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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No. 120112039-2176-03]

RIN 0694-AF45

Implementation of the Understandings Reached at the 2011 Australia Group (AG) Plenary Meeting and Other AG-Related Clarifications to the EAR

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) publishes this final rule to amend the Export Administration Regulations (EAR) to implement the understandings reached at the June 2011 plenary meeting of the Australia Group (AG). This rule amends the Commerce Control List (CCL) entry in the EAR that controls human and zoonotic pathogens and "toxins"

and the entry that controls genetic elements and genetically modified organisms to reflect changes to the AG "List of Biological Agents for Export Control" that were made based on the understandings adopted at the June 2011 AG plenary meeting. In addition, this rule amends the CCL entries in the EAR that control chemical manufacturing facilities and equipment, and equipment capable of use in handling biological materials to reflect the June 2011 AG plenary changes to the "Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology and Software" and the "Control List of Dual-Use Biological Equipment and Related Technology and Software," respectively.

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

ADDRESSES: Send comments regarding this collection of information, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget (OMB), by e-mail to Jasmeet_K._Seehra@omb.eop.gov, or by fax to (202) 395-7285; and to the Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, 14th Street & Pennsylvania Avenue, N.W., Room 2705, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sangine, 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 June 2011 plenary meeting of the Australia Group (AG). The AG is a multilateral forum consisting of 40 participating countries that maintain export controls on a list of chemicals, biological agents, and related equipment and technology that could be used in a chemical or biological weapons program. The AG periodically reviews items on its control list to enhance the effectiveness of participating governments' national controls and to achieve greater harmonization among these controls.

The June 2011 AG plenary meeting adopted understandings that affected the AG "List of Biological Agents for Export Control," the AG "Control List of Dual-Use Chemical Manufacturing Facilities and Equipment and Related Technology and Software" and the AG "Control List of Dual-Use Biological Equipment and Related Technology and Software."

This rule amends Export Control Classification Numbers (ECCNs) 1C351 and 1C353 to reflect the AG changes to the "List of Biological Agents for Export Control." Specifically, ECCN 1C351 (Human and zoonotic pathogens and "toxins") is amended by removing and reserving paragraph .b (Rickettsiae), since these organisms are more appropriately identified as bacteria. Coxiella burnetii and Rickettsia prowasecki (a.k.a. Rickettsia prowazekii), which were

previously controlled under ECCN 1C351.b.2 and .b.3, respectively, are now controlled as bacteria under ECCN 1C351.c.10 and .c.13, respectively. Bartonella Quintana (Rochalimea Quintana, Rickettsia Quintana) and Rickettsia rickettsii, which were previously controlled under ECCN 1C351.b.1 and .b.4, respectively, are removed from ECCN 1C351, since they are no longer included on the AG "List of Biological Agents."

ECCN 1C353 (Genetic elements and genetically modified organisms) is amended by revising Technical Note 1 and adding a new Technical Note 4 to clarify that this ECCN controls certain de novo chemically synthesized genetic material and artificially-produced organisms. Specifically, Technical Note 1 to ECCN 1C353 is revised to indicate that "genetic elements" also include chromosomes, genomes, plasmids, transposons, and vectors that have been "chemically synthesized in whole or in part." New Technical Note 4 to ECCN 1C353 indicates that "genetically modified organisms" include "organisms in which the genetic material (nucleic acid sequences) has been altered in a way that does not occur naturally by mating and/or natural recombination, and encompasses those produced artificially in whole or in part."

This rule also amends ECCN 2B350 (Chemical manufacturing facilities and equipment) by adding a new Technical Note 3, at the end of the entry, to clarify that materials used for gaskets, packing, seals, screws or washers, or other materials performing a sealing function, do not determine the control status of the items listed in ECCN 2B350, provided that such components are designed to be interchangeable.

In addition, this rule amends ECCN 2B352 (Equipment capable of use in handling biological materials) by revising the introductory text of paragraph .d.1 to remove the phrase "without propagation of aerosols." Participating countries at the 2011 AG plenary agreed that this phrase was redundant, as it applied to cross (tangential) flow filtration equipment capable of separation of pathogenic microorganisms, viruses, toxins or cell cultures.

Finally, this rule amends ECCNs 2B350 and 2B352 to clarify certain control parameters for pumps (i.e., multiple-seal and seal-less pumps and vacuum pumps) and steam sterilizable freeze-drying (lyophilization) equipment, respectively. Specifically, ECCN 2B350.i is amended by adding two parenthetical phrases in the introductory text to specify the maximum flow-rate of such pumps in liters of water per hour, as follows: "multiple-seal and seal-less pumps with manufacturer's specified maximum flow-rate greater than 0.6 m^3 /hour (600 liters/hour), or vacuum pumps with manufacturer's specified maximum flow-rate greater than 5 m^3 /hour (5000 liters/hour)." ECCN 2B352.e is amended by adding two parenthetical phrases that specify the condenser capacity of such equipment in liters of water per 24 hours, as follows: "10 kgs of ice or greater in 24 hours (10 liters of water or greater in 24 hours), but less than 1,000 kgs of ice in 24 hours (less than 1,000 liters of water in 24 hours)." These changes are being made by BIS in order to indicate these AG control parameters in units of measure that are more commonly used in the United States.

None of the changes made by this rule increase the scope of the controls in ECCNs 1C351, 1C353, 2B350 and 2B352. Except for the removal of Bartonella Quintana and Rickettsia

rickettsii from ECCN 1C351, the items that are controlled under these ECCNs remain the same.

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 12, 2011, 76 FR 50661 (August 16, 2011), has continued the EAR in effect under the International Emergency Economic Powers Act.

Rulemaking Requirements

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

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) (PRA), unless that collection of information displays a currently valid Office of

Management and Budget (OMB) Control Number. This rule contains a collection of information subject to the requirements of the PRA. This collection has been approved by OMB under Control Number 0694-0088 (Multi-Purpose Application), which carries a burden hour estimate of 58 minutes to prepare and submit form BIS-748. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet Seehra, Office of Management and Budget (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 (See 5 U.S.C. 553(a)(1)). Immediate implementation of these amendments is non-discretionary and fulfills the United States' international obligation to the Australia Group (AG). The AG contributes to international security and regional stability through the harmonization of export controls and seeks to ensure that exports do not contribute to the development of chemical and biological weapons. The AG consists of 40 member countries that act on a consensus basis and the amendments set forth in this rule implement the understandings reached at the June 2011 AG plenary meeting and other changes that are necessary to ensure

consistency with the controls maintained by the AG. Since the United States is a significant exporter of the items in this rule, immediate implementation of this provision is necessary for the AG to achieve its purpose. Any delay in implementation will create a disruption in the movement of affected items globally because of disharmony between export control measures implemented by AG members, resulting in tension between member countries. Export controls work best when all countries implement the same export controls in a timely and coordinated manner.

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

List of Subjects in 15 CFR Part 774

Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, Part 774 of the Export Administration Regulations (15 CFR Parts 730-774) is amended as follows:

PART 774 - [AMENDED]

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

Authority: 50 U.S.C. app. 2401 *et seq*.; 50 U.S.C. 1701 *et seq*.; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq*., 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq*.; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2011, 76 FR 50661 (August 16, 2011).

2. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, ECCN 1C351 is amended under the "Items" paragraph in the List of Items Controlled section by removing and reserving paragraph b. and by revising paragraph c. to read as follows:

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

* * * * *

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

* * * * *

List of Items Controlled

* * * * *

Items:

* * * * *

b. [Reserved]

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. Chlamydophila psittaci (formerly known as Chlamydia psittaci);

c.8. Clostridium botulinum;

c.9. Clostridium perfringens, epsilon toxin producing types;

c.10. Coxiella burnetii;

c.11. Enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing serotypes;

c.12. Francisella tularensis;

c.13. Rickettsia prowasecki (a.k.a. Rickettsia prowazekii);

c.14. Salmonella typhi;

c.15. Shigella dysenteriae;

c.16. Vibrio cholerae; or

c.17. Yersinia pestis.

* * * * *

3. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1, ECCN 1C353 is amended under the "Items" paragraph in the List of Items Controlled section by revising Technical Note 1 and by adding a new Technical Note 4 in numerical order, to read as follows:

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

* * * * *

List of Items Controlled

* * * * *

Items:

* * * * *

Technical Notes: 1. "Genetic elements" include, inter alia, chromosomes, genomes,

plasmids, transposons, and vectors, whether genetically modified or unmodified, or chemically synthesized in whole or in part.

* * * * *

4. "Genetically modified organisms" include organisms in which the genetic material (nucleic acid sequences) has been altered in a way that does not occur naturally by mating and/or natural recombination, and encompasses those produced artificially in whole or in part.

4. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2, ECCN 2B350 is amended under the "*Items*" paragraph in the List of Items Controlled section by revising the introductory text of paragraph i. and by adding a new "Technical Note 3," in numerical order, 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

* * * * *

Items:

* * * * *

i. Multiple-seal and seal-less pumps with manufacturer's specified maximum flow-rate greater than 0.6 m^3 /hour (600 liters/hour), or vacuum pumps with manufacturer's specified maximum flow-rate greater than 5 m^3 /hour (5000 liters/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 following materials:

* * * * *

Technical Note 3: The materials used for gaskets, packing, seals, screws or washers, or other materials performing a sealing function, do not determine the control status of the items in this ECCN, provided that such components are designed to be interchangeable.

5. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2, ECCN 2B352 is amended under the "*Items*" paragraph in the List of Items Controlled section by revising the introductory text of paragraph d.1 and by revising paragraph e to read as follows:

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

* * * * *

List of Items Controlled

* * * * *

Items:

* * * * *

d. * * *

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

* * * * *

e. Steam sterilizable freeze-drying (lyophilization) equipment with a condenser capacity of 10 kgs of ice or greater in 24 hours (10 liters of water or greater in 24 hours), but less than 1,000 kgs of ice in 24 hours (less than 1,000 liters of water in 24 hours).

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DATED: June 22, 2012

Kevin J. Wolf

Assistant Secretary

for Export Administration

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