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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 742, 745, and 774

[Docket No. 030523133-3133-01]

RIN 0694-AC70

Implementation of the Understandings Reached at the June 2002 Australia Group (AG) Plenary Meeting and the AG Intersessional Decision on Cross Flow Filtration Equipment—Chemical and Biological Weapons Controls in the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is publishing this final rule to describe the understandings reached at the June 2002 plenary meeting of the Australia Group (AG) and to amend the Export Administration Regulations (EAR), as needed, to implement these AG understandings. This final rule amends the licensing policy provisions in the EAR that apply to exports and reexports of items on the AG control list by clarifying several factors that are among those used to evaluate license applications for these AG-listed items and by identifying additional factors not previously listed in the EAR. In addition, this rule clarifies the circumstances under which BIS would deny license applications to export or reexport these AG-listed items. All of these changes are intended to ensure that the EAR provisions that apply to AG-listed items are consistent with the "Guidelines for Transfers of Sensitive Chemical or Biological Items," which were adopted at the June 2002 AG plenary meeting.

This rule also implements understandings reached at the June 2002 plenary meeting concerning AG controls on fermenters and toxins. The control threshold for AG-listed fermenters described on the Commerce Control List (CCL) is lowered from a capacity of 100 liters or greater to a capacity of 20 liters or greater. In addition, this rule adds eight new toxins to the list of AG-listed human and zoonotic pathogens and toxins described on the CCL.

In addition to the AG plenary meeting changes described above, this rule implements an AG intersessional decision concerning cross (tangential) flow filtration equipment.

The rule makes corrections in four CCL entries that contain AG-listed items. One entry, containing AG-listed genetic elements and genetically modified organisms, is amended to correct errors in the use of the terms "organism" and "microorganism." Another entry, containing AG-listed chemical manufacturing facilities and equipment, is amended to clarify the scope of that entry's controls on certain valves containing nickel and nickel alloys and on agitators for use in reaction vessels or reactors. Two other CCL entries are amended to clarify the license requirements that apply to technology for the "development" or "production" of AG-listed valves containing nickel and nickel alloys. In addition, the rule amends the AG-based licensing provisions in the EAR to identify certain CCL entries that were inadvertently omitted when BIS amended these provisions on previous occasions.

Finally, this rule updates the list of countries that are currently States Parties to the Chemical Weapons Convention (CWC) by adding six countries that recently became States Parties: Andorra, Guatemala, Palau, Saint Vincent and the Grenadines, Samoa, and Thailand.

DATES: This rule is effective June 10, 2003.

ADDRESSES: Written comments should be sent to Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, Room 2705, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Douglas Brown, Office of Chemical and Biological Controls and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482-7900.

SUPPLEMENTARY INFORMATION:

Background

A. Revisions to the EAR Based on the June 2002 Plenary Meeting of the Australia Group

The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) to implement understandings reached at the annual plenary meeting of the Australia Group (AG) that was held in Paris on June 3-6, 2002. The Australia Group is a multilateral forum, consisting of 33 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.

This rule implements two understandings reached at the June 2002 plenary meeting concerning AG controls on fermenters and toxins. The control threshold for AG-listed fermenters, described in ECCN 2B352.b on the Commerce Control List (CCL), is lowered from a capacity (*i.e.*, volume) of 100 liters or greater to a capacity of 20 liters or greater. In addition, this rule adds the following eight toxins to the list of AG-listed toxins described in ECCN 1C351.d on the CCL: (1) abrin, (2) cholera toxin, (3) diacetoxyscirpenol toxin, (4) T-2 toxin, (5) HT-2 toxin, (6) modeccin toxin, (7) volkensin toxin, and (8) viscum album lectin 1 (viscumin). These AG-listed toxins, along with all other items controlled by ECCN 1C351, require a license for export or reexport to all destinations, worldwide.

This rule makes conforming changes to the List of Items Controlled in ECCN 1C991 by revising ECCN 1C991.d to include medical products containing any of the eight toxins that were added to ECCN 1C351.d by this rule. In addition, this rule revises the Related Definitions paragraph in the List of Items Controlled by ECCN 1C991 by adding the AG definition of "vaccine," which was adopted at the June 2002 AG plenary meeting. For the purpose of ECCN 1C991, "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. ECCN 1C991.a is revised to conform with the AG definition of "vaccine" by clarifying the control language to indicate that 1C991.a controls vaccines against items controlled by ECCN 1C351, 1C352, 1C353, or 1C354.

This final rule also amends the EAR to ensure that the licensing policy provisions in the EAR that apply to AG-listed items are consistent with the "Guidelines for Transfers of Sensitive Chemical or Biological Items," which were adopted by the AG at the June 2002 plenary meeting. Specifically, this rule amends section 742.2(b)(2) of the EAR by clarifying several factors that are among those used to evaluate license applications to export or reexport these AG-listed items and by identifying