

Issued in Renton, Washington, on May 31, 2006.

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*Acting Manager, Transport Airplane
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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003-NM-233-AD; Amendment 39-14585; AD 2006-10-01]

RIN 2120-AA64

Airworthiness Directives; Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects a typographical error that appeared in AD 2006-10-01 that was published in the **Federal Register** on May 8, 2006 (71 FR 26682). The typographical error resulted in an incorrect revision date for a referenced service bulletin. This AD is applicable to certain Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes. This AD requires the installation of protective tape on the fire and overheat control unit in the flight compartment, and repetitive inspections of the condition of the protective tape and related corrective action. This AD also mandates eventual replacement of the existing fire and overheat control unit with a modified unit, which ends the repetitive inspections.

DATES: Effective June 12, 2006.

FOR FURTHER INFORMATION CONTACT:

Rocco Viselli (or James Delisio), Aerospace Engineer, Airframe and Propulsion Branch, ANE-171, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, suite 410, Westbury, New York; telephone (516) 228-7331 (or (516) 228-7321); fax (516) 794-5531.

SUPPLEMENTARY INFORMATION:

Airworthiness Directive (AD) 2006-10-01, amendment 39-14585, applicable to certain Bombardier Model CL-600-2B19 (Regional Jet Series 100 & 440) airplanes, was published in the **Federal Register** on May 8, 2006 (71 FR 26682). That AD requires the installation of protective tape on the fire and overheat control unit in the flight compartment, and repetitive inspections of the condition of the protective tape and related corrective action. That AD also

mandates eventual replacement of the existing fire and overheat control unit with a modified unit, which ends the repetitive inspections.

As published, the AD reads throughout, "Bombardier Alert Service Bulletin A601R-26-017, Revision "C," dated November 6, 2003." The correct date of the service bulletin revision should be November 3, 2003.

Since no other part of the regulatory information has been changed, the final rule is not being republished in the **Federal Register**.

The effective date of this AD remains June 12, 2006.

§ 39.13 [Corrected]

On page 26685, in the left-hand column, paragraph (g) of AD 2006-10-01 is corrected to read as follows:

* * * * *

(g) Actions accomplished before the effective date of this AD in accordance with Bombardier Alert Service Bulletin A601R-26-017, Revision "C," dated November 3, 2003; and Bombardier Service Bulletin 601R-26-018, dated December 2, 2002; or Revision "A," dated February 27, 2003; as applicable; are considered acceptable for compliance with the corresponding requirements of this AD.

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Issued in Renton, Washington, on May 31, 2006.

Kalene C. Yanamura,

*Acting Manager, Transport Airplane
Directorate, Aircraft Certification Service.*

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 738, 742, 745, and 774

[Docket No. 060228055-6055-01]

RIN 0694-AD62

Implementation of Unilateral Chemical/Biological (CB) Controls on Certain Biological Agents and Toxins; Clarification of Controls on Medical Products Containing Certain Toxins on the Australia Group (AG) Common Control Lists; 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

expand export and reexport controls on certain biological agents and toxins (referred to, herein, as "select agents and toxins") that have been determined by the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, and the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, to have the potential to pose a severe threat to human, animal and plant life, as well as certain sectors of the U.S. economy (e.g., agriculture). Prior to the publication of this rule, twenty-two of these agents were not listed on the Commerce Control List (CCL) and one of these agents was incompletely specified therein. By amending the EAR to add a new CCL entry that controls CDC and/or APHIS select agents and toxins (including associated genetic elements, recombinant nucleic acids, and recombinant organisms) not previously specified on the CCL, this rule complements the controls that CDC and APHIS have imposed on the possession, use, and transfer of these select agents and toxins within the United States. The addition of these items to the CCL is expected to have a minimal impact on U.S. industry, since the volume of exports and reexports is extremely limited.

This rule also amends the EAR to clarify controls on certain medical products containing AG-controlled toxins, other than ricin or saxitoxin, by revising the definition of such products to clearly indicate that they include pharmaceutical formulations, prepackaged for distribution as clinical or medical products, that have been approved by the Food and Drug Administration (FDA) for use as an "Investigational New Drug" (IND). Specifically, this rule clarifies that FDA-approved IND products containing AG-controlled toxins (except ricin or saxitoxin) are considered to be "medical products" as described in the CCL entry that controls vaccines, immunotoxins, medical products, and diagnostic and food testing kits. BIS is making this clarification because the previous revision to the definition of medical products inadvertently failed to specify that such products include IND items. Furthermore, this clarification is consistent with the language in the AG exemption for clinical and medical products containing botulinum toxins and conotoxins, since the AG exemption applies when such products are designed for "testing," as well as human administration, in the treatment of medical conditions.

In addition, this rule removes the license requirements for exports and

reexports to St. Kitts and Nevis of items that require a license for export or reexport only to countries of concern for chemical and biological weapons proliferation (CB) reasons. This change is being made because St. Kitts and Nevis is not listed in Country Group D:3. As a result of this change, there is now a one-to-one correspondence between the countries included in Country Group D:3 and the countries for which a license requirement is indicated under CB Column 3 of the Commerce Country Chart.

Finally, this rule updates the list of countries that currently are States Parties to the Chemical Weapons Convention (CWC) by adding Antigua and Barbuda, Bhutan, Cambodia, the Democratic Republic of the Congo, Djibouti, Grenada, Haiti, Honduras, Liberia, and Vanuatu, 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 June 12, 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-AD62, by any of the following methods:

- E-mail: public.comments@bis.doc.gov. Include "RIN 0694-AD62" 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-AD62.

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-AD62)—all comments on the latter should be submitted by one of the three methods outlined above.

FOR FURTHER INFORMATION CONTACT: Douglas Brown, Director, Chemical and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482-5808.

SUPPLEMENTARY INFORMATION:

Background

A. Amendments to the EAR Establishing Export and Reexport Controls on Certain Select Agents and Toxins

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to expand export and reexport controls on certain select agents and toxins (including associated genetic elements, recombinant nucleic acids, and recombinant organisms) that have been determined by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) to have the potential to pose a severe threat to human, animal and plant life and to certain sectors of the U.S. economy. APHIS and CDC regulate the domestic possession, use, and transfer of these select agents and toxins in accordance with the following regulations: 7 CFR part 331, which contains the APHIS regulations regarding the Possession, Use, and Transfer of PPQ (Plant Protection and Quarantine Programs) Select Agents and Toxins; 9 CFR part 121, which contains the APHIS regulations regarding the Possession, Use, and Transfer of VS (Veterinary Services Programs) and Overlap Select Agents and Toxins; and 42 CFR part 73, which contains the CDC regulations regarding HHS (Department of Health and Human Services) and Overlap Select Agents and Toxins.

This rule amends the Commerce Control List (CCL) (Supplement No. 1 to Part 774 of the EAR) to include those CDC and/or APHIS select agents and toxins (including associated genetic elements, recombinant nucleic acids, and recombinant organisms) not previously specified on the CCL. Prior to the publication of this rule, twenty-two of these agents and toxins were not listed on the CCL and one was only partially specified on the CCL. However, most of these agents and toxins were listed on the CCL prior to the publication of this rule. Currently, they are controlled under Export Control Classification Numbers (ECCNs) 1C351, 1C352, 1C353, and 1C354. Together, these four ECCNs control sixty items identified as CDC and/or APHIS select agents and toxins, all of which are included on the Australia Group (AG) Common Control Lists.

The export and reexport controls established by this rule will complement the controls that CDC and APHIS have imposed on the possession, use, and transfer of these select agents and toxins and associated genetic elements, recombinant nucleic acids, and recombinant organisms within the United States. BIS is taking this action with the understanding that CDC and APHIS have not imposed controls on the export and reexport of these items in recognition of the Department of Commerce's role in regulating the export and reexport of biological agents and toxins. Their regulations do, however, apply to imports of select agents and toxins. Collectively, the controls administered by BIS, CDC, and APHIS will significantly reduce the potential availability of these items for use in unauthorized activities that could pose a serious threat to human, animal or plant health and disrupt certain sectors of the U.S. economy (*e.g.*, agriculture). Although none of the 23 agents and toxins (and associated genetic elements, recombinant nucleic acids, and recombinant organisms) are currently identified on any of the AG Common Control Lists, the United States intends to work in cooperation with the governments of other AG participating countries to consider the addition of these items to the appropriate AG control lists.

Specifically, this rule adds new ECCN 1C360 to the CCL and revises ECCN 1C353 to control the select agents and toxins and associated genetic elements, recombinant nucleic acids, and recombinant organisms identified in 7 CFR part 331, 9 CFR part 121, and/or 42 CFR part 73 that are not specified elsewhere on the CCL. The current CDC/APHIS select agents and toxins that are controlled under new ECCN 1C360 are listed, below, under the categories human and zoonotic pathogens/toxins, animal pathogens, and plant pathogens. One of these items is specified elsewhere on the CCL, as indicated below.

A. Human and zoonotic pathogens and toxins:

1. Viruses:
 - a. Central European tick-borne encephalitis viruses:
 - i. Absettarov;
 - ii. Hanzalova;
 - iii. Hypr;
 - iv. Kumlinge;
 - b. Cercopithecine herpesvirus 1 (Herpes B virus);
 - c. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments;

2. Fungi:
 - a. *Coccidioides immitis*;
 - b. *Coccidioides posadasii*;
 3. Toxins: Shiga-like ribosome inactivating proteins not controlled under ECCN 1C351.d.10;
- B Animal pathogens:
 1. Viruses:
 - a. Akabane virus;
 - b. Bovine spongiform encephalopathy agent;
 - c. Camel pox virus;
 - d. Malignant catarrhal fever virus;
 - e. Menangle virus;
 2. Mycoplasma:
 - a. *Mycoplasma capricolum*;
 - b. *Mycoplasma F38*;
 3. *Rickettsia: Erhlichia ruminantium* (a.k.a. *Cowdria ruminantium*);
 - C. Plant pathogens:
 1. Bacteria:
 - a. *Candidatus Liberobacter africanus* (a.k.a. *Liberobacter africanus*);
 - b. *Candidatus Liberobacter asiaticus* (a.k.a. *Liberobacter asiaticus*);
 - c. *Xylella fastidiosa* pv. *citrus* variegated chlorosis (CVC);
 2. Fungi:
 - a. *Peronosclerospora philippinensis*;
 - b. *Sclerophthora rayssiae* var. *zeae*;
 - c. *Synchytrium endobioticum*.

New ECCN 1C360 controls these CDC/APHIS select agents and toxins for chemical and biological weapons proliferation (CB) reasons (to destinations indicated under CB Column 1) and anti-terrorism (AT) reasons (to destinations indicated under AT Column 1). Items controlled for CB Column 1 reasons require a license for export or reexport to all destinations, worldwide, as set forth in Section 742.2(a)(1) of the EAR and as indicated on the Commerce Country Chart (see Supplement No. 1 to Part 738 of the EAR). Items controlled for AT Column 1 reasons require a license to Libya, North Korea, Sudan, and Syria, as indicated on the Commerce Country Chart. See Part 742 of the EAR for additional information on these AT license requirements. Exports and reexports of these "select agents" may also require a license for reasons specified elsewhere in the EAR (*e.g.*, the end-user/end-use license requirements described in Part 744 of the EAR and the embargoes and other special controls described in Part 746 of the EAR).

This final rule also amends ECCNs 1E001 and 1E351 to control certain technology related to the select agents and toxins listed in new ECCN 1C360. The License Requirements section of ECCN 1E001 is revised to indicate that a license is required, for CB reasons, to export technology for the "development" or "production" of these items to all destinations, worldwide, as

set forth in Section 742.2(a)(1) of the EAR and as indicated under CB Column 1 on the Commerce Country Chart. Such technology also is controlled under ECCN 1E001 for AT reasons and requires a license to Libya, North Korea, Sudan, and Syria, as indicated under AT Column 1 on the Commerce Country Chart. The heading of ECCN 1E351 is revised to indicate that this ECCN controls technology for the disposal of microbiological materials listed in new ECCN 1C360. Such technology requires a license under ECCN 1E351 for export or reexport to all destinations, worldwide, as set forth in Section 742.2(a)(1) of the EAR and as indicated under CB Column 1 on the Commerce Country Chart, and to Libya, North Korea, Sudan, and Syria, as indicated under AT Column 1 on the Commerce Country Chart. See Part 742 of the EAR for additional information on the AT license requirements for these ECCNs. Exports and reexports of this technology may also require a license for reasons specified elsewhere in the EAR (*e.g.*, the end-user/end-use license requirements described in Part 744 of the EAR and the embargoes and other special controls described in Part 746 of the EAR).

This rule also makes conforming changes to ECCNs 1C351 and 1C353 to reflect the addition of new ECCN 1C360 to the CCL. This rule amends ECCN 1C351 to clarify the scope of controls on verotoxins in 1C351.d.10 by adding a new Technical Note, at the end of the List of Items Controlled, to indicate that verotoxins are Shiga-like ribosome inactivating proteins, which are among the select agents and toxins subject to the domestic controls administered by CDC and APHIS (see new ECCN 1C360.a.3.a). In addition, this rule amends ECCN 1C353 by revising the List of Items Controlled to indicate that this ECCN controls genetic elements and genetically modified organisms containing nucleic acid sequences associated with the pathogenicity of microorganisms controlled by new ECCN 1C360 (*i.e.*, genetic elements, recombinant nucleic acids, and recombinant organisms associated with the CDC and/or APHIS select agents and toxins controlled by new ECCN 1C360), as well as microorganisms controlled by ECCN 1C351.a to .c, 1C352, or 1C354. This rule also revises the List of Items Controlled in ECCN 1C353 to indicate that this ECCN controls genetically modified organisms that contain nucleic acid sequences coding for any of the "toxins" controlled by new ECCN 1C360, or "sub-units of toxins" thereof. Items controlled under ECCN 1C351 or ECCN 1C353 are subject to the same

CCL-based license requirements (*i.e.*, CB Column 1 and AT Column 1), as described above, for items controlled under new ECCN 1C360.

This rule also amends ECCNs 1C351, 1C352, 1C353, and 1C354 by revising the "Related Controls" paragraph in the List of Items Controlled for each entry to indicate that APHIS and/or CDC maintain controls on the transfer and possession within the United States of certain items controlled by the ECCN. These changes reflect the fact that most of the select agents and toxins subject to the domestic controls of APHIS and/or CDC are already included on the control lists maintained by the AG.

This rule amends the List of Items Controlled in ECCN 1C991 by expanding the scope of this ECCN to control vaccines against items in new ECCN 1C360, immunotoxins containing items in 1C360.a.3 (currently, these include Shiga-like ribosome inactivating proteins not controlled under ECCN 1C351.d.10), medical products containing items in 1C360.a.3, and diagnostic and food testing kits containing items in 1C360.a.3. Controlling these specific vaccines, immunotoxins, medical products, and diagnostic and food testing kits under ECCN 1C991, instead of new ECCN 1C360, means that they generally may be exported or reexported, without a license, to all destinations, except embargoed destinations and countries indicated under AT Column 1 on the Commerce Country Chart (Supplement No. 1 to Part 738 of the EAR)—see Parts 742 and 746 of the EAR for additional information on these license requirements. A license also may be required to export or reexport these items for reasons specified elsewhere in the EAR (*e.g.*, Part 744 of the EAR).

In addition, this rule makes conforming changes to Section 742.2 of the EAR to reflect the addition of new ECCN 1C360 to the CCL. A reference to new ECCN 1C360 is added to paragraph (a)(1)(i), which identifies the ECCNs containing human and zoonotic pathogens/toxins, animal pathogens, plant pathogens, genetic elements, and genetically modified microorganisms that require a license for CB reasons to destinations indicated under CB Column 1 on the Commerce Country Chart (*i.e.*, all destinations, worldwide).

The changes described above are expected to have a minimal impact on U.S. industry, since the volume of exports and reexports of the select agents and toxins (controlled under new ECCN 1C360), associated genetic elements, recombinant nucleic acids, and recombinant organisms (controlled under ECCN 1C353) and the related

technology for these items (controlled under ECCN 1E001 or 1E351) is extremely limited.

B. Amendments to the EAR Clarifying Controls on Medical Products Containing Certain AG-Controlled Toxins

This rule amends ECCN 1C991 on the CCL to clarify the controls on medical products containing AG-controlled toxins other than ricin and saxitoxin. Specifically, this rule clarifies that the “medical products” controlled by ECCN 1C991 include pharmaceutical formulations, prepackaged for distribution as clinical or medical products, that have been approved by the U.S. Food and Drug Administration (FDA) for use as an “Investigational New Drug” (IND). Consistent with this definition, FDA-approved IND products containing any of the toxins in ECCN 1C351.d, except those controlled for Chemical Weapons Convention (CW) reasons under 1C351.d.5 or .d.6 (i.e., ricin and saxitoxin), are treated as “medical products” controlled under ECCN 1C991.c. or .d. This clarification is intended to eliminate any uncertainty concerning the control status of these IND products since the publication of the final rule that revised the definition of “medical products” in ECCN 1C991 on October 3, 2000 (65 FR 58911). Furthermore, this clarification is consistent with language in the AG exemption for clinical and medical products containing botulinum toxins and conotoxins, since the AG exemption applies when such products are designed for “testing,” as well as human administration, in the treatment of medical conditions. Such medical products, when exported for the legitimate medical treatment for which they are intended, pose no significant proliferation concerns.

This rule further clarifies the types of medical products controlled under ECCN 1C991 by revising the “Related Definitions” paragraph in the List of Items Controlled for that ECCN to indicate that ECCN 1C991 controls FDA-approved “clinical” or medical products, having the characteristics in 1C991.c or .d, that are: (1) designed for “testing,” as well as human administration, in the treatment of medical conditions, and (2) prepackaged for distribution as either “clinical” products or medical products. This clarification is intended to make the description of medical products, in the Related Definitions paragraph of ECCN 1C991, more consistent with the language of the AG exemption for clinical and medical products

containing botulinum toxins and conotoxins.

Medical products specified in 1C991.c generally may be exported or reexported without a license to all destinations, except embargoed destinations and countries indicated under AT Column 1 on the Commerce Country Chart (Supplement No. 1 to Part 738 of the EAR). Medical products specified in 1C991.d require a license for export or reexport to countries of concern for CB reasons (i.e., Country Group D:3), as set forth in Section 742.2(a)(3) of the EAR and as indicated under CB Column 3 on the Commerce Country Chart, and to countries indicated under AT Column 1 on the Commerce Country Chart. See Part 742 of the EAR for additional information on these AT license requirements. A license also may be required to export or reexport these items for reasons specified elsewhere in the EAR (e.g., the end-user/end-use license requirements described in Part 744 of the EAR and the embargoes and other special controls described in Part 746 of the EAR). Medical products intended for export or reexport in any configuration other than “prepackaged units applicable to the intended medical treatment” (e.g., bulk shipments), or intended for any end-uses other than medical treatment, are controlled under ECCN 1C351 or ECCN 1C360.

In addition to the export requirements described in the EAR, the export of an IND, as defined in FDA regulations set forth in 21 CFR 312.3, is subject to certain FDA requirements pursuant to 21 CFR 312.110. These FDA requirements are independent of the export requirements described in the EAR, and exporters must satisfy them in addition to any requirements specified in the EAR.

Finally, note that, in accordance with the policy set forth in the General Technology Note in Supplement No. 2 to Part 774 of the EAR (i.e., “‘technology’ ‘required’ for the ‘development,’ ‘production,’ or ‘use’ of a controlled product remains controlled even when applicable to a product controlled at a lower level”), technology for the “development” or “production” of items controlled under ECCN 1C351, 1C352, 1C353, 1C354, or 1C360, which is controlled under ECCN 1E001 and requires a license to all destinations, worldwide, continues to require a license to all destinations even if such technology is applicable to a product controlled at a lower level, such as a vaccine or immunotoxin controlled under ECCN 1C991 that requires a license only to embargoed destinations and countries of concern for chemical and biological weapons proliferation

reasons (Country Group D:3 in Supplement No. 1 to Part 740 of the EAR).

C. Reduction in the Scope of the Chemical and Biological Weapons Proliferation (CB) License Requirements Applicable to St. Kitts and Nevis

This rule removes the license requirements for exports and reexports to St. Kitts and Nevis of items that require a license for export or reexport only to countries of concern for CB reasons (i.e., ECCN 1C991.d items to countries listed in Country Group D:3 in Supplement No. 1 to Part 740 of the EAR). Specifically, this rule amends the Commerce Country Chart (Supplement No. 1 to Part 738 of the EAR) by removing the “X” that indicated a license requirement for St. Kitts and Nevis under CB Column 3. This change is being made because St. Kitts and Nevis is not listed in Country Group D:3. As a result of this change, there is now a one-to-one correspondence between the countries included in Country Group D:3 and the countries for which a license requirement is indicated under CB Column 3 of the Commerce Country Chart. This change also eliminates the discrepancy that existed, prior to the publication of this rule, with respect to the country scope of the CB license requirements described in Section 742.2(a)(3) of the EAR.

D. Revisions to the EAR Based on the Addition of New States Parties to the Chemical Weapons Convention (CWC)

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 Antigua and Barbuda, Bhutan, Cambodia, the Democratic Republic of the Congo, Djibouti, Grenada, Haiti, Honduras, Liberia, and Vanuatu, 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 seven 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 2, 2005, 70 FR 45273 (August 5, 2005), has continued the Export Administration Regulations in

effect under the International Emergency Economic Powers Act.

Expansion of Foreign Policy-Based Export Controls

This rule imposes new export controls for foreign policy reasons. As required by section 6 of the Export Administration Act of 1979, as amended (the Act), a report on the imposition of these controls was delivered to the Congress on June 1, 2006. Although the Act expired on August 20, 2001, Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as extended by the Notice of August 2, 2005, 70 FR 45273 (August 5, 2005), 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 July 12, 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 July 27, 2006. Any such items not actually exported or reexported before midnight, on July 27, 2006, 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 July 27, 2006. Beginning at midnight on July 27, 2006, 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 738

Administrative practice and procedure, Exports, Foreign trade.

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 738, 742, 745, and 774 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

PART 738—[AMENDED]

■ 1. The authority citation for 15 CFR part 738 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; 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 2, 2005, 70 FR 45273 (August 5, 2005).

■ 2. Supplement No. 1 to part 738 is amended by revising the entry for “St. Kitts and Nevis” to read as follows:

SUPPLEMENT NO. 1 TO PART 738—COMMERCE COUNTRY CHART

Countries	Chemical & biological weapons			Nuclear non-proliferation		National security		Missile tech	Regional stability		Firearms convention	Crime control			Anti-terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
St. Kitts and Nevis	X	X		X		X	X	X	X	X	X	X		X		

PART 742—[AMENDED]

■ 3. 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 2, 2005, 70 FR 45273 (August 5, 2005); Notice of October 25, 2005, 70 FR 62027 (October 27, 2005).

§ 742.2 [Amended]

■ 4. Section 742.2 is amended by revising the phrase “ECCNs 1C351, 1C352, 1C353 and 1C354” in paragraph (a)(1)(i) to read “ECCNs 1C351, 1C352, 1C353, 1C354 and 1C360”.

PART 745—[AMENDED]

■ 5. 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 25, 2005, 70 FR 62027 (October 27, 2005).

Supplement No. 2 to Part 745—[Amended]

■ 6. Supplement No. 2 to Part 745 is amended by revising the undesignated center heading “List of States Parties as of August 1, 2005” to read “List of States Parties as of March 25, 2006” and by adding, in alphabetical order, the countries “Antigua and Barbuda”, “Bhutan”, “Cambodia”, “Congo (Democratic Republic of the)”, “Djibouti”, “Grenada”, “Haiti”, “Honduras”, “Liberia”, and “Vanuatu”.

PART 774—[AMENDED]

■ 7. 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; 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 2, 2005, 70 FR 45273 (August 5, 2005).

Supplement No. 1 to Part 774—[Amended]

■ 8. 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;
 - 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).

Technical Note: Verotoxins (1C351.d.10) are Shiga-like ribosome inactivating proteins (also see ECCN 1C360.a.3.a).

■ 9. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, “Microorganisms” & “Toxins,” ECCN 1C352 is amended by revising the Related Controls paragraph in the List of Items Controlled to read as follows:

1C352 Animal pathogens, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: * * *
Related Controls: (1) All vaccines are excluded from the scope of this entry. See also 1C991. (2) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (for APHIS, see 7 CFR 331.3(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: * * *

Items: * * * * *

■ 10. 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 1C360.a.3, 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 1C360.a.3, 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.

■ 11. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, “Microorganisms” & “Toxins,” ECCN 1C354 is amended by revising the Related Controls paragraph in the List of Items Controlled to read as follows:

1C354 Plant pathogens, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Unit: * * *
Related Controls: (1) All vaccines are excluded from the scope of this entry. See ECCN 1C991. (2) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, maintains controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (see 7 CFR 331.3(c), 9 CFR 121.3(c), and 9 CFR 121.4(c)).

Related Definitions: * * *

Items: * * * * *

■ 12. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, “Microorganisms” & “Toxins,” a new ECCN 1C360 is added, immediately following ECCN 1C355, to read as follows:

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

License Requirements

Reason for Control: CB, AT

Controls	Country chart
CB applies to entire entry.	CB Column 1
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: (1) All vaccines and “immunotoxins” are excluded from the scope of this entry. Certain medical products and diagnostic and food testing kits, which contain biological toxins identified in paragraph (a)(3) of this entry, are excluded from the scope of this entry. Vaccines, “immunotoxins”, certain medical products, and diagnostic and food testing kits excluded from the scope of this entry are controlled under ECCN 1C991. (2) 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 and toxins, 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. Fungi, as follows:

a.2.a. *Coccidioides immitis*;

a.2.b. *Coccidioides posadasii*;

a.3. Toxins, as follows:

a.3.a. Shiga-like ribosome inactivating proteins not controlled under ECCN 1C351.d.10;

a.3.b. [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. Ehrlichia 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. citris 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.

■ 13. 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 (RCAII), also known as ricin D, or Ricinus Communis Lectin III (RCLIII);

(b) Ricinus Communis Lectin IV (RCLIV), 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 or 1C360.a.3;

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

d. Medical products containing any of the following items:

d.1. 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);

d.2. Items controlled by ECCN 1C360.a.3;

e. Diagnostic and food testing kits containing any of the following items:

e.1. Items controlled by ECCN 1C351.d (except items controlled for CW reasons under ECCN 1C351.d.5 or .d.6);

e.2. Items controlled by ECCN 1C360.a.3.

■ 14. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, “Microorganisms” & “Toxins,” ECCN 1E001 is amended by revising the License Requirements section of the ECCN to read as follows:

1E001 “Technology” according to the General Technology Note for the “development” or “production” of items controlled by 1A001.b, 1A001.c, 1A002, 1A003, 1A004, 1A005, 1A101, 1B, or 1C (except 1C355, 1C980 to 1C984, 1C988, 1C990, 1C991, 1C992, and 1C995).

License Requirements

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

Control(s)	Country chart
NS applies to “technology” for items controlled by 1A001.b and .c, 1A002, 1A003, 1A005, 1B001 to 1B003, 1B018, 1C001 to 1C011, or 1C018.	NS Column 1.
NS applies to “technology” for items controlled by 1A004 MT applies to “technology” for items MT Column 1 controlled by 1A101, 1B001, 1B101, 1B102, 1B115 to 1B119, 1C001, 1C007, 1C011, 1C101, 1C102, 1C107, 1C111, 1C116, 1C117, or 1C118 for MT reasons.	NS Column 2.
NP applies to “technology” for items controlled by 1A002, 1B001, 1B101, 1B201, 1B225 to 1B233, 1C002, 1C010, 1C116, 1C202, 1C210, 1C216, 1C225 to 1C240 for NP reasons.	NP Column 1.
CB applies to “technology” for items controlled by 1C351, 1C352, 1C353, 1C354, or 1C360	CB Column 1.
CB applies to “technology” for materials controlled by 1C350 and for chemical detection systems and dedicated detectors therefor, in 1A004.c, that also have the technical characteristics described in 2B351.a.	CB Column 2.
AT applies to entire entry	AT Column 1.

License Requirements Note: See § 743.1 of the EAR for reporting requirements for exports under License Exceptions.

* * * * *

■ 15. In Supplement No. 1 to Part 774 (the Commerce Control List), Category

1—Materials, Chemicals, “Microorganisms” & “Toxins,” ECCN 1E351 is amended by revising the ECCN heading and the License Requirements section of the ECCN to read as follows:

1E351 “Technology” according to the “General Technology Note” for the disposal

of chemicals or microbiological materials controlled by 1C350, 1C351, 1C352, 1C353, 1C354, or 1C360.

License Requirements

Reason for Control: CB, AT

Control(s)	Country chart
CB applies to "technology" for the disposal of items controlled by 1C351, 1C352, 1C353, 1C354, or 1C360	CB Column 1.
CB applies to "technology" for the disposal of items controlled by 1C350	CB Column 2.
AT applies to entire entry	AT Column 1.

* * * * *

Dated: June 5, 2006.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. E6-8995 Filed 6-9-06; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09-06-035]

RIN 1625-AA00

Safety Zone: Lake Michigan, Milwaukee, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of Implementation of final rule.

SUMMARY: The Coast Guard is implementing safety zones for annual fireworks displays in the Captain of the Port Sector Lake Michigan Zone during June 2006. This action is necessary to provide for the safety of life and property on navigable waters during these events. These safety zones will restrict vessel traffic from a portion of the Captain of the Port Sector Lake Michigan Zone.

DATES: Regulations at 33 CFR 165.909(a)(1) through (3) and (9) will be enforced from 12:01 a.m. on June 12, 2006 to 11:59 p.m. on June 30, 2006. All times given in this notice are local.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer Brad Hinken, Sector Lake Michigan, (414) 747-7154.

SUPPLEMENTARY INFORMATION: The Coast Guard is implementing the permanent safety zones in 33 CFR 165.909, for fireworks displays in the Captain of the Port Sector Lake Michigan Zone during June 2006. The following safety zones will be enforced during the times indicated below:

(1) *Pridefest Fireworks*, Milwaukee, WI. Location: All waters off of Henry W. Maier Festival Park Harbor Island, outer Milwaukee Harbor from the point of origin at 43[deg]02.209[deg] N, 087[deg]53.714[deg] W; southeast to 43[deg]02.117[deg] N, 087[deg]53.417[deg] W; then south to

43[deg]01.767[deg] N, 087[deg]53.417[deg] W; then southwest to 43[deg]01.555[deg] N, 087[deg]53.772[deg] W; then north following the shoreline back to the point of origin. All geographic coordinates are North American Datum of 1983 (NAD 83). The Harbor Island Lagoon Area is encompassed by this safety zone. This safety zone will be enforced from 9 p.m. to 10:30 p.m. on June 9, 2006.

(2) *Summerfest Fireworks*, Milwaukee, WI. Location: All waters off of Henry W. Maier Festival Park Harbor Island, outer Milwaukee Harbor encompassed by a line drawn from the point of origin at 43[deg]02.209[deg] N, 087[deg]53.714[deg] W; then southeast to 43[deg]02.117[deg] N, 087[deg]53.417[deg] W; then south to 43[deg]01.767[deg] N, 087[deg]53.417[deg] W; then southwest to 43[deg]01.555[deg] N, 087[deg]53.772[deg] W; then north following the shoreline back to the point of origin (NAD 83). The Harbor Island Lagoon Area is encompassed by this safety zone. This safety zone will be enforced from 10:00 p.m. to 11:30 p.m. on June 29, 2006 or, in the event of foul weather, during those same times on June 30, 2006.

(3) *Summerfest Hole-in-One Shoot/Stunt Shows*, Milwaukee, WI. Location: All waters of the Harbor Island Lagoon, outer Milwaukee Harbor from the point of origin at 43[deg]02.50[deg] N, 087[deg]53.78[deg] W then west to 43[deg]02.50[deg] N, 087[deg]53.85[deg] W; then following the shoreline of the Henry W. Maier Festival Park and Harbor Island back to the point of origin (NAD 83). This safety zone will be enforced from 12 p.m. to 12 a.m. on June 29, 2006 and June 30, 2006.

(4) *Riversplash Fireworks*, Milwaukee, WI. Location: All waters and adjacent shoreline of Pere Marquette Park, Milwaukee River encompassed by the arc of a circle with a 210-foot radius of the fireworks barge in approximate position 43[deg]02.33[deg] N, 087[deg]54.46[deg] W (NAD 83). (This safety zone will temporarily close down the Milwaukee River.) This safety zone will be enforced from 8:30 p.m. to 10:30 p.m. on June 2, 2006 and June 3, 2006.

In order to ensure the safety of spectators and transiting vessels, these safety zones will be enforced for the duration of the events. In the event that

these safety zones affect shipping, commercial vessels may request permission from the Captain of the Port, Sector Lake Michigan to transit through the safety zone. Requests must be made in advance and approved by the Captain of Port before transits will be authorized. The Captain of the Port may be contacted via U.S. Coast Guard Sector Lake Michigan on channel 16, VHF-FM. The Coast Guard will give notice to the public via a Broadcast to Mariners that the regulation is in effect.

Dated: June 1, 2006.

S.P. LaRochelle,

Captain, U.S. Coast Guard, Captain of the Port Sector Lake Michigan.

[FR Doc. E6-9131 Filed 6-9-06; 8:45 am]

BILLING CODE 4910-15-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R07-OAR-2006-0462; FRL-8181-8]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a revision to the Missouri State Implementation Plan (SIP). This approval pertains to revisions to the state's rule which restricts emissions from specific Missouri lead smelter-refinery installations. The effect of this approval is to remove duplication between two SIP-approved documents, and does not affect the stringency of the requirements.

DATES: This direct final rule will be effective August 11, 2006, without further notice, unless EPA receives adverse comment by July 12, 2006. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R07-OAR-2006-0462, by one of the following methods: