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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 742, 745, and 774

[Docket No. 061027281–6281–01]

RIN 0694–AD86

Implementation of the Understandings Reached at the June 2006 Australia Group (AG) Plenary Meeting; Clarifications and Corrections; Additions to the List of States Parties to the Chemical Weapons Convention (CWC)

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is publishing this final rule to amend the Export Administration Regulations (EAR) to implement the understandings reached at the June 2006 plenary meeting of the Australia Group (AG). Specifically, this final rule amends the EAR to reflect changes to the AG ''Control List of Biological Agents'' by revising the Commerce Control List (CCL) entry that controls certain human and zoonotic pathogens and toxins to add certain fungi (i.e., Coccidioides immitis and Coccidioides posadasii) and toxins (i.e., Shiga-like ribosome inactivating proteins other than verotoxin). Verotoxin continues to be listed under this CCL entry. Prior to the publication of this rule, the fungi Coccidioides immitis and Coccidioides posadasii and Shiga-like ribosome inactivating proteins other than verotoxin were listed under the CCL entry containing unilaterally controlled select agents and toxins not included on any of the AG Common Control Lists—this rule removes these items from that CCL entry.

As a result of the addition of Shiga-like ribosome inactivating proteins other than verotoxin to the CCL entry that controls certain human and zoonotic pathogens and toxins, this rule makes conforming changes to two additional CCL entries (i.e., the CCL entry that controls certain AG-listed genetic elements and genetically modified organisms and the CCL entry that controls vaccines, immunotoxins, medical products, and diagnostic and food testing kits).

This rule also amends the EAR to reflect changes to the AG ''Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology'' by expanding the scope of the CCL entry that controls certain chemical manufacturing facilities and equipment to include equipment in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from niobium (columbium) or niobium alloys.

In addition, this final rule corrects errors in two CCL entries that were amended by a final rule that BIS published on December 29, 2004. This rule corrects a typographical error involving a Chemical Abstracts Service (CAS) registry number in the CCL entry that controls AG-listed precursor chemicals. This rule also corrects an error in the CCL entry that controls certain Chemical Weapons Convention (CWC) Schedule 2 or Schedule 3 chemicals not included on any of the AG Common Control Lists by removing the Schedule 3 chemical ethyldiethanolamine. The December 29, 2004, final rule added ethyldiethanolamine to the CCL entry that controls AG-listed precursor chemicals, but failed to remove it from the aforementioned entry.

This rule also amends the EAR provisions describing AG-related license requirements and licensing policies to remind applicants that, even if an AG-related item is licensed by ''$ value'' (e.g., human and zoonotic pathogens and toxins, plant pathogens, genetic elements and genetically modified organisms, and select agents and toxins), the EAR still require that the unit of quantity commonly used in the trade be shown on the license application.

Finally, this rule updates the list of countries that currently are States Parties to the Chemical Weapons Convention (CWC) by adding the Central African Republic and Comoros, which recently became States Parties. As a result of this change, the CW (Chemical Weapons) license requirements and policies in the EAR that apply to these countries now conform with those applicable to other CWC States Parties.

DATES: This rule is effective November 24, 2006. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

ADDRESSES: You may submit comments, identified by RIN 0694–AD86, by any of the following methods:

- *E-mail: publiccomments@bis.doc.gov.* Include ''RIN 0694–AD86'' in the subject line of the message.
- *Fax:* (202) 482–3355. Please alert the Regulatory Policy Division, by calling (202) 482–2440, if you are faxing comments.
- *Mail or Hand Delivery/Courier:* Willard Fisher, U.S. Department of Commerce, Bureau of Industry and Security, Regulatory Policy Division, 14th St. & Pennsylvania Avenue, NW., Room 2705, Washington, DC 20230, *Attn:* RIN 0694–AD86.

Send comments regarding this collection of information, including suggestions for reducing the burden, to David Rostker, Office of Management and Budget (OMB), by e-mail to *David_Rostker@omb.eop.gov,* or by fax to (202) 395–7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, P.O. Box 273, Washington, DC 20044. Comments on this collection of information should be submitted separately from comments on the final rule (i.e., RIN 0694–AD86)—all comments on the latter should be submitted by one of the three methods outlined above.

FOR FURTHER INFORMATION CONTACT: Elizabeth Scott, Director, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482–3343.

SUPPLEMENTARY INFORMATION:

Background

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement the understandings reached at the annual plenary meeting of the Australia Group (AG) that was held in Paris on June 12–15, 2006. The Australia Group is a multilateral forum, consisting of 39 participating countries, that maintains 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.

The understandings reached at the June 2006 annual plenary meeting included a decision to add certain fungi and toxins to the AG ''Control List of Biological Agents.'' This rule amends the EAR to reflect that decision by revising Export Control Classification Number (ECCN) 1C351, which controls certain human and zoonotic pathogens and toxins, to add these fungi (i.e.,

Coccidioides immitis and Coccidioides posadasii) and toxins (i.e., Shiga-like ribosome inactivating proteins other than verotoxin). All Shiga-like ribosome inactivating proteins, including verotoxin, are now listed in 1C351.d.10, while the fungi Coccidioides immitis and Coccidioides posadasii are now listed in 1C351.e.1 and e.2, respectively. Prior to the publication of this rule, the fungi Coccidioides immitis and Coccidioides posadasii and Shiga-like ribosome inactivating proteins other than verotoxin were listed under ECCN 1C360, which contains unilaterally controlled select agents not included on any of the AG Common Control Lists. This rule removes these items from ECCN 1C360.

As a result of the addition of Shiga-like ribosome inactivating proteins other than verotoxin to ECCN 1C351 and their removal from ECCN 1C360, this rule makes conforming changes to ECCN 1C353, which controls certain AG-listed genetic elements and genetically modified organisms, and ECCN 1C991, which controls vaccines, immunotoxins, medical products, and diagnostic and food testing kits. The List of Items Controlled in each of these ECCNs is amended to remove all references to ECCN 1C360.a.3.a, since Shiga-like ribosome inactivating proteins other than verotoxin are now controlled under ECCN 1C351.d.10.

The scope of the EAR license requirements that apply to the specific items affected by the amendments to ECCNs 1C351, 1C353, 1C360, and 1C991 (described above) remains unchanged. The affected items in ECCNs 1C351, 1C353, and 1C360 continue to require a license for export or reexport to all countries or destinations indicated under CB Column 1 or AT Column 1 on the Commerce Country Chart (Supplement No. 1 to Part 738 of the EAR)—none of these items are controlled under 1C351.d.5. or .d.6, which also require a license for Chemical Weapons Convention (CW) reasons. The affected items in ECCN 1C991 continue to require a license for export or reexport to all destinations indicated under CB Column 3 or AT Column 1 on the Commerce Country Chart.

This rule also amends the EAR to reflect the understanding reached at the June 2006 annual plenary meeting to expand the scope of the AG ''Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology'' to include equipment in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from niobium (columbium) or niobium alloys. Specifically, this rule amends ECCN 2B350, which controls certain chemical manufacturing facilities and equipment, to include the following equipment in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from niobium (columbium) or niobium alloys: Reaction vessels or reactors; agitators for use in reaction vessels or reactors (including impellers, blades or shafts designed for such agitators); certain storage tanks, containers or receivers; certain heat exchangers or condensers (including tubes, plates, coils or blocks designed for such heat exchangers or condensers); certain distillation or absorption columns (including liquid distributors, vapor distributors or liquid collectors designed for such distillation or absorption columns); certain valves (including casings and preformed casing liners designed for such valves); multi-walled piping incorporating a leak detection port; and certain multiple-seal and seal-less pumps or vacuum pumps (including casings, preformed casing liners, impellers, rotors or jet pump nozzles designed for such pumps).

Like all other items controlled under ECCN 2B350, the newly controlled equipment and accessories, in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from niobium (columbium) or niobium alloys, require a license to all countries or destinations indicated under CB Column 2 or AT Column 1 on the Commerce Country Chart. A license generally is not required to export or reexport ECCN 2B350 equipment and components to AG participating countries; however, certain transactions may be subject to license requirements described elsewhere in the EAR (e.g., Part 744 of the EAR).

In addition, this final rule corrects errors contained in two CCL entries that were amended by a final rule that BIS published on December 29, 2004 (69 FR 77890). This rule corrects a typographical error involving a Chemical Abstracts Service (C.A.S.) registry number in ECCN 1C350, which controls AG-listed precursor chemicals. Specifically, the C.A.S. number for N,N-dimethylaminophosphoryl dichloride in 1C350.b.23 is revised to read ''C.A.S. #677–43–0,'' instead of ''C.A.S. #667–43–0.'' This rule also corrects an error in ECCN 1C355, which controls certain Chemical Weapons Convention (CWC) Schedule 2 or Schedule 3 chemicals not included on any of the AG Common Control Lists. The December 29, 2004, final rule amended ECCN 1C350 by adding the CWC Schedule 3 chemical ethyldiethanolamine (C.A.S. #139–87–7) and eight other precursor chemicals to reflect an AG intersessional decision, which was adopted after the June 2004 annual plenary meeting, to add these precursor chemicals to the ''Chemical Weapons Precursors'' AG Common Control List. As part of this change, the rule also should have removed ethyldiethanolamine (C.A.S. #139–87–7) from ECCN 1C355.b.2.a, but inadvertently failed to do so. This final rule corrects that oversight.

This rule also amends Section 742.2 of the EAR, which describes AG-related license requirements and licensing policies, to clarify certain AG-related license application requirements. Specifically, this rule adds a new paragraph (e) to indicate that, even if an AG-related item is licensed by ''$ value'' (e.g., human and zoonotic pathogens and toxins, plant pathogens, genetic elements and genetically modified organisms, and select agents and toxins), the EAR still require that the unit of quantity commonly used in the trade also be shown on the license application. This new paragraph also contains a reference to paragraph (a) of Supplement No. 2 to Part 748 of the EAR, which describes unique application and submission requirements for chemicals, medicinals, and pharmaceuticals.

Finally, this rule revises Supplement No. 2 to Part 745 of the EAR (titled ''States Parties to the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and on Their Destruction'') by adding the Central African Republic and Comoros, which recently became States Parties to the CWC. As a result of this change, the license requirements and policies that apply to exports and reexports of items controlled for CW reasons to each of these countries now conform with those applicable to other CWC States Parties, as described in Section 742.18 of the EAR.

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 extended by the Notice of August 3, 2006, 71 FR 44551 (August 7, 2006), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act.

Saving Clause

Shipments of items removed from eligibility for export or reexport under a license exception or without a license (i.e., under the designator ''NLR'') as a

result of this regulatory action that were on dock for loading, on lighter, laden aboard an exporting carrier, or en route aboard a carrier to a port of export, on December 26, 2006, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination under the previously applicable license exception or without a license (NLR) so long as they are exported or reexported before January 8, 2007. Any such items not actually exported or reexported before midnight, on January 8, 2007, 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 January 8, 2007. Beginning at midnight on January 8, 2007, 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.

Rulemaking Requirements

1. This 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 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 David Rostker, Office of Management and Budget (OMB), and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, as indicated in the **ADDRESSES** section of this rule.

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 (Sec. 5 U.S.C. 553(a)(1)). 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 5 U.S.C. 553 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. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis.

List of Subjects

15 CFR Part 742

Exports, Foreign trade.

15 CFR Part 745

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

15 CFR Part 774

Exports, Foreign trade, Reporting and recordkeeping requirements.

■ Accordingly, parts 742, 745, and 774 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

PART 742—[AMENDED]

■ 1. The authority citation for 15 CFR part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 3, 2006, 71 FR 44551 (August 7, 2006); Notice of October 27, 2006, 71 FR 64109 (October 31, 2006).

■ 2. Section 742.2 is amended by adding a new paragraph (e), at the end of the section, to read as follows:

§ 742.2 Proliferation of chemical and biological weapons.

* * * * *

(e) *License application requirements and instructions.* (1) General instructions for completing Form BIS–748P, Multipurpose Application, are provided in Supplement No. 1 to Part 748 of the EAR. When preparing applications for items controlled for chemical and biological reasons, pay particular attention to the instructions contained in paragraphs (e) and (f) of the Supplement that apply to entering ''Quantity'' and ''Units,'' respectively, on license applications. Paragraphs (e) and (f) require that, if an item is licensed in terms of ''$ value'' (refer to the ''Unit'' paragraph within the appropriate ECCN), the unit of quantity commonly used in the trade must also be shown on the license application. In such cases, Section 750.7 of the EAR provides that the quantity of commodities authorized is limited by the total dollar value as shown on the approved license and not by the quantity specified thereon. Although the EAR do not place a specific limitation on quantity in such cases, the total quantity that may be exported or reexported is limited, to a significant degree, by the fact that the EAR do not provide a shipping tolerance for items licensed by ''dollar value'' (see Section 750.11(b)(1) of the EAR) and require that the ''unit price'' indicated on the license application reflect the fair market value of the items listed on the application (see paragraph (g) of Supplement No. 1 to part 748 of the EAR).

(2) Unique application and submission requirements for chemicals, medicinals, and pharmaceuticals are described in paragraph (a) of Supplement No. 2 to part 748 of the EAR.

PART 745—[AMENDED]

■ 3. The authority citation for 15 CFR part 745 is revised to read as follows:

Authority: 50 U.S.C. 1701 *et seq.*; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of October 27, 2006, 71 FR 64109 (October 31, 2006).

Supplement No. 2 to Part 745 [Amended]

■ 4. Supplement No. 2 to part 745 is amended by revising the undesignated center heading ''List of States Parties as of March 25, 2006'' to read ''List of States Parties as of November 1, 2006'' and by adding, in alphabetical order, the countries ''Central African Republic'' and ''Comoros''.

PART 774—[AMENDED]

■ 5. The authority citation for 15 CFR part 774 is revised 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; 30 U.S.C. 185(s), 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; Sec. 901–911, Pub. L. 106–387; Sec. 221, Pub. L. 107–56; 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 3, 2006, 71 FR 44551 (August 7, 2006).

Supplement No. 1 to Part 774—[Amended]

■ 6. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C350 is amended by revising the parenthetical ''(C.A.S. #667–43–0)'' in paragraph b.23 under *Items*, in the List of Items Controlled, to read ''(C.A.S. #677–43–0)''.

■ 7. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C351 is amended by revising the List of Items Controlled to read as follows:

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

* * * * *

List of Items Controlled

Unit: $ value.

Related Controls: (1) Certain forms of ricin and saxitoxin in 1C351.d.5. and d.6 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 additional CWC Schedule 1 chemicals controlled by the Department of State. (2) 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.5 and d.6, 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. (3) For the purposes of this entry, only saxitoxin is controlled under paragraph d.6; other members of the paralytic shellfish poison family (e.g. neosaxitoxin) are classified as EAR99. (4) Clostridium perfringens strains, other than the epsilon toxin-producing strains of Clostridium perfringens described in c.14, are excluded from the scope of this entry, since they may be used as positive control cultures for food testing and quality control. (5) 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(c), 9 CFR 121.3(c), and 9 CFR 121.4(c); for CDC, see 42 CFR 73.3(c) and 42 CFR 73.4(c)).

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, as follows:

a.1. Chikungunya virus;

a.2. Congo-Crimean haemorrhagic fever virus (a.k.a. Crimean-Congo haemorrhagic fever virus);

a.3. Dengue fever virus;

a.4. Eastern equine encephalitis virus;

a.5. Ebola virus;

a.6. Hantaan virus;

a.7. Japanese encephalitis virus;

a.8. Junin virus;

a.9. Lassa fever virus

a.10. Lymphocytic choriomeningitis virus;

a.11. Machupo virus;

a.12. Marburg virus;

a.13. Monkey pox virus;

a.14. Rift Valley fever virus;

a.15. Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus);

a.16. Variola virus;

a.17. Venezuelan equine encephalitis virus;

a.18. Western equine encephalitis virus;

a.19. White pox;

a.20. Yellow fever virus;

a.21. Kyasanur Forest virus;

a.22. Louping ill virus;

a.23. Murray Valley encephalitis virus;

a.24. Omsk haemorrhagic fever virus;

a.25. Oropouche virus;

a.26. Powassan virus;

a.27. Rocio virus;

a.28. St. Louis encephalitis virus;

a.29. Hendra virus (Equine morbillivirus);

a.30. South American haemorrhagic fever (Sabia, Flexal, Guanarito);

a.31. Pulmonary and renal syndrome-haemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre); *or*

a.32. Nipah virus.

b. Rickettsiae, as follows:

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

b.2. Coxiella burnetii;

b.3. Rickettsia prowasecki (a.k.a. Rickettsia prowazekii); *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. Salmonella typhi;

c.11. Shigella dysenteriae;

c.12. Vibrio cholerae;

c.13. Yersinia pestis;

c.14. Clostridium perfringens, epsilon toxin producing types; *or*

c.15. Enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing serotypes.

d. ''Toxins'', as follows, and ''subunits'' thereof:

d.1. Botulinum toxins;

d.2. Clostridium perfringens toxins;

d.3. Conotoxin;

d.4. Microcystin (Cyanginosin);

d.5. Ricin;

d.6. Saxitoxin;

d.7. Shiga toxin;

d.8. Staphylococcus aureus toxins;

d.9. Tetrodotoxin;

d.10. Verotoxin and other Shiga-like ribosome inactivating proteins;

d.11. Aflatoxins;

d.12. Abrin;

d.13. Cholera toxin;

d.14. Diacetoxyscirpenol toxin;

d.15. T–2 toxin;

d.16. HT–2 toxin;

d.17. Modeccin toxin;

d.18. Volkensin toxin; *or*

d.19. Viscum Album Lectin 1 (Viscumin).

e. ''Fungi'', as follows:

e.1. Coccidioides immitis; *or*

e.2. Coccidioides posadasii.

■ 8. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C353 is amended by revising the List of Items Controlled to read as follows:

1C353 Genetic elements and genetically-modified organisms, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: $ value.

Related Controls: Vaccines that contain genetic elements or genetically modified organisms identified in this entry are controlled by ECCN 1C991. The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN, including (but not limited to) genetic elements, recombinant nucleic acids, and recombinant organisms associated with the agents or toxins in ECCN 1C360 (for APHIS, see 7 CFR 331.3(c), 9 CFR 121.3(c), and 9 CFR 121.4(c); for CDC, see 42 CFR 73.3(c) and 42 CFR 73.4(c)).

Related Definition: N/A.

Items:

a. Genetic elements, as follows:

a.1. Genetic elements that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a to .c, 1C352, 1C354, or 1C360;

a.2. Genetic elements that contain nucleic acid sequences coding for any of the ''toxins'' controlled by 1C351.d or ''sub-units of toxins'' thereof.

b. Genetically modified organisms, as follows:

b.1. Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of microorganisms controlled by 1C351.a to .c, 1C352, 1C354, or 1C360;

b.2. Genetically modified organisms that contain nucleic acid sequences coding for any of the ''toxins'' controlled by 1C351.d or ''sub-units of toxins'' thereof.

Technical Note: 1. ''Genetic elements'' include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified.

2. This ECCN does not control nucleic acid sequences associated with the pathogenicity of enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing strains, except those nucleic acid sequences that contain coding for the verotoxin or its sub-units.

3. ''Nucleic acid sequences associated with the pathogenicity of any of the microorganisms controlled by 1C351.a to .c, 1C352, 1C354, or 1C360'' means any sequence specific to the relevant controlled microorganism that:

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

b. Is known to enhance the ability of a microorganism controlled by 1C351.a to .c, 1C352, 1C354, or 1C360, or any other organism into which it may be inserted or otherwise integrated, to cause serious harm to human, animal or plant health.

■ 9. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C355 is amended by revising the List of Items Controlled to read as follows:

1C355 Chemical Weapons Convention (CWC) Schedule 2 and 3 chemicals and families of chemicals not controlled by ECCN 1C350 or by the Department of State under the ITAR.

* * * * *

List of Items Controlled

Unit: Liters or kilograms, as appropriate.

Related Controls: See also ECCNs 1C350 1C351, 1C395, and 1C995. See §§ 742.18 and 745.2 of the EAR for End-Use Certification requirements.

Related Definitions: N/A.

Items:

a. CWC Schedule 2 chemicals and mixtures containing Schedule 2 chemicals:

a.1. Toxic chemicals, as follows, and mixtures containing toxic chemicals:

a.1.a. PFIB: 1,1,3,3,3-Pentafluoro-2-(trifluoromethyl)-1-propene (C.A.S. 382–21–8) and mixtures in which PFIB constitutes more than 1 percent of the weight of the mixture;

a.1.b. [RESERVED]

a.2. Precursor chemicals, as follows, and mixtures in which at least one of the following precursor chemicals constitutes more than 10 percent of the weight of the mixture:

a.2.a. Chemicals, except for those listed in Schedule 1, containing a phosphorus atom to which is bonded one methyl, ethyl, or propyl (normal or iso) group but not further carbon atoms.

Note: 1C355.a.2.a does *not* control Fonofos: O-Ethyl S-phenyl ethylphosphono thiolothionate (C.A.S. 944–22–9).

a.2.b. FAMILY: N,N-Dialkyl (Me, Et, n-Pr or i-Pr) phosphoramidic dihalides;

a.2.c. FAMILY: Dialkyl (Me, Et, n-Pr or i-Pr) N,N-Dialkyl (Me, Et, n-Pr, or i-Pr)-phosphoramidates;

a.2.d. FAMILY: N,N-Dialkyl (Me, Et, n-Pr or i-Pr) aminoethyl-2-chlorides and corresponding protonated salts;

a.2.e. FAMILY: N,N-Dialkyl (Me, Et, n-Pr or i-Pr) aminoethane-2-ols and corresponding protonated salts;

Note: 1C355.a.2.e. does *not* control N,N-Dimethylaminoethanol and corresponding protonated salts (C.A.S. 108–01–0) or N,N-Diethylaminoethanol and corresponding protonated salts (C.A.S. 100–37–8).

a.2.f. FAMILY: N,N-Dialkyl (Me, Et, n-Pr or i-Pr) aminoethane-2-thiols and corresponding protonated salts.

b. CWC Schedule 3 chemicals and mixtures containing Schedule 3 chemicals:

b.1. Toxic chemicals, as follows, and mixtures in which at least one of the following toxic chemicals constitutes 30 percent or more of the weight of the mixture:

b.1.a. Phosgene: Carbonyl dichloride (C.A.S. 75–44–5);

b.1.b. Cyanogen chloride (C.A.S. 506–77–4);

b.1.c. Hydrogen cyanide (C.A.S. 74–90–8);

b.1.d. Chloropicrin: Trichloronitromethane (C.A.S. 76–06–2).

b.2. Precursor chemicals, as follows, and mixtures in which at least one of the following precursor chemicals constitutes 30 percent or more of the weight of the mixture:

b.2.a.. [Reserved];

b.2.b. Methyldiethanolamine (C.A.S. 105–59–9).

■ 10. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C360 is amended by revising the ECCN heading and the List of Items Controlled to read as follows:

1C360 Select agents not controlled under ECCN 1C351, 1C352, or 1C354.

* * * * *

List of Items Controlled

Unit: $ value.

Related Controls: (1) All vaccines are excluded from the scope of this entry. Vaccines excluded from the scope of this entry are controlled under ECCN 1C991. (2) Also see ECCNs 1C351 (AG-controlled human and zoonotic pathogens and ''toxins''), 1C352 (AG-controlled animal pathogens), and 1C354 (AG-controlled plant pathogens). (3) 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 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)).

Related Definitions: N/A.

Items:

Note: The control status of items listed in this ECCN is not affected by the exemptions or exclusions contained in the domestic possession, use, and transfer regulations maintained by APHIS (at 7 CFR part 331 and 9 CFR part 121) and/or CDC (at 42 CFR part 73).

a. Human and zoonotic pathogens, as follows:

a.1. Viruses, as follows:

a.1.a. Central European tick-borne encephalitis viruses, as follows:

a.1.a.1. Absettarov;

a.1.a.2. Hanzalova;

a.1.a.3. Hypr;

a.1.a.4. Kumlinge;

a.1.b. Cercopithecine herpesvirus 1 (Herpes B virus);

a.1.c. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments;

a.2. [Reserved];

b. Animal pathogens, as follows:

b.1. Viruses, as follows:

b.1.a. Akabane virus;

b.1.b. Bovine spongiform encephalopathy agent;

b.1.c. Camel pox virus;

b.1.d. Malignant catarrhal fever virus;

b.1.e. Menangle virus;

b.2. Mycoplasma, as follows:

b.2.a. Mycoplasma capricolum;

b.2.b. Mycoplasma F38;

b.3. Rickettsia, as follows:

b.3.a. Erhlichia ruminantium (a.k.a. Cowdria ruminantium);

b.3.b. [Reserved].

c. Plant pathogens, as follows:

c.1. Bacteria, as follows:

c.1.a. Candidatus Liberobacter africanus (a.k.a. Liberobacter africanus);

c.1.b. Candidatus Liberobacter asiaticus (a.k.a. Liberobacter asiaticus);

c.1.c. Xylella fastidiosa pv. citrus variegated chlorosis (CVC);

c.2. Fungi, as follows:

c.2.a. Peronosclerospora philippinensis;

c.2.b. Sclerophthora rayssiae var. zeae;

c.2.c. Synchytrium endobioticum.

■ 11. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms'' & ''Toxins,'' ECCN 1C991 is amended by revising the List of Items Controlled to read as follows:

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

* * * * *

List of Items Controlled

Unit: $ value.

Related Controls: (1) Medical products containing ricin or saxitoxin, as follows, are controlled for CW reasons under ECCN 1C351:

(a) Ricinus Communis Agglutinin$_{II}$ (RCA_{II}), also known as ricin D, or Ricinus Communis Lectin$_{III}$ (RCL_{III});

(b) Ricinus Communis Lectin$_{IV}$ (RCL_{IV}), also known as ricin E; or

(c) Saxitoxin identified by C.A.S. #35523–89–8.

(2) The export of a ''medical product'' that is an ''Investigational New Drug'' (IND), as defined in 21 CFR 312.3, is subject to certain U.S. Food and Drug Administration (FDA) requirements that are independent of the export requirements specified in this ECCN or elsewhere in the EAR. These FDA requirements are described in 21 CFR 312.110 and must be satisfied in addition to any requirements specified in the EAR.

(3) Also see 21 CFR 314.410 for FDA requirements concerning exports of new drugs and new drug substances.

Related Definitions: For the purpose of this entry, ''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. For the purpose of this entry, ''medical products'' are: (1) Pharmaceutical formulations designed for testing and human administration in the treatment of medical conditions, (2) prepackaged for distribution as clinical or medical products, and (3) approved by the U.S. Food and Drug Administration either to be marketed as clinical or medical products or for use as an ''Investigational New Drug'' (IND) (see 21 CFR part 312). For the purpose of this entry, ''diagnostic and food testing kits'' are specifically developed, packaged and marketed for diagnostic or public health purposes. Biological toxins in any other configuration, including bulk shipments, or for any other end-uses are controlled by ECCN 1C351 or ECCN 1C360. For the purpose of this entry, ''vaccine'' is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.

Items:

a. Vaccines against items controlled by ECCN 1C351, 1C352, 1C353, 1C354, or 1C360;

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

c. Medical products containing botulinum toxins controlled by ECCN 1C351.d.1 or conotoxins controlled by ECCN 1C351.d.3;

d. Medical products containing items controlled by ECCN 1C351.d (except botulinum toxins controlled by ECCN 1C351.d.1, conotoxins controlled by ECCN 1C351.d.3, and items controlled for CW reasons under 1C351.d.5 or .d.6);

e. Diagnostic and food testing kits containing items controlled by ECCN 1C351.d (except items controlled for CW reasons under ECCN 1C351.d.5 or .d.6).

■ 12. In Supplement No. 1 to part 774 (the Commerce Control List), Category 2—Materials Processing,'' ECCN 2B350 is amended by revising the List of Items Controlled to read as follows:

2B350 Chemical manufacturing facilities and equipment, except valves controlled by 2A226 or 2A292, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: Equipment in number.

Related Controls: The controls in this entry do not apply to equipment that is both:

(a) specially designed for use in civil applications (e.g., food processing, pulp and paper processing, or water purification); and (b) inappropriate, by the nature of its design, for use in storing, processing, producing or conducting and controlling the flow of chemical weapons precursors controlled by 1C350.

Related Definitions: For purposes of this entry the term ''chemical warfare agents'' are those agents subject to the export licensing authority of the U.S. Department of State, Directorate of Defense Trade Controls. (See 22 CFR part 121.)

Items:

a. Reaction vessels or reactors, with or without agitators, with total internal (geometric) volume greater than 0.1 m^3 (100 liters) and less than 20 m^3 (20,000 liters), where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

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

a.2. Fluoropolymers;

a.3. Glass (including vitrified or enameled coating or glass lining);

a.4. Nickel or alloys with more than 40% nickel by weight;

a.5. Tantalum or tantalum alloys;

a.6. Titanium or titanium alloys;

a.7. Zirconium or zirconium alloys; or

a.8. Niobium (columbium) or niobium alloys.

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

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

b.2. Fluoropolymers;

b.3. Glass (including vitrified or enameled coatings or glass lining);

b.4. Nickel or alloys with more than 40% nickel by weight;

b.5. Tantalum or tantalum alloys;

b.6. Titanium or titanium alloys;

b.7. Zirconium or zirconium alloys; or

b.8. Niobium (columbium) or niobium alloys.

c. Storage tanks, containers or receivers with a total internal (geometric) volume greater than 0.1 m^3 (100 liters) where all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

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

c.2. Fluoropolymers;

c.3. Glass (including vitrified or enameled coatings or glass lining);

c.4. Nickel or alloys with more than 40% nickel by weight;

c.5. Tantalum or tantalum alloys;

c.6. Titanium or titanium alloys;

c.7. Zirconium or zirconium alloys; or

c.8. Niobium (columbium) or niobium alloys.

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

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

d.2. Fluoropolymers;

d.3. Glass (including vitrified or enameled coatings or glass lining);

d.4. Graphite or carbon-graphite;

d.5. Nickel or alloys with more than 40% nickel by weight;

d.6. Silicon carbide;

d.7. Tantalum or tantalum alloys;

d.8. Titanium or titanium alloys;

d.9. Titanium carbide;

d.10. Zirconium or zirconium alloys; or

d.11. Niobium (columbium) or niobium alloys.

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

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

e.2. Fluoropolymers;

e.3. Glass (including vitrified or enameled coatings or glass lining);

e.4. Graphite or carbon-graphite;

e.5. Nickel or alloys with more than 40% nickel by weight;

e.6. Tantalum or tantalum alloys;

e.7. Titanium or titanium alloys;

e.8. Zirconium or zirconium alloys; or

e.9. Niobium (columbium) or niobium alloys.

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

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

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

g. Valves with nominal sizes greater than 1.0 cm (.4 in.), and casings (valve bodies) or preformed casing liners designed for such valves, in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:

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

g.2. Alloys with more than 25% nickel and 20% chromium by weight;

g.3. Fluoropolymers;

g.4. Glass or glass lined (including vitrified or enameled coatings);
g.5. Tantalum or tantalum alloys;
g.6. Titanium or titanium alloys;
g.7. Zirconium or zirconium alloys; or
g.8. Niobium (columbium) or niobium alloys.
h. Multi-walled piping incorporating a leak detection port, in which all surfaces that come in direct contact with the chemical(s) being processed or contained are made from any of the following materials:
h.1. Alloys with more than 25% nickel and 20% chromium by weight;
h.2. Fluoropolymers;
h.3. Glass (including vitrified or enameled coatings or glass lining);
h.4. Graphite or carbon-graphite;
h.5. Nickel or alloys with more than 40% nickel by weight;
h.6. Tantalum or tantalum alloys;
h.7. Titanium or titanium alloys;
h.8. Zirconium or zirconium alloys; or
h.9. Niobium (columbium) or niobium alloys.
i. Multiple-seal and seal-less pumps with manufacturer's specified maximum flow-rate greater than 0.6 m^3/hour, or vacuum pumps with manufacturer's specified maximum flow-rate greater than 5 m^3/hour (under standard temperature (273 K (0 °C)) and pressure (101.3 kPa) conditions), and casings (pump bodies), preformed casing liners, impellers, rotors or jet pump nozzles designed for such pumps, in which all surfaces that come into direct contact with the chemical(s) being processed are made from any of the of the following materials:
i.1. Alloys with more than 25% nickel and 20% chromium by weight;
i.2. Ceramics;
i.3. Ferrosilicon;
i.4. Fluoropolymers;
i.5. Glass (including vitrified or enameled coatings or glass lining);
i.6. Graphite or carbon-graphite;
i.7. Nickel or alloys with more than 40% nickel by weight;
i.8. Tantalum or tantalum alloys;
i.9. Titanium or titanium alloys;
i.10. Zirconium or zirconium alloys; or
i.11. Niobium (columbium) or niobium alloys.
j. Incinerators designed to destroy chemical warfare agents, chemical weapons precursors controlled by 1C350, or chemical munitions having specially designed waste supply systems, special handling facilities and an average combustion chamber temperature greater than 1000 °C in which all surfaces in the waste supply system that come into direct contact with the waste products are made from or lined with any of the following materials:
j.1. Alloys with more than 25% nickel and 20% chromium by weight;
j.2. Ceramics; or
j.3. Nickel or alloys with more than 40% nickel by weight.

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

Dated: November 16, 2006.

Christopher A. Padilla,

Assistant Secretary for Export Administration.

[FR Doc. E6–19825 Filed 11–22–06; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 634

[FHWA Docket No. FHWA–2005–23200]

RIN 2125–AF11

Worker Visibility

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: Pursuant to Section 1402 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), this final rule establishes a policy for the use of high-visibility safety apparel. The FHWA establishes a new Part in title 23, Code of Federal Regulations (CFR) that requires the use of high-visibility safety apparel and provides guidance on its application. This rulemaking applies only to workers who are working within the rights-of-way of Federal-aid highways. The FHWA is taking this action to decrease the likelihood of fatalities or injuries to workers on foot who are exposed either to traffic (vehicles using the highway for purposes of travel) or to construction vehicles or equipment while working within the rights-of-way of Federal-aid highways.

DATES: *Effective Date:* This final rule is effective November 24, 2008. The incorporation by reference of the publication listed in this regulation is approved by the Director of the Office of the Federal Register as of November 24, 2008.

FOR FURTHER INFORMATION CONTACT: Mr. Hari Kalla, Office of Transportation Operations, (202) 366–5915; or Mr. Raymond W. Cuprill, Office of the Chief Counsel, (202) 366–0791, U.S. Department of Transportation, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

This document, the notice of proposed rulemaking (NPRM), and all comments received may be viewed online through the Document Management System (DMS) at *http://dms.dot.gov.* The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the Web site.

An electronic copy of this document may also be downloaded from the Office of the Federal Register's home page at: *http://www.archives.gov* and the Government Printing Office's Web page at: *http://www.access.gpo.gov/nara.*

Background

On April 24, 2006, at 71 FR 20925, the FHWA published a NPRM proposing to establish a policy for the use of high-visibility safety apparel for workers who are working within the Federal-aid highway rights-of-way. This NPRM proposed regulations implementing the requirements of Section 1402 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) (Pub. L. 109–59; August 10, 2005), which directed the Secretary of Transportation to, within one year, issue regulations to decrease the likelihood of worker injury and maintain the free flow of vehicular traffic by requiring workers whose duties place them on or in close proximity to a Federal-aid highway to wear high-visibility safety apparel. The comment period for the NPRM closed on June 23, 2006.

There has been an increase in the amount of maintenance and reconstruction of the nation's highways that is being accomplished in stages while traffic continues to use a portion of the street or highway for purposes of travel. This has resulted in an increase in the exposure of workers on foot to high-speed traffic and a corresponding increase in the risk of injury or death for highway workers.

High visibility is one of the most prominent needs for workers who must perform tasks near moving vehicles or equipment. The need to be seen by those who drive or operate vehicles or equipment is recognized as a critical issue for worker safety. The sooner a worker in or near the path of travel is seen, the more time the operator has to avoid an incident. The FHWA recognized this fact and included language in the 2000 Edition of the Manual on Uniform Traffic Control Devices (MUTCD) [1] to address this issue. This text in the 2000 MUTCD led

[1] Manual on Uniform Traffic Control Devices (MUTCD) is recognized as the national standard for all traffic control devices installed on any street, highway, or bicycle trail open to public travel. It is available at *http://www.mutcd.fhwa.dot.gov.*