

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 71****[Airspace Docket No. 01-AWP-18]****Establishment of Class E Airspace; Calipatria, CA****AGENCY:** Federal Aviation Administration (FAA), DOT.**ACTION:** Final rule.

**SUMMARY:** This action establishes a Class E airspace area at Calipatria, CA. The establishment of a Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) RNAV (GPS) Runway (RWY) 08 SIAP to Cliff Hatfield Memorial Airport, Calipatria, CA has made action necessary. Additional controlled airspace extending upward from 700 feet or more above the surface of the earth is needed to contain aircraft executing the RNAV (GPS) RWY 08 SIAP to Cliff Hatfield Memorial Airport. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules operations at Cliff Hatfield Memorial Airport, Calipatria, CA.

**EFFECTIVE DATE:** 0901 UTC June 13, 2002.

**FOR FURTHER INFORMATION CONTACT:** Jeri Carson, Airspace Specialist, Airspace Branch, AWP-520, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725-6611.

**SUPPLEMENTARY INFORMATION:****History**

On April 29, 2002, the FAA proposed to amend 14 CFR part 71 establishing a Class E airspace area at Calipatria, CA (67 FR 20921). Additional controlled airspace extending upward from 700 feet or more above the surface is needed to contain aircraft executing the RNAV (GPS) RWY 08 SIAP to Cliff Hatfield Memorial Airport. This action will provide adequate controlled airspace for aircraft executing the RNAV (GPS) RWY 08 SIAP to Cliff Hatfield Memorial Airport, Calipatria, CA.

Interested parties were invited to participate in this rulemaking, proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. Class E airspace designations for airspace extending from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA

Order 7400.9J, dated August 31, 2001, and effective September 16, 2001, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

**The Rule**

This amendment to 14 CFR part 71 establishes a Class E airspace area at Calipatria, CA. The establishment of a RNAV (GPS) RWY 08 SIAP to Cliff Hatfield Memorial Airport has made this action necessary. The effect of this action will provide adequate airspace for aircraft executing the RNAV (GPS) RWY 08 SIAP to Cliff Hatfield Memorial Airport, Calipatria, CA.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**Adoption of the Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

**PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS**

1. The authority citation for 14 CFR part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

**§ 71.1 [Amended]**

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9J, Airspace Designations and Reporting Points, dated August 31, 2001, and effective September 16, 2001, is amended as follows:

*Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.*

\* \* \* \* \*

**AWP CA E5 Calipatria, CA [New]**

Cliff Hatfield Memorial Airport, CA  
(Lat 33°07'47" N, long. 115°31'18" W)

Brawley Municipal Airport, CA  
(Lat. 32°59'35" N., long. 115°31'01" W)

That airspace extending upward from 700 feet above the surface within a 6.3 mile radius of the Cliff Hatfield Memorial Airport; excluding that portion within the Brawley Municipal Airport, CA, Class E airspace area.

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Issued in Los Angeles, California, on May 14, 2002.

**Dawna J. Vicars,**

*Assistant Manager, Air Traffic Division  
Western-Pacific Region.*

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**BILLING CODE 4910-13-M****DEPARTMENT OF COMMERCE****Bureau of Industry and Security****15 CFR Parts 736, 738, 740, 742, 745, and 774****[Docket No. 020509118-2118-01]****RIN 0694-AC62**

**Revisions and Clarifications to the  
Export Administration Regulations—  
Chemical and Biological Weapons  
Controls: Australia Group; Chemical  
Weapons Convention**

**AGENCY:** Bureau of Industry and Security, Commerce.**ACTION:** Final rule.

**SUMMARY:** The Bureau of Industry and Security (BIS), formerly the Bureau of Export Administration (BXA), is amending the Export Administration Regulations (EAR) to implement the understandings reached at the October 2001 plenary meeting of the Australia Group (AG). This final rule amends the Commerce Control List (CCL) and the corresponding export licensing provisions in the EAR to: authorize exports and reexports without a license, to most destinations, of medical, analytical, diagnostic, and food testing kits containing small quantities of any chemicals controlled only by the AG (*i.e.*, not also listed on any Schedule to the Chemical Weapons Convention (CWC)), provided that the testing kits meet certain criteria specified in the EAR; clarify the scope of the AG controls that apply to certain genetic elements and genetically modified organisms; establish controls on exports and reexports of critical components of

certain AG-controlled chemical manufacturing equipment, in which all surfaces that come into direct contact with the chemical(s) being processed or contained are made from specified materials; and add Bulgaria to Country Group A:3 (AG participating countries).

This rule also implements three AG intersessional decisions that affect AG controls on valves, freeze-drying equipment, and protective and containment equipment (including protective suits). This rule revises AG controls on valves to include all valves with nominal sizes greater than 1.0 cm in which all surfaces that come into direct contact with the chemical(s) being processed or contained are made from specified materials. The rule revises AG controls on freeze-drying equipment by changing the control threshold for such equipment from a minimum condenser capacity of "greater than 50 kgs of ice in 24 hours" to a minimum condenser capacity of "10 kgs of ice or greater in 24 hours." The rule revises AG controls on protective suits to apply to hoods, as well as protective full and half suits, that are dependant upon a tethered external air supply and operate under positive pressure. Suits designed to be worn with self-contained breathing apparatus are excluded from control. Furthermore, the rule clarifies the AG controls that apply to Class III biological safety cabinets and isolators with similar characteristics by including several examples of the types of equipment subject to these controls.

In addition to making the 2001 AG plenary and intersessional changes described above, this rule creates a new entry and restructures several entries on the CCL in order to clarify which mixtures are controlled for CB (chemical/biological: AG-based) or CW (chemical weapons: CWC-based) reasons. The restructuring does not alter the scope of the controls that apply to these mixtures.

This rule also harmonizes AT (anti-terrorism) controls among a number of entries on the CCL that describe chemicals controlled for CB or CW reasons and mixtures that contain these chemicals. Specifically, this rule expands AT controls to apply to all chemicals previously controlled for CW reasons only and to all mixtures that contain these chemicals. This rule further harmonizes the application of AT controls by requiring a license, for AT reasons, to export or reexport mixtures containing chemicals controlled for CB or CW reasons to all of the designated terrorist supporting countries.

In addition, this rule imposes a license requirement for exports to Canada of human pathogens and toxins, animal and plant pathogens, and genetically modified organisms that are controlled for CB reasons. This change harmonizes export controls on biological agents and related technology by requiring a license to export such items to all destinations, worldwide.

Finally, this rule makes two changes related to the CWC requirements in the EAR. First, the rule updates the list of countries that are currently States Parties to the CWC by adding the following countries: Nauru and Uganda. Second, the rule clarifies that a license is required to reexport CWC Schedule 3 chemicals and mixtures controlled on the CCL for CW reasons from a State not Party to the CWC to any other State not Party to the CWC and that applications for such reexports generally will be denied.

**DATES:** This rule is effective May 31, 2002.

**FOR FURTHER INFORMATION CONTACT:** James Seevaratnam, Office of Chemical and Biological Controls and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 501-7900.

**SUPPLEMENTARY INFORMATION:**

**Background**

*A. Revisions to the EAR Based on the October 2001 Plenary Meeting of the Australia Group*

The Bureau of Industry and Security (BIS), formerly the Bureau of Export Administration (BXA), is amending the Export Administration Regulations (EAR) to implement understandings reached at the annual plenary meeting of the Australia Group (AG) chemical and biological weapons nonproliferation control regime that was held in Paris on October 1-4, 2001. 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 final rule amends the EAR to implement an understanding on test kits that was reached at the October 2001 AG plenary meeting. Specifically, this rule authorizes exports without a license, to most destinations, of medical, analytical, diagnostic, and food testing kits containing small quantities

of any chemicals controlled only by the AG, provided that the kits: (1) Are pre-packaged materials of defined composition, (2) are specifically developed, packaged, and marketed for diagnostic, analytical, or public health purposes, and (3) contain no more than 300 grams of any single AG-controlled chemical. In addition, an export license for such test kits continues to be required, to certain destinations and entities, for anti-terrorism (AT) reasons or for other reasons specified in the EAR (e.g., embargoes).

The following license requirements apply to such test kits. Test kits that contain CWC Schedule 1 chemicals continue to be controlled under ECCN 1C350 (note that this rule restructures 1C350.a to control certain Schedule 1 chemicals that are subject to the EAR). These test kits require a license for all destinations, including Canada, for CW reasons, and also require a license to certain destinations for chemical/biological (CB) and anti-terrorism (AT) reasons. Test kits that contain CWC Schedule 2 or 3 chemicals listed in restructured 1C350.b or .c, respectively, are now controlled under new ECCN 1C395 and continue to require a license to States not Party to the CWC, for CB and CW reasons, and to designated terrorist supporting countries (*i.e.*, Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria), for AT reasons. Test kits that contain precursor chemicals listed in restructured 1C350.d, which are not subject to the CW controls described in that ECCN, are controlled under ECCN 1C995 for AT reasons only. This rule also amends Section 742.2 of the EAR by revising the license requirements to reflect the AG understanding on test kits described above.

Participants at the October 2001 AG plenary meeting also reached an understanding to control exports and reexports of critical components of certain AG-controlled chemical manufacturing equipment listed in ECCN 2B350. Specifically, this rule revises ECCN 2B350 to control the following components: (1) Impellers, blades or shafts designed for agitators controlled by 2B350.b; (2) tubes, plates, coils or blocks (cores) designed for heat exchangers or condensers controlled by 2B350.d; (3) liquid distributors, vapor distributors or liquid collectors designed for distillation or absorption columns controlled by 2B350.e; (4) casings (valve bodies) or preformed casing liners designed for valves controlled by 2B350.g; and (5) casing (pump bodies), preformed casing liners, impellers, rotors or jet pump nozzles designed for pumps controlled by 2B350.i.

The October 2001 AG plenary meeting also resulted in an understanding concerning the scope of controls on the genetic elements and genetically modified organisms controlled by ECCN 1C353. This rule adds a technical note to ECCN 1C353 to indicate that "genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified."

Finally, this rule amends the EAR to add Bulgaria as the newest participating country in the Australia Group (which now includes a total of 33 countries). Supplement No. 1 to Part 740 (Country Groups) is revised to add Bulgaria to Country Group A:3 (Australia Group) and Supplement No. 1 to Part 738 (Commerce Country Chart) is revised to remove the licensing requirements for Bulgaria under CB Columns 2 and 3 in conformance with the licensing policy that applies to other AG participating countries.

#### *B. Revisions to the EAR Based on Intersessional Decisions by the Australia Group*

BIS is amending the EAR to implement three intersessional decisions by the AG, made subsequent to the October 2001 plenary meeting, that affect AG controls on valves, freeze-drying equipment, and protective and containment equipment. This rule revises AG controls on valves by amending ECCN 2B350 to control valves with nominal sizes greater than 1.0 cm in which all surfaces that come into direct contact with the chemical(s) being processed or contained are made from specified materials. The change more clearly defines valves that would pose a concern for proliferation reasons.

This rule also revises AG controls on freeze-drying equipment controlled by ECCN 2B352 by changing the control threshold for such equipment from a minimum condenser capacity of "greater than 50 kgs of ice in 24 hours" to a minimum condenser of "10 kgs of ice or greater in 24 hours." As a result of this change, 2B352.e now controls steam sterilizable freeze-drying equipment that has a condenser capacity of 10 kgs of ice or greater, but less than 1,000 kgs of ice, in 24 hours.

In addition, this rule revises AG controls on the protective suits controlled by ECCN 2B352 to apply to hoods, as well as protective full and half suits, that are dependant upon a tethered external air supply and operate under positive pressure. A technical note is added to 2B352.f.1 to exclude from control those suits that are designed to be worn with self-contained breathing apparatus. In addition, this

rule clarifies the controls that apply to Class III biological safety cabinets and isolators with similar characteristics by adding, in ECCN 2B352.f.2, several examples of the types of equipment subject to these controls (e.g., flexible isolators, dry boxes, anaerobic chambers, glove boxes or laminar flow hoods (closed with vertical flow)).

#### *C. Restructuring of AG and CWC-Related Entries on the Commerce Control List (CCL)*

In addition to implementing the 2001 AG plenary and intersessional changes described above, BIS is amending the EAR by restructuring several entries on the CCL in order to clarify which chemicals and mixtures are controlled for CB (chemical/biological: AG-based) or CW (chemical weapons: CWC-based) reasons. This restructuring does not, by itself, alter the scope of the controls that apply to these chemicals and mixtures. Specifically, this rule amends ECCN 1C350 to reorganize the List of Items Controlled into four categories: (1) 1C350.a, which lists certain AG-controlled chemicals also identified on CWC Schedule 1 and controlled for CB, CW, and AT (anti-terrorism) reasons; (2) 1C350.b, which lists certain AG-controlled chemicals also identified on CWC Schedule 2 and controlled for CB, CW, and AT reasons; (3) 1C350.c, which lists certain AG-controlled chemicals also identified on CWC Schedule 3 and controlled for CB, CW, and AT reasons; and (4) 1C350.d, which lists AG-controlled chemicals controlled for CB and AT reasons only. This rule also amends ECCN 1C350 and ECCN 1C355 to place the description of the mixtures controlled by each entry in the List of Items Controlled for that entry. As part of this change, the mixtures notes for these two ECCNs have been revised to simplify the language describing the license requirements that apply to mixtures containing chemicals controlled by these ECCNs.

This rule also restructures ECCN 1C995 and adds a new ECCN 1C395 to provide greater clarity concerning the license requirements that apply to certain mixtures and test kits containing chemicals controlled by ECCN 1C350. Specifically, ECCN 1C995 is revised to control mixtures and test kits that require a license for AT reasons only. As a result of this change ECCN 1C995 now controls all mixtures that contain AG-controlled chemicals (i.e., chemicals controlled by ECCN 1C350) in concentrations less than the control thresholds specified for mixtures identified in ECCN 1C350, except for those mixtures that contain greater than 10 percent, but less than 30 percent, by

weight of any single AG-controlled chemical also identified under Schedule 2 of the CWC. The latter are controlled under new ECCN 1C395, because they require a license, for CB and CW reasons, for export to States not Party to the CWC. ECCN 1C995 continues to control the following mixtures for AT reasons only: (1) Mixtures that contain 10 percent or less, by weight, of any single AG-controlled chemical also identified under Schedule 2 of the CWC, (2) mixtures that contain less than 30 percent by weight of any single AG-controlled chemical also identified under Schedule 3 of the CWC, and (3) mixtures that contain less than 30 percent by weight of any single AG-controlled chemical not also identified under any schedule of the CWC (i.e., AG-controlled chemicals in ECCN 1C350 not also controlled for CW reasons). As noted below (see harmonization of AT controls), ECCN 1C995 is revised by this rule to also control, for AT reasons, mixtures not controlled by ECCN 1C355 that contain chemicals controlled by that ECCN. In addition, ECCN 1C995 controls test kits that contain precursor chemicals listed in 1C350.d, which are not subject to CW controls.

New ECCN 1C395 controls test kits excluded from control under ECCN 1C350.b and .c by License Requirement Note 4 of that ECCN (i.e., test kits containing CWC Schedule 2 or 3 chemicals). These test kits are included in new ECCN 1C395, instead of ECCN 1C995, because they are controlled for CB and CW reasons to States not Party to the CWC. ECCN 1C395 also controls mixtures containing greater than 10 percent, but less than 30 percent, by weight of any single AG-controlled chemical also identified under Schedule 2 of the CWC. These mixtures are controlled under ECCN 1C395 for CB and CW reasons. All items controlled by new ECCN 1C395 require a license, for AT reasons, to designated terrorist supporting countries (i.e., Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria).

This rule amends General Prohibition Seven (Section 736.2(b)(7) of the EAR) and the AG and CWC licensing requirements and policies in Sections 742.2 and 742.18 of the EAR to include references to new ECCN 1C395. The rule also amends the CWC licensing requirements and policies in Section 742.18 of the EAR to include references to mixtures controlled by ECCN 1C350, ECCN 1C355, or new ECCN 1C395.

*D. Harmonization of Anti-Terrorism (AT) Controls in the AG and CWC-Related Entries on the Commerce Control List (CCL)*

BIS is also amending several AG and CWC-related entries on the CCL to harmonize the application of anti-terrorism (AT) controls among these entries. Specifically, this rule revises ECCN 1C355 to require a license, for AT reasons, to export or reexport any of the chemicals or mixtures controlled by this ECCN to all of the designated terrorist supporting countries (*i.e.*, Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria). Prior to the publication of this rule, the chemicals and mixtures listed in ECCN 1C355 required a license for CW reasons only. This action will have no impact on exports to Cuba, Iran, Iraq, Libya, and Sudan, which are subject to comprehensive trade sanctions, or on exports to Syria and North Korea, which continue to be subject to CW controls.

In addition, this rule revises ECCN 1C995 to harmonize the application of AT controls among ECCNs containing chemicals and chemical mixtures by requiring a license to export or reexport any mixture controlled by ECCN 1C995 to all of the designated terrorist supporting countries. Prior to the publication of this rule, mixtures controlled by ECCN 1C995 that contained chemicals controlled by ECCN 1C350 required a license, for AT reasons, only to Cuba, Libya, North Korea, and Iran. In practice, this action will have no impact on exports to Sudan and Iraq, which are subject to comprehensive trade sanctions, but it may have a slight impact on exports of these mixtures to Syria.

This rule also revises ECCN 1C995 to control, for AT reasons, mixtures not controlled by ECCN 1C355 that contain chemicals controlled by 1C355. Prior to the publication of this rule, these mixtures were classified as EAR99 and generally could be exported to most destinations, except embargoed destinations and entities (*i.e.*, Cuba, Iran, Iraq, Libya, and Sudan), without prior U.S. Government authorization. In practice, this action will have no impact on exports to Cuba, Iran, Iraq, Libya, and Sudan, which are subject to comprehensive trade sanctions, but it may have a slight impact on exports of these mixtures to Syria and North Korea.

In addition, this rule expands AT controls on test kits that were previously controlled under ECCN 1C995, but which are now controlled under ECCN 1C395 (*i.e.*, test kits containing AG-controlled chemicals also identified on CWC Schedule 2 or

3), by requiring a license, for AT reasons, to export these test kits to Iraq. This rule also expands AT controls, to include Iraq, for certain test kits that were previously controlled under ECCN 1C350, but which are now controlled under ECCN 1C995.c (*i.e.*, test kits containing AG-controlled chemicals that are not also controlled for CW reasons). Previously, exports of these test kits required a license, for AT reasons, only to Cuba, Iran, Libya, North Korea, Sudan, and Syria. This action will have no impact on exports of these test kits to Iraq, since that country is subject to comprehensive trade sanctions and a license also continues to be required, for CB and CW reasons, to export these test kits to Iraq.

Finally, this rule revises ECCN 1C350 to expand AT controls to include Iraq. Previously, items controlled by ECCN 1C350 were controlled for AT reasons to all designated terrorist-supporting countries, except Iraq (*i.e.*, Cuba, Iran, Libya, North Korea, Sudan, and Syria).

*E. Establishment of Worldwide Export Controls on Certain Australia Group-Controlled Biological Items*

This rule also imposes a license requirement for exports to Canada of human pathogens and toxins, animal and plant pathogens, and genetically modified organisms that are controlled for CB reasons under ECCNs 1C351, 1C352, 1C353, and 1C354 and related technology controlled for CB reasons under ECCNs 1E001 and 1E351. Specifically, this rule amends the Commerce Country Chart (Supplement No. 1 to part 738 of the EAR) by inserting an "X" for Canada under CB Column 1. Prior to the publication of this rule, these items required a license to all destinations, except Canada. As a result of this action, these pathogens, toxins, and microorganisms require a license for export to all destinations, including Canada. This change harmonizes export controls on biological agents and related technology by requiring a license to export such items, worldwide.

*F. Clarification of Controls on Mixtures That Contain Trace Amounts of Controlled Chemicals*

This rule clarifies the control status of certain mixtures that contain only trace amounts of controlled chemicals. First, License Requirements Note 2 in ECCN 1C350 is revised to clarify that this entry does not control mixtures containing less than 0.5% aggregate quantities, by weight, of the CWC Schedule 1 chemicals controlled by 1C350.a as unavoidable by-products or impurities. Such mixtures are classified as EAR99,

instead. However, all other mixtures containing these Schedule 1 chemicals are controlled by ECCN 1C350.a. Second, a new License Requirements Note is added in ECCN 1C995 to clarify that this ECCN does not control mixtures containing less than 0.5% of any single AG-controlled chemical listed in ECCN 1C350 (except those also identified as CWC Schedule 1 chemicals) or any single CW-controlled chemical listed in ECCN 1C355 as unavoidable by-products or impurities. Such mixtures are classified as EAR99, instead.

*G. Addition of New States Parties to the Chemical Weapons Convention (CWC) and Clarification of EAR Licensing Policy for Reexports of CWC Schedule 3 Chemicals*

This rule makes two changes related to the CWC requirements in the EAR. First, the rule revises Supplement No. 2 to Part 745 (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 names of countries that have recently become States Parties to the CWC (*i.e.*, Nauru and Uganda). Second, the rule clarifies (in Section 742.18 of the EAR and in the License Requirements sections of ECCNs 1C350, 1C355, and 1C395) that a license is required, for CW reasons, to reexport CWC Schedule 3 chemicals and mixtures identified in these ECCNs from a State not Party to the CWC (a destination not listed in Supplement No. 2 to part 745 of the EAR) to any other State not Party to the CWC and that applications for such reexports generally will be denied.

The Department of Commerce is taking these measures having consulted with the Department of State. The harmonization and expansion of AT controls on chemicals and chemical mixtures and the revised CB controls are described in a report to the Congress, dated May 30, 2002.

**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, unless that collection of information displays a currently valid OMB Control Number. This rule contains collections of information subject to the requirements of the Paperwork Reduction Act of 1980 (44



**PART 740—[AMENDED]**

revising the entry for “Bulgaria” to read as follows:

9. In Supplement No. 1 to Part 740, Country Group A is amended by

**Supplement No. 1 to Part 740**

Country Group A

Country	[A:1]	Missile technology control regime	Australia group	Nuclear suppliers group
		[A:2]	[A:3]	[A:4]
Bulgaria	*	*	X	X

**PART 742—[AMENDED]**

10. Section 742.2 is amended by revising paragraphs (a)(1) introductory text, (a)(2)(i)(A), and (a)(2)(i)(C), and by adding a new paragraph (a)(4) to read as follows:

**§ 742.2 Proliferation of chemical and biological weapons.**

(a) \* \* \*

(1) If CB Column 1 of the Country Chart (Supplement No. 1 to part 738 of the EAR) is indicated in the appropriate ECCN, a license is required to all destinations, including Canada, for the following:

\* \* \* \* \*

(2) \* \* \*

(i) \* \* \*

(A) This licensing requirement identifies chemical mixtures identified in ECCN 1C350.a, .b, .c, or .d, except as specified in License Requirements Note 2 to that ECCN.

\* \* \* \* \*

(C) This licensing requirement does not apply to any of the following medical, analytical, diagnostic, and food testing kits that consist of pre-packaged materials of defined composition that are specifically developed, packaged, and marketed for diagnostic, analytical, or public health purposes:

(1) Test kits containing no more than 300 grams of any chemical controlled by ECCN 1C350.b or .c (CB-controlled chemicals also identified as Schedule 2 or 3 chemicals under the CWC) that are destined for export or reexport to CWC States Parties (destinations listed in Supplement No. 2 to Part 745 of the EAR). Such test kits are controlled by ECCN 1C395 for CB and CW reasons, to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745 of the EAR), and for AT reasons.

(2) Test kits that contain no more than 300 grams of any chemical controlled by ECCN 1C350.d (CB-controlled chemicals not also identified as Schedule 1, 2, or

3 chemicals under the CWC). Such test kits are controlled by ECCN 1C995 for AT reasons.

\* \* \* \* \*

(4) A license is required, to States not Party to the CWC (destinations not listed in Supplement No. 2 to Part 745 of the EAR), for mixtures controlled by 1C395.a and test kits controlled by 1C395.b.

\* \* \* \* \*

11. Section 742.18 is revised to read as follows:

**§ 742.18 Chemical Weapons Convention (CWC or Convention).**

States that are parties to the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, also known as the Chemical Weapons Convention (CWC or Convention), undertake never to develop, produce, acquire, stockpile, transfer, or use chemical weapons. As a State Party to the Convention, the United States is subjecting certain toxic chemicals and their precursors listed in Schedules within the Convention to trade restrictions. Trade restrictions include: a prohibition on the export of Schedule 1 chemicals to States not Party to the CWC; a prohibition on the reexport of Schedule 1 chemicals to all destinations (both States Parties to the CWC and States not Party to the CWC); license requirements for the export of Schedule 1 chemicals to all States Parties; a prohibition on the export of Schedule 2 chemicals to States not Party to the CWC; and an End-Use Certificate requirement for exports of Schedule 3 chemicals to States not Party to the CWC. Exports of CWC chemicals that do not require a license for CW reasons (e.g., exports and reexports of Schedule 2 and Schedule 3 chemicals to States Parties to the CWC) may require a license for other reasons set forth in the EAR. (See, in particular, the license requirements in § 742.2 of the EAR that

apply to exports and reexports of precursor chemicals controlled by ECCN 1C350, for CB reasons. Also note the end-use and end-user restrictions in part 744 of the EAR and the restrictions that apply to embargoed countries in part 746 of the EAR.)

(a) *License requirements.* (1) *Schedule 1 chemicals and mixtures controlled under ECCN 1C350 or ECCN 1C351.* A license is required for CW reasons to export or reexport Schedule 1 chemicals and mixtures controlled under ECCN 1C350.a or Schedule 1 chemicals controlled under ECCN 1C351.d.5 or d.6 to all destinations *including Canada*. CW applies to 1C351.d.5 for ricin in the form of Ricinus Communis Agglutinin<sub>II</sub> (RCA<sub>II</sub>), which is also known as ricin D or Ricinus Communis Lectin<sub>III</sub> (RCL<sub>III</sub>), and Ricinus Communis Lectin<sub>IV</sub> (RCL<sub>IV</sub>), which is also known as ricin E. CW applies to 1C351.d.6 for saxitoxin identified by C.A.S. #35523–89–8. (Note that the advance notification procedures and annual reporting requirements described in § 745.1 of the EAR also apply to exports of Schedule 1 chemicals.)

(2) *Schedule 2 and 3 chemicals and mixtures controlled under ECCN 1C350, ECCN 1C355, or ECCN 1C395.* (i) *States Parties to the CWC.* Neither a license nor an End-Use Certificate is required for CW reasons to export or reexport Schedule 2 or 3 chemicals and mixtures controlled under ECCN 1C350, ECCN 1C355, or ECCN 1C395 to States Parties to the CWC (destinations listed in Supplement No. 2 to part 745 of the EAR).

(ii) *States not Party to the CWC.* (A) *Schedule 2 chemicals.* A license is required for CW reasons to export or reexport Schedule 2 chemicals and mixtures controlled under ECCN 1C350.b, ECCN 1C355.a, or ECCN 1C395 to States not Party to the CWC (destinations *not* listed in Supplement No. 2 to part 745 of the EAR).

(B) *Schedule 3 chemicals.* (1) *Exports.* A license is required for CW reasons to

export Schedule 3 chemicals and mixtures controlled under ECCN 1C350.c, ECCN 1C355.b, or ECCN 1C395.b to States not Party to the CWC (destinations *not* listed in Supplement No. 2 to Part 745 of the EAR), *unless* the exporter obtains from the consignee an End-Use Certificate (issued by the government of the importing country) prior to exporting the Schedule 3 chemicals and submits it to BIS in accordance with the procedures described in § 745.2 of the EAR. Note, however, that obtaining an End-Use Certificate does not relieve the exporter from the responsibility of complying with other license requirements set forth elsewhere in the EAR.

(2) *Reexports.* (i) *Reexports from States Parties to the CWC.* Neither a license nor an End-Use Certificate is required for CW reasons to reexport Schedule 3 chemicals and mixtures controlled under ECCN 1C350.c, ECCN 1C355.b, or ECCN 1C395.b from States Parties to the CWC (destinations listed in Supplement No. 2 to part 745 of the EAR) to States not Party to the CWC. However, a license may be required for other reasons set forth elsewhere in the EAR. In addition, reexports of Schedule 3 chemicals may be subject to an End-Use Certificate requirement by governments of other countries when the chemicals are destined for States not Party to the CWC.

(ii) *Reexports from States not Party to the CWC.* A license is required for CW reasons to reexport Schedule 3 chemicals and mixtures controlled under ECCN 1C350.c, ECCN 1C355.b, or ECCN 1C395.b from a State not Party to the CWC (a destination *not* listed in Supplement No. 2 to part 745 of the EAR) to any other State not Party to the CWC.

(C) *Technology controlled under ECCN 1E355.* A license is required for CW reasons to export or reexport technology controlled under ECCN 1E355 to all States not Party to the CWC (destinations *not* listed in Supplement No. 2 to part 745 of the EAR), except for Israel and Taiwan.

(b) *Licensing policy.* (1) *Schedule 1 chemicals and mixtures.* (i) *Exports to States Parties to the CWC.* Applications to export Schedule 1 chemicals and mixtures controlled under ECCN 1C350.a or Schedule 1 chemicals controlled under ECCN 1C351.d.5 or d.6 to States Parties to the CWC (destinations listed in Supplement No. 2 to part 745 of the EAR) generally will be denied, *unless* all of the following conditions are met:

(A) The chemicals are destined only for purposes not prohibited under the

CWC (*i.e.*, research, medical, pharmaceutical, or protective purposes);

(B) The types and quantities of chemicals are strictly limited to those that can be justified for those purposes;

(C) The Schedule 1 chemicals were not previously imported into the United States (this does not apply to Schedule 1 chemicals imported into the United States prior to April 29, 1997, or imported into the United States directly from the same State Party to which they now are to be returned, *i.e.*, exported); *and*

(D) The aggregate amount of Schedule 1 chemicals in the country of destination at any given time is equal to or less than one metric ton *and* receipt of the proposed export will *not* cause the country of destination to acquire or to have acquired one metric ton or more of Schedule 1 chemicals in any calendar year.

(ii) *Exports to States not Party to the CWC.* Applications to export Schedule 1 chemicals and mixtures controlled under ECCN 1C350.a or Schedule 1 chemicals controlled under ECCN 1C351.d.5 or d.6 to States not Party to the CWC (destinations *not* listed in Supplement No. 2 to part 745 of the EAR) generally will be denied, consistent with U.S. obligations under the CWC to prohibit exports of these chemicals to States not Party to the CWC.

(iii) *Reexports.* Applications to reexport Schedule 1 chemicals and mixtures controlled under ECCN 1C350.a or Schedule 1 chemicals controlled under ECCN 1C351.d.5 or d.6 generally will be denied to all destinations (including both States Parties to the CWC and States not Party to the CWC).

(2) *Schedule 2 chemicals and mixtures.* Applications to export or reexport Schedule 2 chemicals and mixtures controlled under ECCN 1C350.b, ECCN 1C355.a, or ECCN 1C395 to States not Party to the CWC (destinations *not* listed in Supplement No. 2 to part 745 of the EAR) generally will be denied, consistent with U.S. obligations under the CWC to prohibit exports of these chemicals to States not Party to the CWC.

(3) *Schedule 3 chemicals and mixtures.* (i) *Exports.* Applications to export Schedule 3 chemicals and mixtures controlled under ECCN 1C350.c, ECCN 1C355.b, or ECCN 1C395.b to States not Party to the CWC (destinations *not* listed in Supplement No. 2 to part 745 of the EAR) generally will be denied.

(ii) *Reexports from States not Party to the CWC.* Applications to reexport Schedule 3 chemicals and mixtures

controlled under ECCN 1C350.c, ECCN 1C355.b, or ECCN 1C395.b from a State not Party to the CWC (a destination *not* listed in Supplement No. 2 to part 745 of the EAR) to any other State not Party to the CWC generally will be denied.

(4) *Technology controlled under ECCN 1E355.* Exports and reexports of technology controlled under ECCN 1E355 will be reviewed on a case-by-case basis.

(c) *Contract sanctity.* Contract sanctity provisions are not available for license applications reviewed under this section.

## PART 745—[AMENDED]

12. Supplement No. 2 to Part 745 is amended by revising the undesignated center heading “List of States Parties as of August 1, 2001” to read “List of States Parties as of May 1, 2002” and by adding, in alphabetical order, the countries Nauru and Uganda.

## PART 774—[AMENDED]

13. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, “Microorganisms,” & “Toxins,” is amended by revising ECCN 1C350 to read as follows:

*1C350 Chemicals that may be used as precursors for toxic chemical agents.*

### License Requirements

*Reason for Control:* CB, CW, AT

Control(s)	Country Chart
CB applies to entire entry.	CB Column 2
CW applies to 1C350.a, .b, and .c.	The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons. A license is required, for CW reasons, to export or reexport Schedule 1 chemicals and mixtures identified in 1C350.a to all destinations, including Canada. A license is required, for CW reasons, to export or reexport Schedule 2 chemicals and mixtures identified in 1C350.b to States not Party to the CWC (destinations <i>not</i> listed in Supplement No. 2 to part 745 of the EAR). A license is required, for CW reasons, to export Schedule 3 chemicals and mixtures identified in 1C350.c to States not Party to the CWC, unless an End-Use Certificate issued by the government of the importing country has been obtained by the exporter prior to export. A license is required, for CW reasons, to reexport Schedule 3 chemicals and mixtures identified in 1C350.c from a State not Party to the CWC to any other State not Party to the CWC. (See § 742.18 of the EAR for license requirements and policies for toxic and precursor chemicals controlled for CW reasons. See § 745.2 of the EAR for End-Use Certificate requirements that apply to exports of Schedule 3 chemicals to countries not



listed in Supplement No. 2 to part 745 of the EAR.) AT applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for AT reasons in 1C350. A license is required, for AT reasons, to export or reexport items controlled by 1C350 to Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria. (See Part 742 of the EAR for additional information on the AT controls that apply to Iran, North Korea, Sudan, and Syria. See Part 746 of the EAR for additional information on the comprehensive trade sanctions that apply to Cuba, Iran, Iraq, and Libya.)

**License Requirement Notes:**

1. **SAMPLE SHIPMENTS:** Subject to the following requirements and restrictions, a license is not required for sample shipments when the cumulative total of these shipments does not exceed a 55-gallon container or 200 kg of a single chemical to any one consignee during a calendar year. A consignee that receives a sample shipment under this exclusion may not resell, transfer, or reexport the sample shipment, but may use the sample shipment for any other legal purpose unrelated to chemical weapons.

a. **Chemicals Not Eligible:**

A. **CWC Schedule 1 chemicals (all destinations).** The CWC Schedule 1 chemicals and mixtures identified in 1C350.a are *not* eligible for sample shipment to any destination without a license.

B. **CWC Schedule 2 chemicals (States not Party to the CWC).** No CWC Schedule 2 chemical or mixture identified in 1C350.b is eligible for sample shipment to *States not Party to the CWC* (destinations *not* listed in Supplement No. 2 to part 745 of the EAR) without a license.

b. **Countries Not Eligible:** The following countries are *not* eligible to receive sample shipments of any chemicals controlled by this ECCN without a license: Cuba, Iran, Iraq, Libya, North Korea, Sudan, Syria.

c. **Sample shipments that require an End-Use Certificate for CW reasons:** No CWC Schedule 3 chemical or mixture identified in 1C350.c is eligible for sample shipment to *States not Party to the CWC* (destinations *not* listed in Supplement No. 2 to Part 745 of the EAR) without a license, unless an End-Use Certificate issued by the government of the importing country is obtained by the exporter prior to export (see § 745.2 of the EAR for End-Use Certificate requirements).

d. **Sample shipments that require a license for reasons set forth elsewhere in the EAR:** Sample shipments, as described in this Note 1, may require a license for reasons set forth elsewhere in the EAR. See, in particular, the end-use/end-user restrictions in Part 744 of the EAR, and the restrictions that apply to embargoed countries in Part 746 of the EAR.

e. **Quarterly report requirement.** The exporter is required to submit a quarterly written report for shipments of samples made under this Note 1. The report must be on company letterhead stationery (titled "Report of Sample Shipments of Chemical Precursors" at the top of the first page) and identify the chemical(s), Chemical Abstract Service Registry (C.A.S.) number(s), quantity(ies), the ultimate consignee's name and address, and the date exported. The report must be sent to the U.S. Department

of Commerce, Bureau of Industry and Security, P.O. Box 273, Washington, DC 20044, Attn: "Report of Sample Shipments of Chemical Precursors".

2. **MIXTURES:**

a. Mixtures that contain precursor chemicals identified in ECCN 1C350, in concentrations that are below the levels indicated in 1C350.a through .d, are controlled by ECCN 1C395 or 1C995 and are subject to the license requirements specified in those ECCNs.

b. A license is not required for mixtures controlled under this ECCN when the controlled chemical in the mixture is a normal ingredient in consumer goods packaged for retail sale for personal use. Such consumer goods are classified as EAR99.

c. A license is not required for mixtures containing less than 0.5% aggregate quantities, by weight, of the CWC Schedule 1 chemicals controlled by 1C350.a as unavoidable by-products or impurities. Such mixtures are classified as EAR99. All other mixtures containing these Schedule 1 chemicals are controlled by ECCN 1C350.a.

**Note to Mixtures:** Calculation of concentrations of controlled chemicals;

a. **Exclusion.** No chemical may be added to the mixture (solution) for the sole purpose of circumventing the Export Administration Regulations;

b. **Percent Weight Calculation.** When calculating the percentage, by weight, of components in a chemical mixture, include all components of the mixture, including those that act as solvents.

3. **COMPOUNDS:** Compounds created with any chemicals identified in this ECCN 1C350 may be shipped NLR (No License Required), without obtaining an End-Use Certificate, unless those compounds are also identified in this entry or require a license for reasons set forth elsewhere in the EAR.

4. **TESTING KITS:** Certain medical, analytical, diagnostic, and food testing kits containing small quantities of chemicals identified in this ECCN 1C350, except chemicals identified as Schedule 1 chemicals under the CWC, are excluded from the scope of this ECCN and are controlled under ECCN 1C395 or ECCN 1C995. (Note that replacement reagents for such kits are controlled by this ECCN 1C350 if the reagents contain at least one of the precursor chemicals identified in 1C350 in concentrations equal to or greater than the control levels for mixtures indicated in 1C350.)

**Technical Notes:** 1. For purposes of this entry, a "mixture" is defined as a solid, liquid or gaseous product made up of two or more components that do not react together under normal storage conditions.

2. The scope of this control applicable to Hydrogen Fluoride (see 1C350.d.7 in the List of Items Controlled) includes its liquid, gaseous, and aqueous phases, and hydrates.

**License Exceptions**

LVS: N/A

GBS: N/A

CIV: N/A

**List of Items Controlled**

**Unit:** Liters or kilograms, as appropriate.

**Related Controls:** 1C350.a controls certain 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 §§ 742.18 and 745.1 of the EAR for notification and annual report requirements. See 22 CFR part 121, Category XIV and § 121.7 for additional CWC Schedule 1 chemicals controlled by the Department of State. Also see ECCNs 1C355, 1C395, and 1C995.

**Related Definitions:** See § 770.2(k) of the EAR for synonyms for the chemicals listed in this entry.

**Items:**

a. Australia Group-controlled precursor chemicals also identified as Schedule 1 chemicals under the CWC, as follows, and mixtures containing any amount of the following chemicals, except mixtures that contain less than 0.5% aggregate quantities (by weight) of these chemicals as unavoidable by-products or impurities (*i.e.*, the Schedule 1 chemicals are not intentionally produced or added):

a.1. (C.A.S. #57856-11-8) 0-Ethyl-2-diisopropylaminoethyl methyl phosphonite (QL);

a.2. (C.A.S. #753-98-0) Ethyl phosphonyl difluoride;

a.3. (C.A.S. #676-99-3) Methyl phosphonyl difluoride.

b. Australia Group-controlled precursor chemicals also identified as Schedule 2 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:

b.1. (C.A.S. #7784-34-1) Arsenic trichloride;

b.2. (C.A.S. #76-93-7) Benzoic acid;

b.3. (C.A.S. #78-38-6) Diethyl ethylphosphonate;

b.4. (C.A.S. #15715-41-0) Diethyl methylphosphonite;

b.5. (C.A.S. #2404-03-7) Diethyl-N,N-dimethylphosphoroamidate;

b.6. (C.A.S. #5842-07-9) N,N-Diisopropyl-beta-aminoethane thiol;

b.7. (C.A.S. #4261-68-1) N,N-Diisopropyl-beta-aminoethyl chloride hydrochloride;

b.8. (C.A.S. #96-80-0) N,N-Diisopropyl-beta-aminoethanol;

b.9. (C.A.S. #96-79-7), N,N-Diisopropyl-beta-aminoethyl chloride;

b.10. (C.A.S. #6163-75-3) Dimethyl ethylphosphonate;

b.11. (C.A.S. #756-79-6) Dimethyl methylphosphonate;

b.12. (C.A.S. #1498-40-4) Ethyl phosphonous dichloride [Ethyl phosphinyl dichloride];

b.13. (C.A.S. #430-78-4) Ethyl phosphonous difluoride [Ethyl phosphinyl difluoride];

b.14. (C.A.S. #1066-50-8) Ethyl phosphonyl dichloride;

b.15. (C.A.S. #676-83-5) Methyl phosphonous dichloride [Methyl phosphinyl dichloride];

b.16. (C.A.S. #753-59-3) Methyl phosphonous difluoride [Methyl phosphinyl difluoride];

b.17. (C.A.S. #676-97-1) Methyl phosphonyl dichloride;



b.18. (C.A.S. #464-07-3) Pinacolyl alcohol;  
 b.19. (C.A.S. #1619-34-7) 3-Quinuclidinol;  
 b.20. (C.A.S. #111-48-8) Thiodiglycol.  
 c. Australia Group-controlled precursor chemicals also identified as Schedule 3 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:  
 c.1. (C.A.S. #762-04-9) Diethyl phosphite;  
 c.2. (C.A.S. #868-85-9) Dimethyl phosphite (dimethyl hydrogen phosphite);  
 c.3. (C.A.S. #10025-87-3) Phosphorus oxychloride;  
 c.4. (C.A.S. #10026-13-8) Phosphorus pentachloride;  
 c.5. (C.A.S. #7719-12-2) Phosphorus trichloride;  
 c.6. (C.A.S. #10025-67-9) Sulfur monochloride;  
 c.7. (C.A.S. #10545-99-0) Sulfur dichloride;  
 c.8. (C.A.S. #7719-09-7) Thionyl chloride;  
 c.9. (C.A.S. #102-71-6) Triethanolamine;  
 c.10. (C.A.S. #122-52-1) Triethyl phosphite;  
 c.11. (C.A.S. #121-45-9) Trimethyl phosphite.  
 d. Other Australia Group-controlled precursor chemicals not also identified as Schedule 1, 2, or 3 chemicals under the CWC, as follows, and mixtures in which at least one of the following chemicals constitutes 30 percent or more of the weight of the mixture:  
 d.1. (C.A.S. #1341-49-7) Ammonium hydrogen fluoride;  
 d.2. (C.A.S. #107-07-3) 2-Chloroethanol;  
 d.3. (C.A.S. #100-37-8) N,N-Diethylaminoethanol;  
 d.4. (C.A.S. #108-18-9) Di-isopropylamine;  
 d.5. (C.A.S. #124-40-3) Dimethylamine;  
 d.6. (C.A.S. #506-59-2) Dimethylamine hydrochloride;  
 d.7. (C.A.S. #7664-39-3) Hydrogen fluoride;  
 d.8. (C.A.S. #3554-74-3) 3-Hydroxyl-1-methylpiperidine;  
 d.9. (C.A.S. #76-89-1) Methyl benzilate;  
 d.10. (C.A.S. #1314-80-3) Phosphorus pentasulfide;  
 d.11. (C.A.S. #75-97-8) Pinacolone;  
 d.12. (C.A.S. #151-50-8) Potassium cyanide;  
 d.13. (C.A.S. #7789-23-3) Potassium fluoride;  
 d.14. (C.A.S. #7789-29-9) Potassium bifluoride;  
 d.15. (C.A.S. #3731-38-2) 3-Quinuclidone;  
 d.16. (C.A.S. #1333-83-1) Sodium bifluoride;  
 d.17. (C.A.S. #143-33-9) Sodium cyanide;  
 d.18. (C.A.S. #7681-49-4) Sodium fluoride;  
 d.19. (C.A.S. #1313-82-2) Sodium sulfide;  
 d.20. (C.A.S. #637-39-8) Triethanolamine hydrochloride.

14. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, “Microorganisms,” & “Toxins,” is amended by revising ECCN 1C353 to read as follows:

*1C353 Genetic elements and genetically modified “microorganisms”, as follows (see List of Items Controlled).*

#### License Requirements

*Reason for Control:* CB, AT

<i>Control(s)</i>	<i>Country Chart</i>
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:* Vaccines that contain genetic elements or genetically modified organisms identified in this entry are controlled by ECCN 1C991.

*Related Definitions:* N/A

*Items:*

a. Genetic elements, as follows:

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

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.

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

b. Genetically modified organisms, as follows:

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

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.

15. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, “Microorganisms,” & “Toxins,” is amended by revising ECCN 1C355 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.*

#### License Requirements

*Reason for Control:* CW, AT  
*Control(s)*

CW applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons. A license is required to export or reexport CWC Schedule 2 chemicals and mixtures identified in 1C355.a to States not Party to the CWC (destinations not listed in Supplement No. 2 to part 745). A license is required to export CWC Schedule 3 chemicals and mixtures

identified in 1C355.b to States not Party to the CWC, unless an End-Use Certificate issued by the government of the importing country is obtained by the exporter, prior to export. A license is required to reexport CWC Schedule 3 chemicals and mixtures identified in 1C355.b from a State not Party to the CWC to any other State not Party to the CWC. (See § 742.18 of the EAR for license requirements and policies for toxic and precursor chemicals controlled for CW reasons.)

AT applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for AT reasons in 1C355. A license is required, for AT reasons, to export or reexport items controlled by 1C355 to Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria. (See Part 742 of the EAR for additional information on the AT controls that apply to Iran, North Korea, Sudan, and Syria. See Part 746 of the EAR for additional information on the comprehensive trade sanctions that apply to Cuba, Iran, Iraq, and Libya.)

*License Requirements Notes:*

#### 1. MIXTURES:

a. Mixtures containing toxic and precursor chemicals identified in ECCN 1C355, in concentrations that are below the control levels indicated in 1C355.a and .b, are controlled by ECCN 1C995 and are subject to the license requirements specified in that ECCN.

b. Mixtures containing chemicals identified in this entry are not controlled by ECCN 1C355 when the controlled chemical is a normal ingredient in consumer goods packaged for retail sale for personal use or packaged for individual use. Such consumer goods are classified as EAR99.

**Note to Mixtures:** Calculation of concentrations of CW-controlled chemicals:

a. Exclusion. No chemical may be added to the mixture (solution) for the sole purpose of circumventing the Export Administration Regulations;

b. Percent Weight Calculation. When calculating the percentage, by weight, of components in a chemical mixture, include all components of the mixture, including those that act as solvents.

2. **COMPOUNDS:** Compounds created with any chemicals identified in this ECCN 1C355 may be shipped NLR (No License Required), without obtaining an End-Use Certificate, unless those compounds are also identified in this entry or require a license for reasons set forth elsewhere in the EAR.

**Technical Notes:** For purposes of this entry, a “mixture” is defined as a solid, liquid, or gaseous product made up of two or more components that do not react together under normal storage conditions.

#### License Exceptions

LVS: N/A.

GBS: N/A.

CIV: N/A.

#### 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. See 22 CFR part 121, Category

XIV and § 121.7 for chloropicrin (trichloronitromethane) (C.A.S. 76-06-2) (Schedule 3). Mixtures containing chloropicrin (trichloronitromethane) that have been transferred to the Department of Commerce from the Department of State through a commodity jurisdiction determination are controlled under this entry.

*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. FAMILY: 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 with no additional carbon atoms in the structure;

**Note:** 1C355.a.2.a does not control Fonofos: O-Ethyl S-phenyl ethylphosphonothiolothionate (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.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. Ethyldiethanolamine (C.A.S. 139-87-7);

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

b.3. Mixtures containing chloropicrin (trichloronitromethane) (C.A.S. 76-06-2),

transferred from the Department of State (see Related Controls).

16. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, “Microorganisms,” & “Toxins,” is amended by adding a new ECCN 1C395 immediately following ECCN 1C355 to read as follows:

*1C395 Mixtures and Medical, Analytical, Diagnostic, and Food Testing Kits Not Controlled by ECCN 1C350, as follows (See List of Items Controlled).*

**License Requirements**

Reason for Control: CB, CW, AT

**Control(s)**

**Country Chart**

CB applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CB reasons in 1C395. A license is required, for CB reasons, to export or reexport mixtures controlled by 1C395.a and test kits controlled by 1C395.b to States not Party to the CWC (destinations *not* listed in Supplement No. 2 to part 745 of the EAR).

CW applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons. A license is required for CW reasons, as follows, to States not Party to the CWC (destinations *not* listed in Supplement No. 2 to Part 745 of the EAR): (1) Exports and reexports of mixtures controlled by 1C395.a, (2) exports and reexports of test kits controlled by 1C395.b that contain CWC Schedule 2 chemicals controlled by ECCN 1C350, (3) exports of test kits controlled by 1C395.b that contain CWC Schedule 3 chemicals controlled by ECCN 1C350, except that a license is not required, for CW reasons, to export test kits containing CWC Schedule 3 chemicals if an End-Use Certificate issued by the government of the importing country is obtained by the exporter prior to export, and (4) reexports from States not Party to the CWC of test kits controlled by 1C395.b that contain CWC Schedule 3 chemicals. (See § 742.18 of the EAR for license requirements and policies for toxic and precursor chemicals controlled for CW reasons.)

AT applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for AT reasons in 1C395. A license is required, for AT reasons, to export or reexport items controlled by 1C395 to Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria. (See Part 742 of the EAR for additional information on the AT controls that apply to Iran, North Korea, Sudan, and Syria. See Part 746 of the EAR for additional information on the comprehensive trade sanctions that apply to Cuba, Iran, Iraq, and Libya.)

**License Requirement Notes:**

1. 1C395.b does not control mixtures that contain precursor chemicals identified in ECCN 1C350.b or .c in concentrations below the control levels for mixtures indicated in 1C350.b or .c. 1C395.a and 1C995.a.1 and a.2.a control such mixtures, unless they are consumer goods as described in License Requirements Note 2 of this ECCN.

2. This ECCN does not control mixtures when the controlled chemicals are normal ingredients in consumer goods packaged for retail sale for personal use. Such consumer goods are classified as EAR99.

**License Exceptions**

LVS: N/A

GBS: N/A

GIV: N/A

**List of Items Controlled**

*Unit:* \$ value

*Related Controls:* 1. ECCN 1C350 controls mixtures containing 30 percent or higher concentrations, by weight, of any single CWC Schedule 2 chemical identified in ECCN 1C350.b; ECCN 1C995 controls such mixtures containing concentrations of 10 percent or less. 2. ECCN 1C995 controls “medical, analytical, diagnostic, and food testing kits” (as defined in the Related Definitions paragraph of this ECCN) that contain precursor chemicals listed in 1C350.d. ECCN 1C350 controls any such kits that contain CWC Schedule 1 chemicals listed in 1C350.a or testing kits in which the amount of any single chemical listed in 1C350.b, .c, or .d exceeds 300 grams by weight.

*Related Definitions:* For the purpose of this entry, “medical, analytical, diagnostic, and food testing kits” are pre-packaged materials of defined composition that are specifically developed, packaged and marketed for medical, analytical, diagnostic, or public health purposes. Replacement reagents for medical, analytical, diagnostic, and food testing kits described in 1C395.b are controlled by ECCN 1C350 if the reagents contain at least one of the precursor chemicals identified in that ECCN in concentrations equal to or greater than the control levels for mixtures indicated in 1C350.b. or .c.

*Items:*

a. Mixtures containing more than 10 percent, but less than 30 percent, by weight of any single CWC Schedule 2 chemical identified in ECCN 1C350.b (For controls on other mixtures containing these chemicals, see Note 1 in the Related Controls paragraph of this ECCN.).

b. “Medical, analytical, diagnostic, and food testing kits” (as defined in the Related Definitions for this ECCN) that contain CWC Schedule 2 or 3 chemicals controlled by ECCN 1C350.b or .c in an amount *not* exceeding 300 grams per chemical. (For controls on other such test kits containing these and other controlled chemicals, see Note 2 in the Related Controls paragraph of this ECCN.)

17. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—Materials, Chemicals, “Microorganisms,” & “Toxins,” is amended by revising ECCN 1C995 to read as follows:

*1C995 Mixtures not controlled by ECCN 1C350, ECCN 1C355 or ECCN 1C395 that contain chemicals controlled by ECCN 1C350 or ECCN 1C355 and medical, analytical, diagnostic, and food testing kits not controlled by ECCN 1C350 or ECCN 1C395 that contain chemicals controlled by ECCN*

1C350.d, as follows (see List of Items controlled).

#### License Requirements

*Reason for Control: AT*

Control(s)	Country Chart
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AT applies to entire entry. The Commerce Country Chart is not designed to determine licensing requirements for items controlled for AT reasons in 1C995. A license is required, for AT reasons, to export or reexport items controlled by 1C995 to Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria. (See Part 742 of the EAR for additional information on the AT controls that apply to Iran, North Korea, Sudan, and Syria. See Part 746 of the EAR for additional information on the comprehensive trade sanctions that apply to Cuba, Iran, Iraq, and Libya.)

#### License Requirement Notes:

1. This ECCN does not control mixtures containing less than 0.5% of any single toxic or precursor chemical controlled by ECCN 1C350.b, .c, or .d or ECCN 1C355 as unavoidable by-products or impurities. Such mixtures are classified as EAR99.

2 1C995.c does not control mixtures that contain precursor chemicals identified in 1C350.d in concentrations below the control levels for mixtures indicated in 1C350.d. 1C995.a.2.b controls such mixtures, unless they are consumer goods as described in License Requirements Note 3 of this ECCN.

3. This ECCN does not control mixtures when the controlled chemicals are normal ingredients in consumer goods packaged for retail sale for personal use. Such consumer goods are classified as EAR99.

#### License Exceptions

LVS: N/A  
GBS: N/A  
CIV: N/A

#### List of Items Controlled

*Unit:* \$ value

*Related Controls:* 1. ECCN 1C350 controls mixtures containing 30 percent or higher concentrations of any single CWC Schedule 2 chemical identified in ECCN 1C350.b. ECCN 1C395 controls mixtures containing concentrations of more than 10 percent, but less than 30 percent, of any single CWC Schedule 2 chemical identified in ECCN 1C350.b. 2. ECCN 1C350 controls mixtures containing chemicals identified in ECCN 1C350.c or .d that exceed the concentration levels indicated in 1C995.a.2. 3. ECCN 1C355 controls mixtures containing chemicals identified in ECCN 1C355 that exceed the concentration levels indicated in 1C995.b. 4. ECCN 1C395 controls "medical, analytical, diagnostic, and food testing kits" (as defined in the Related Definitions paragraph of this ECCN) that contain CWC Schedule 2 or 3 chemicals listed in 1C350.b or .c. ECCN 1C350 controls any such kits that contain CWC Schedule 1 chemicals listed in 1C350.a or testing kits in which the amount of any single chemical listed in 1C350.b, .c, or .d exceeds 300 grams by weight.

*Related Definitions:* For the purpose of this entry, "medical, analytical, diagnostic, and food testing kits" are pre-packaged materials

of defined composition that are specifically developed, packaged and marketed for medical, analytical, diagnostic, or public health purposes. Replacement reagents for medical, analytical, diagnostic, and food testing kits described in 1C995.c are controlled by ECCN 1C350 if the reagents contain at least one of the precursor chemicals identified in that ECCN in concentrations equal to or greater than the control levels for mixtures indicated in 1C350.d.

#### Items:

a. Mixtures containing the following concentrations of precursor chemicals controlled by ECCN 1C350 (For controls on other mixtures containing these chemicals, see Notes 1 and 2 in the Related Controls paragraph of this ECCN.):

a.1. Mixtures containing 10 percent or less, by weight, of any single CWC Schedule 2 chemical controlled by ECCN 1C350.b;

a.2. Mixtures containing less than 30 percent, by weight, of:

a.2.a. Any single CWC Schedule 3 chemical controlled by ECCN 1C350.c; or

a.2.b. Any single precursor chemical controlled by ECCN 1C350.d.

b. Mixtures containing the following concentrations of toxic or precursor chemicals controlled by ECCN 1C355 (For controls on other mixtures containing these chemicals, see Note 3 in the Related Controls paragraph of this ECCN.):

b.1. Mixtures containing the following concentrations of CWC Schedule 2 chemicals controlled by ECCN 1C355.a:

b.1.a. Mixtures containing 1 percent or less, by weight, of any single CWC Schedule 2 chemical controlled by ECCN 1C355.a.1 (i.e., mixtures containing PFIB); or

b.1.b. Mixtures containing 10 percent or less, by weight, of any single CWC Schedule 2 chemical controlled by 1C355.a.2;

b.2. Mixtures containing less than 30 percent, by weight, of any single CWC Schedule 3 chemical controlled by ECCN 1C355.b.

c. "Medical, analytical, diagnostic, and food testing kits" (as defined in the Related Definitions for this ECCN) that contain precursor chemicals controlled by ECCN 1C350.d in an amount *not* exceeding 300 grams per chemical. (For controls on other such test kits containing these and other controlled chemicals, see Note 4 in the Related Controls paragraph of this ECCN.)

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

*2B350 Chemical manufacturing facilities and equipment, 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: 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, Office 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<sup>3</sup> (100 liters) and less than 20 m<sup>3</sup> (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 enamelled 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; or

a.7. Zirconium or zirconium alloys.

b. Agitators for use in reaction vessels or reactors, 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 enamelled 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; or

b.7. Zirconium or zirconium alloys.

c. Storage tanks, containers or receivers with a total internal (geometric) volume greater than 0.1 m<sup>3</sup> (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 enamelled 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; or

c.7. Zirconium or zirconium alloys.

d. Heat exchangers or condensers with a heat transfer surface area of less than 20 m<sup>2</sup>, but greater than 0.15 m<sup>2</sup>, 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 enamelled 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; *or*  
 d.10. Zirconium or zirconium 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 enamelled 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; *or*  
 e.8. Zirconium or zirconium 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 (3/8 in.), 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; *or*  
 g.7. Zirconium or zirconium 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 enamelled 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; *or*  
 h.8. Zirconium or zirconium alloys.  
 i. Multiple-seal, canned drive, magnetic drive, bellows or diaphragm pumps, with manufacturer's specified maximum flow-rate greater than 0.6 m<sup>3</sup>/hour, or vacuum pumps with manufacturer's specified maximum flow-rate greater than 5 m<sup>3</sup>/hour (under standard temperature (273 K (0° C)) and pressure (101.3 kPa) conditions), and casing (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 enamelled 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; *or*  
 i.10. Zirconium or zirconium 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.

19. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 2—Materials Processing, is amended by revising the List of Items Controlled section in ECCN 2B352 to read as follows:

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

\* \* \* \* \*

#### List of Items Controlled

*Unit:* Equipment in number.

*Related Controls:* N/A.

*Related Definitions:* For purposes of this entry, isolators include flexible isolators, dry boxes, anaerobic chambers and glove boxes.

#### Items:

a. Complete containment facilities at P3 or P4 containment level.

**Technical Note:** P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the WHO Laboratory Biosafety Manual (Geneva, 1983).

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

**Technical Note:** Fermenters include bioreactors, chemostats, and continuous-flow systems.

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

c.1. One or more sealing joints within the steam containment area;

c.2. A flow rate greater than 100 liters per hour;  
 c.3. Components of polished stainless steel or titanium; *and*  
 c.4. Capable of *in situ* steam sterilization in a closed state.

**Technical Note:** Centrifugal separators include decanters.

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

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

d.2. Capable of *in situ* sterilization.

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

f. Protective and containment equipment, as follows:

f.1. Protective full or half suits, or hoods dependant upon a tethered external air supply and operating under positive pressure;

**Technical Note:** This entry does not control suits designed to be worn with self-contained breathing apparatus.

f.2. Class III biological safety cabinets or isolators with similar performance standards, *e.g.*, flexible isolators, dry boxes, anaerobic chambers, glove boxes or laminar flow hoods (closed with vertical flow).

g. Chambers designed for aerosol challenge testing with microorganisms, viruses, or toxins and having a capacity of 1 m<sup>3</sup> or greater.

Dated: May 23, 2002.

**James J. Jochum,**

*Assistant Secretary for Export Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 314 and 601

[Docket No. 98N–0237]

RIN 0910–AC05

### New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its new drug and biological product regulations to allow appropriate studies in animals in certain cases to provide