control numbers 0694-0005, 0694-0010, 0694-0067, and 0694-0088.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 603(b)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. 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. Section 13(b) of the EAA does not require that this rule be published in proposed form because this rule does not impose a new control. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Hillary Hess, Regulatory Policy Division, Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects

15 CFR part 774

Exports, Foreign trade.

15 CFR part 799A

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 774 and 799A of the Export Administration Regulations (15 CFR parts 730-799) are amended as follows:

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

Authority: 50 U.S.C. app. 2401 et seq.; 50 U.S.C. 1701 et seq.; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 18 U.S.C. 2510 et seq.; 22 U.S.C. 287c; 22 U.S.C. 3201 et seq.; 22 U.S.C. 6004; Sec. 201, Pub. L. 104-58, 109 Stat. 557 (30 U.S.C. 185(s)); 30 U.S.C. 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; Notice of August 15, 1995 (60 FR 42767, August 17, 1995).

2. The authority citation for 15 CFR part 799A continues to read as follows:

Authority: Pub. L. 90-351, 82 Stat. 197 (18 U.S.C. 2510 et seq.), as amended; Pub. L. 95-223, 91 Stat. 1626 (50 U.S.C. 1701 et seq.); Pub. L. 95-242, 92 Stat. 120 (22 U.S.C. 3201 et seq. and 42 U.S.C. 2139a); Pub. L. 96-72, 93 Stat. 503 (50 U.S.C. App. 2401 et seq.), as amended [(extended by Pub. L. 103-10, 107 Stat. 40 and by Pub. L. 103-277, 108 Stat. 1407)]; Pub. L. 102-484, 106 Stat. 2575 (22 U.S.C. 6004); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 12, 1993 (58 FR 60361, November 15, 1993); E.O. 12851 of June 11, 1993 (58 FR 33181, June 15, 1993); E.O. 12867 of September 30, 1993 (58 FR 51747, October 4, 1993); E.O. 12930 of September 29, 1994 (59 FR 50475, October 3, 1994); E.O. 12924 of August 19, 1994 (59 FR 43437 of August 23, 1994); E.O. 12930 (59 FR 50475 of October 3, 1994); and Notice of August 15, 1995 (60 FR 42767).

PART 774 - [AMENDED]

Supplement No. 1 to part 774

3. In Category 1, Materials, ECCN 1C991 is amended to read as follows:

1C991 Vaccines containing items controlled by ECCNs 1C351, 1C352, 1C353 and 1C354, and immunotoxins.

LICENSE REQUIREMENTS:

Reason for Control: AT

Control(s)	Country Chart
AT applies to entire entry	AT Column 1

LICENSE EXCEPTIONS:

LVS: N/A

GBS: N/A

CIV: N/A

LIST OF ITEMS CONTROLLED:

Unit: $ value

Related Controls: N/A

Related Definitions: 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.

Items:

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

PART 799A - [AMENDED]

Supplement No. 1 to §799A.1

4. In Category 1, Materials, ECCNs 1B71E, 1C61B, and 1C91F are amended to read as follows:

1B71E Equipment that can be used in the production of biological weapons.

Requirements:

Validated License Required: SZ, Supplement 5 to Part 778 (see Note)

Unit: Number

Reason for Control: CB

GLV: $0

GCT: No

GFW: No

Note: Special chemical License Available: see §773.9 of this subchapter.

List of Items Controlled

a. Biohazard containment equipment as follows:

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

a.2. Equipment that incorporates or is contained in a P3 or P4 containment housing.

b. Fermenters capable of cultivation of pathogenic microorganisms, viruses or for toxin production, without the propagation of aerosols, having a capacity equal to or greater than 100 liters.

NOTE: Sub-groups of fermenters include bioreactors, chemostats, and continuous-flow systems.

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

c.1. A flow rate greater than 100 liters per hour;

c.2. Components of polished stainless steel or titanium;

c.3. Double or multiple sealing joints within the stream containment area;

c.4. Capable of in-situ stream sterilization in a closed state.

NOTE: Centrifugal separators include decanters.

d. Cross-flow filtration equipment capable of continuous separation of pathogenic microorganisms, viruses, toxins, and cell cultures without the propagation of aerosols, having all of the following characteristics:

d.1. Equal to or greater than 5 square meters;

d.2. Capable of in-situ sterilization.

e. Steam sterilizable freeze-drying equipment with condenser capacity greater than 50 kgs. but less than 1,000 kgs. of ice in 24 hours.

f. Equipment that incorporates or is contained in P3 or P4

containment housing, as follows:

f.1. Independently ventilated protective full or half suits; and

f.2. Class III biological safety cabinets or isolators with similar performance standards.

g. Chambers designed for aerosol challenge testing with microorganisms, viruses, or toxins and having a capacity of 1 cubic meter or greater.

1C61B Microorganisms, toxins, and aflatoxins.

Requirements:

Validated License Required: QSTVWYZ

Unit: $ value

Reason For Control: CB

GLV: $0

GCT: No

GFW: No

Note: Notwithstanding the provisions of this entry, all vaccines and immunotoxins are excluded from the scope of this entry. See ECCN 1C91F.

Technical Note: For the purposes of ECCN 1C61B, the following definitions apply:

a. "Immunotoxin" is an antibody-toxin conjugate intended to destroy specific target cells, e.g., tumor cells, that bear antigens homologous to the antibody; and

b. "Subunit" is a portion of the toxin.

List of Items Controlled

a. Viruses, as follows:

a.1. African swine fever virus;

a.2. Avian influenza virus;

a.3. Bluetongue virus;

a.4. Chikungunya virus

a.5. Congo-Crimean haemorrhagic fever virus;

a.6. Dengue fever virus;

a.7. Eastern equine encephalitis virus;

a.8. Ebola virus;

a.9. Foot and mouth disease virus;

a.10. Goat pox virus;

a.11. Hantaan virus;

a.12. Herpes virus (Aujeszky's disease);

a.13. Hog cholera virus;

a.14. Japanese encephalitis virus;

a.15. Junin virus;

a.16. Lassa fever virus;

a.17. Lymphocytic choriomeningitis virus;

a.18. Machupo virus;

a.19. Marburg virus;

a.20. Monkey pox virus;

a.21. Newcastle disease virus;

a.22. Peste des petits ruminants virus;

a.23. Porcine enterovirus type 9;

a.24. Rift Valley fever virus;

a.25. Rinderpest virus;

a.26. Sheep pox virus;

a.27. Teschen disease virus;

a.28. Tick-borne encephalitis virus (Russian Spring-Summer

encephalitis virus);

a.29. Variola virus;

a.30. Venezuelan equine encephalitis virus;

a.31. Vesicular stomatitis virus;

a.32. Western equine encephalitis virus;

a.33. White pox; or

a.34. Yellow fever virus.

b. Rickettsiae, as follows:

b.1. Bartonella quintana (Rochalimea quintana, Rickettsia quintana);

b.2. Coxiella burnetii;

b.3. Rickettsia prowasecki; or

b.4. Rickettsia rickettsii.

c. Bacteria, 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;

c.8. Clostridium botulinum;

c.9. Francisella tularensis;

c.10. Mycoplasma mycoides;

c.11. Pseudomonas solanacerum;

c.12. Salmonella typhi;

c.13. Shigella dysenteriae;

c.14. Vibrio cholerae;

c.15. Xanthonomas albilineas;

c.16. Xanthonomas campestris pv citri;

c.17. Xanthomonas campestris pv oryzae; or

c.18. Yersinia pestis.

d. Fungi, as follows:

d.1. Cochliobolus miyabeanus (Helminthosporium oryzae);

d.2. Colletotrichum coffeanum var. virulans (Colletotrichum kahawae);

d.3. Heliminthosporium maydis;

d.4. Heliminthosprium oryzae;

d.5. Microcyclus ulei (syn. Dothidella ulei);

d.6. Puccinia glumarum;

d.7. Puccinia graminis (syn. Puccinia graminis f. sp. tritici);

d.8. Puccinia striiformis (syn. Puccinia glumarum);

d.9. Pyricularia grisea/Pyricularia oryzae; or

d.10. Ustilago maydis.

e. Genetically modified microorganisms, as follows:

e.1. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity and are derived from organisms identified in this ECCN;

e.2. Genetically modified micro-organisms or genetic elements that contain nucleic acid sequences associated with pathogenicity derived from plant pathogens identified in this ECCN; or

e.3. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins, or their subunits listed in paragraph f of this ECCN.

f. Toxins, as follows and subunits thereof:

f.1. Botulinum toxins;

f.2. Clostridium perfringens toxins;

f.3. Conotoxin;

f.4. Microcystin (cyanogenosin);

f.5. Ricin;

f.6. Saxitoxin;

f.7. Shiga toxin;

f.8. Staphylococcus aureus toxins;

f.9. Tetrodotoxin; or

f.10. Verotoxin.

1C91F Vaccines containing microorganisms and/or toxins controlled by ECCN 1C61B, and immunotoxins.

Requirements:

Validated License Required: SZ, Iran

Unit: $ value

Reason for Control: FP

GLV: No

GCT: No

GFW: No

Note: Vaccines that do not contain items controlled by ECCN 1C61B are controlled by ECCN 1C96G.

Technical Note: For the purposes of ECCN 1C91F, the definition of "Immunotoxin" is an antibody-toxin conjugate intended to destroy specific target cells, e.g., tumor cells, that bear antigens homologous to the antibody.

DATED:

Sue E. Eckert
Assistant Secretary
for Export Administration