-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 738, 740, 742, and 774

[Docket No. 230920-0229]

RIN 0694-AJ29

Allied Governments Favorable Treatment: Revisions to Certain Australia Group Controls; Revisions to Certain Crime Control and Detection Controls

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is amending the Export Administration Regulations (EAR) by removing Proliferation of Chemical and Biological Weapons (CB) controls on specified pathogens and toxins that are destined for Australia Group (AG) member countries and by revising the Commerce Country Chart to remove Crime Control and Detection (CC) controls on certain items that are destined for Austria, Finland, Ireland, Liechtenstein, South Korea, Sweden, and Switzerland. These changes are being made as part of a broader effort announced today that will liberalize several categories of export licensing requirements and the availability of export license exceptions for key allied and partner countries, as well as for members of certain multilateral export control regimes.

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

FOR FURTHER INFORMATION CONTACT:

For questions on pathogens and toxins discussed in this rule, contact Dr. Tara Gonzalez, Chemical

and Biological Controls Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, Telephone: (202) 482-3343, Email: Tara.Gonzalez@bis.doc.gov.
For all other questions pertaining to this rule, contact Logan Norton, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482-1762, Email: RPD2@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

Liberalizing Controls for Allies and Partners

Historically, the United States has relied on deep connections with its allies and partners to protect its vital national security and foreign policy interests. In particular, the United States acts in close cooperation with its allies and partners to bring together the international community to address military aggression, threats to sovereignty, and human rights abuses around the world. This is especially true in the context of export controls, in which multilateral and plurilateral controls are typically the most effective path toward accomplishing our national security and foreign policy objectives.

In remarks made at the U.S. State Department on February 4, 2021, regarding America's place in the world, President Biden noted that America's alliances are some of our greatest assets and that leading with diplomacy means standing shoulder to shoulder and working closely with our allies and key partners, thereby protecting the world against nefarious actors. At that time, President Biden highlighted the fact that the United States would be "more effective in dealing with Russia when we work in coalition and coordination with other like-minded partners." (https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/02/04/remarks-by-president-biden-on-americas-place-in-the-world/). Consistent with this direction, a year later, following Russia's unjustifiable further invasion of Ukraine and Belarus's complicity in that invasion, the United States led the formation of and continues to lead alignment within the Global Export

Controls Coalition (GECC), now comprising the United States and 38 other global economies. BIS's export controls on Russia and Belarus have been successful because they have been imposed and maintained in coordination with U.S. allies and partners. At the same time, in addition to the GECC, BIS has forged deeper ally and partner country relationships through a series of bilateral and multilateral export controls dialogues, including under the auspices of the U.S.-European Union Trade and Technology Council (TTC) and the U.S.-Japan Commercial and Industrial Partnership (JUCIP).

The changes made with this rule and two other ally and partner rules published today are part of a broad effort to liberalize controls for allies and partner countries under the EAR (15 CFR parts 730-774). Together, these rules will ease several categories of export licensing requirements and increase the availability of export license exceptions for key allied and partner countries, as well as members of certain multilateral export control regimes.

Overview of Regulatory Changes

As described below, in recognition of key allies' and partners' support of our efforts against Russia, along with their leadership in the areas of chemical and biological weapons nonproliferation and the promotion of human rights, BIS is making two sets of amendments to the EAR. First, it is revising the Chemical and Biological Nonproliferation (CB) controls that apply to certain pathogens and toxins that are destined for members of the Australia Group (AG). Second, it is removing Crime Controls (CC) on seven key allied and partner countries, Austria, Finland, Ireland, Liechtenstein, South Korea, Sweden, and Switzerland. These amendments to the EAR eliminate certain controls on allied and partner countries, as well as on AG member countries, thereby facilitating exports and reexports involving these countries and allowing BIS to apply its resources toward reviewing and monitoring more sensitive exports and higher-risk transactions. These amendments are part of a larger effort announced by BIS today that includes several EAR

amendments eliminating certain license requirements and broadening the availability of license exceptions for allied and partner countries, including member countries of international regimes.

Pathogens and Toxins

The AG is the multilateral export control regime responsible for controlling chemical and biological items to ensure that such items do not contribute to chemical and biological weapons proliferation. The AG currently has 43 members, including the United States. All items controlled under ECCNs 1C351, 1C353, 1C354, 1E001, and 1E351 on the Commerce Control List (CCL) (supp. no. 1 to part 774 of the EAR) are controlled multilaterally by the AG, except those items controlled under ECCN 1C351.b.

Prior to this rule, entries for pathogens and toxins controlled under ECCNs 1C351, 1C353, 1C354, and their related technologies controlled under ECCNs 1E001, and 1E351, listed CB Column 1 (CB:1) (see Commerce Country Chart, supp. no. 1 to part 738) as a reason for control applying to each entry. Pursuant to § 742.2(a)(1) of the EAR, ECCNs with a CB:1 reason for control require a BIS license for export or reexport to all destinations, regardless of AG membership. Separately, the controls on ECCNs referring to CB Column 2 (CB:2) are described in § 742.2(a)(2); items with a CB:2 reason for control require a BIS license for all destinations except AG member countries (see Country Group A:3, supp. no. 1 to part 740).

BIS is amending the EAR in recognition of the fact that each of the AG member countries has an effective export control system capable of regulating dual-use exports in a manner consistent with U.S. national security, foreign policy, and nonproliferation objectives. In particular, all AG members implement AG control agreements under their domestic laws, including by imposing stringent biosafety and biosecurity standards and maintaining comparable license requirements. Consequently, exports, reexports, and transfers (in-country) of items controlled under these ECCNs to AG member countries are low-risk transactions. This assessment is evidenced by recent licensing data on approved and denied BIS license applications for the items controlled under these ECCNs

to AG member countries. In 2021, BIS approved approximately 1,000 applications for ECCN 1C351, 1C353, 1C354, 1E001, and 1E351 items to AG member countries and did not deny any license applications for such items to AG member countries. Consistent with the demonstrated low risk posed by these items when destined to AG member countries, BIS is amending the reason for control from CB:1 to CB:2 in each of the entries for these items. Although these items remain CB-controlled, they will no longer require a license for CB reasons when destined to AG member countries. By amending the reason for control from CB:1 to CB:2 in each of the entries for these items, BIS estimates that it is alleviating a burden of approximately 1,000 license applications per year. This decrease in burden will benefit both the public, by reducing the need to submit applications and wait for processing, and BIS, by freeing resources for applications involving higher-risk destinations.

Regulatory Change

With this rule, BIS revises ECCNs 1C351, 1C353, 1C354, 1E001, and 1E351 on the CCL. This rule revises the reason for control in each of these ECCNs from CB:1 to CB:2. As a conforming change, BIS revises § 742.2(a) of the EAR such that it reflects the changes to ECCNs 1C351, 1C353, 1C354, 1E001, and 1E351.

This rule does not make changes to the item paragraphs or other reasons for control associated with these ECCNs. Notably, CB:1 will continue to be the reason for control in ECCN 1C351.d.14 and .15 and genetic elements of ECCN 1C353 of toxins controlled in 1C351.d.14 and .15, pursuant to the requirements of the Chemical Weapons Convention. Relatedly, ECCNs 1E001 and 1E351 will retain CB:1 as the reason for control for "technology" controlled by the ECCN 1C351.d.14 and .15 and the genetic elements thereof.

This rule makes two conforming changes involving ECCN 1C351 that reflect the easing of licensing requirements described above. Prior to this rule, certain toxins controlled under ECCN 1C351 required a license but were eligible for License Exception Strategic Trade Authorization

(STA) when destined to Country Group A:5 countries pursuant to § 740.20(b)(2)(vi). Given the changes made by this rule to ECCN 1C351, there is no longer a license requirement for these toxins when destined for a Country Group A:5 country. Therefore, this rule removes § 740.20(b)(2)(vi) and references to License Exception STA from ECCN 1C351.

Crime Control

Crime controls (CC) on crime control detection equipment, related technology, and software, set forth in § 742.7 of the EAR, support U.S. foreign policy interests that promote the observance of human rights throughout the world. Pursuant to § 742.7(a)(1), ECCNs on the CCL referencing CC Column 1 on the Country Chart (CC:1) require a BIS license for export and reexport. Similarly, § 742.2(a)(3) describes the license requirements for items referencing CC Column 3 on the Country Chart (CC:3). Prior to this rule, Austria, Finland, Ireland, Liechtenstein, South Korea, Sweden, and Switzerland were each subject to license requirements for CC:1 and CC:3 items set forth on the CCL. With this rule, the items specified in § 742.7(a)(1) and (a)(3) will no longer require a license for export and reexport to these seven countries; this reflects – along with their inclusion in Country Group A:5 (see supp. no. 1 to part 740) as well as in supplement no. 3 to part 746 (countries that have implemented export controls on Russia and Belarus that are substantially similar to U.S. export controls) – these seven countries' status as close United States allies and partners. Moreover, these seven countries share the United States' commitment to the observance of human rights worldwide. All seven countries have strong records regarding the safeguarding of civil liberties and individual freedoms and upholding other democratic norms.

In 2021, BIS approved approximately 200 licenses and did not deny any licenses for CC items destined to these seven countries. BIS anticipates that the removal of CC controls on these seven countries will enable the agency to reallocate its licensing application review and processing resources on higher-risk destinations that present human rights concerns.

Regulatory Change

This rule revises the Commerce Country Chart by removing the X for CC reason for control from CC:1 and CC:3 for Austria, Finland, Ireland, Liechtenstein, South Korea, Sweden, and Switzerland. Doing so eliminates the license requirements for items controlled under CC:1 and CC:3. This rule makes no further revisions to the Commerce Country Chart or conforming changes elsewhere in the EAR.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA), 50 U.S.C. Sections 4801–4852. ECRA provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule.

Rulemaking Requirements

1. BIS has examined the impact of this rule as required by Executive Orders 12866, 13563, and 14094, which 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). This rule is considered a "significant regulatory action" under section 3(f) of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or 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 regulation involves collections previously approved by OMB under control number 0694-0088, Simplified Network Application Processing System, which includes, among other things, license applications and commodity classifications, and carries a burden estimate of 29.4 minutes for a manual or electronic submission for a total burden estimate of 35,739 hours. Total burden hours associated with the PRA and OMB control number 0694-0088 are expected to decrease as a

result of this rule. This rule is expected to decrease the licensing burden by approximately 1,200 licenses per year; this will result in an overall reduction in burden house by almost 588 hours per year, for a new total burden estimate of 35,151 hours.

3. This rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to section 1762 of the Export Control Reform Act of 2018, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq*., are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects

15 CFR Part 738

Exports.

15 CFR Part 740

Administrative practice and procedure, Exports, and Reporting and recordkeeping requirements.

15 CFR Part 742

Exports and Terrorism.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, parts 738, 740, 742, and 774 of the Export Administration Regulations (15 CFR parts 730-774) is amended as follows:

PART 738 – COMMERCE CONTROL LIST OVERVIEW AND THE COUNTRY CHART

1. The authority citation for 15 CFR part 738 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 et seq.; 50 U.S.C. 1701 et seq.; 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 et seq.; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 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.

2. In supplement no. 1 to part 738, the table is amended by revising the entries for Austria, Finland, Ireland, Korea, South, Liechtenstein, Sweden, and Switzerland. The revisions read as follows:

Supplement No. 1 to Part 738—Commerce Country Chart

* * * * *

	Commerce Country Chart															
Countries	**Chemical & Biological Weapons**			**Nuclear Nonproliferation**		**National Security**		**Missile Tech**	**Regional Stability**		**Firearms Convention**	**Crime Control**			**Anti-Terrorism**	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
	*		*	*	*		*									
Austria[3 4]	X					X		X	X							
	*		*	*	*		*									
Finland[3 4]	X					X		X	X							
	*		*	*	*		*									
Ireland[3 4]	X					X		X	X							

	*		*		*		*		*							
Korea, South[3] [4]	X					X		X	X							
	*		*		*		*		*							
Liechtenstein[5]	X					X		X	X							
	*		*		*		*		*							
Sweden[3] [4]	X					X		X	X							
Switzerland[3] [4]	X					X		X	X							
	*		*		*		*		*							

* * * * *

[3] See § 742.6(a)(3) for special provisions that apply to "military commodities" that are subject to ECCN 0A919.

[4] See § 742.6(a)(2) and (4)(ii) regarding special provisions for exports and reexports of certain thermal imaging cameras to these countries.

[5] Refer to Switzerland for licensing requirements for Liechtenstein under the EAR.

* * * * *

PART 740 – LICENSE EXCEPTIONS

3. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4801-4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

4. Amend § 740.20 by removing and reserving paragraph (b)(2)(vi).

PART 742 – CONTROL POLICY—CCL BASED CONTROLS

5. The authority citation for part 742 continues to read as follows:

Authority: 50 U.S.C. 4801-4852; 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11,

117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003-23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 8, 2022, 87 FR 68015 (November 10, 2022).

6. Amend § 742.2 by revising paragraph (a) to read as follows:

§ 742.2 Proliferation of chemical and biological weapons.

(a) *License requirements.* The following controls are maintained in support of the U.S. foreign policy of opposing the proliferation and illegal use of chemical and biological weapons. (See also § 742.18 of this part for license requirements pursuant to the Chemical Weapons Convention).

(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:

(i) Toxins identified in ECCNs 1C351.d.14 and .15;

(ii) Genetic elements (ECCN 1C353) of the toxins described in paragraph (a)(1)(i) of this section; and

(iii) Technology (ECCNs 1E001 and 1E351) for the production and/or disposal of toxins described in paragraph (a)(1)(i) of this section.

(2) If CB Column 2 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 except countries in Country Group A:3 (see supplement no. 1 to part 740 of the EAR) (Australia Group members) for the following:

(i) Chemicals identified in ECCN 1C350 (precursor and intermediate chemicals used in the production of chemical warfare agents).

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

(B) This licensing requirement does not include chemical compounds created with any chemicals identified in ECCN 1C350, unless those compounds are also identified in ECCN 1C350.

(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.

(ii) Human pathogens, zoonoses, toxins, animal pathogens, genetically modified microorganisms and plant pathogens identified in ECCNs 1C351 (except .d.14 and .15), 1C353 (except genetic elements of toxins in ECCN 1C351.d.14 and .15), and 1C354; and

(iii) Software (ECCN 1D390) for process control that is specifically configured to control or initiate production of the chemical precursors controlled by ECCN 1C350.

(iv) Technology (ECCN 1E001) for the development or production of chemical detection systems and dedicated detectors therefore, controlled by ECCN 1A004.c, that also have the technical characteristics described in ECCN 2B351.a.

(v) Technology (ECCNs 1E001 and 1E350) involving the following for facilities designed or intended to produce chemicals described in 1C350:

(A) Overall plant design;

(B) Design, specification, or procurement of equipment;

(C) Supervision of construction, installation, or operation of complete plant or components thereof;

(D) Training of personnel; or

(E) Consultation on specific problems involving such facilities.

(vi) Technology (ECCNs 1E001 and 1E351) for:

(A) Production and/or disposal of chemical precursors described in ECCN 1C350; and

(B) Production and/or disposal of microbiological commodities described in paragraph (a)(2)(ii) of this section (except toxins and genetic elements of those toxins in ECCN 1C351.d.14 and .15).

(vii) Equipment and materials identified in ECCN 2B350 or 2B351 on the CCL, chemical detection systems controlled by 1A004.c for detecting chemical warfare agents and having the characteristics of toxic gas monitoring systems described in 2B351.a, and valves controlled by ECCN 2A226 having the characteristics of those described in 2B350.g, which can be used in the production of chemical weapons precursors or chemical warfare agents.

(viii) Equipment and materials identified in ECCN 2B352, which can be used in the production of biological agents.

(ix) Software identified in ECCN 2D351 or 2D352, as follows:

(A) Dedicated software identified in ECCN 2D351 for the “use” of toxic gas monitoring systems and their dedicated detecting components controlled by ECCN 2B351;

(B) Software designed for nucleic acid assemblers and synthesizers controlled by 2B352.j that is capable of designing and building functional genetic elements from digital sequence data.

(x) Technology identified in ECCN 2E001 for the "development" of software controlled by ECCN 2D351 or 2D352.

(xi) Technology identified in ECCN 2E001, 2E002, or 2E301 for:

(A) The development, production, or use of items controlled by ECCN 2B350, 2B351, or 2B352; or

(B) The development or production of valves controlled by ECCN 2A226 having the characteristics of those described in ECCN 2B350.g.

(xii) Technology identified in ECCN 2E201 or 2E290 for the use of valves controlled by ECCN 2A226 having the characteristics of those described in 2B350.g.

(3) If CB Column 3 of the Country Chart (supplement no. 1 to part 738 of the EAR) is indicated in the appropriate ECCN, a license is required to Country Group D:3 (see supplement no. 1 to part 740 of the EAR) for medical products identified in ECCN 1C991.c.

(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.

* * * * *

PART 774 – THE COMMERCE CONTROL LIST

7. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. 4801-4852; 50 U.S.C. 4601 et seq.; 50 U.S.C. 1701 et seq.; 10 U.S.C. 8720; 10 U.S.C. 8730(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 42 U.S.C. 2139a; 15 U.S.C. 1824; 50 U.S.C. 4305; 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.

Supplement No. 1 to part 774 – The Commerce Control List

8. Category 1 is amended by revising ECCNs 1C351, 1C353, 1C354, 1E001, and 1E351 to read as follows:

Category 1 – Materials, Chemicals, Microorganisms and Toxins

C. "MATERIALS"

* * * * *

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

License Requirements

Reason for Control: CB, CW, AT

Control(s)	**Country chart (See Supp. No. 1 to part 738)**
CB applies to items controlled by 1C351.d.14 and .15	CB Column 1
CB applies to entire entry	CB Column 2

CW applies to 1C351.d.14 and .d.15 and a license is required for CW reasons for all destinations, including Canada, as follows: CW applies to 1C351.d.14 for ricin in the form of (1) Ricinus communis AgglutininII (RCA_{II}), also known as ricin D or Ricinus Communis LectinIII (RCL_{III}) and (2) Ricinus communis LectinIV (RCL_{IV}), also known as ricin E. CW applies to 1C351.d.15 for saxitoxin identified by C.A.S. #35523-89-8. See § 742.18 of the EAR for licensing information pertaining to chemicals subject to restriction pursuant to the Chemical Weapons Convention (CWC). The Commerce Country Chart is not designed to determine licensing requirements for items controlled for CW reasons.

Control(s)	**Country chart (See Supp. No. 1 to part 738)**
AT applies to entire entry	AT Column 1

LICENSE REQUIREMENT NOTES: *1. All vaccines and 'immunotoxins' are excluded from the scope of this entry. Certain medical products and diagnostic and food testing kits that contain biological toxins controlled under 1C351.d, with the exception of toxins controlled for CW reasons under 1C351.d.14 or .d.15, are excluded from the scope of this entry. Vaccines, 'immunotoxins,' certain medical products, and diagnostic and food testing kits excluded from the scope of this entry are controlled under ECCN 1C991.*

2. For the purposes of this entry, only saxitoxin is controlled under 1C351.d.15; other members of the paralytic shellfish poison family (e.g., neosaxitoxin) are designated EAR99.

3. Clostridium perfringens strains, other than the epsilon toxin-producing strains of Clostridium perfringens described in 1C351.c.12, are excluded from the scope of this entry, since they may be used as positive control cultures for food testing and quality control.

4. Unless specified elsewhere in this ECCN 1C351 (e.g., in License Requirement Notes 1-3), this ECCN controls all biological agents and "toxins," regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including small quantities or attenuated strains of select biological agents or "toxins" that are excluded from the lists of select biological agents or "toxins" by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS), in accordance with their regulations in 9 CFR part 121 and 42 CFR part 73, respectively.

5. Biological agents and pathogens are controlled under this ECCN 1C351 when they are an isolated live culture of a pathogen agent, or a preparation of a toxin agent that has been isolated or extracted from any source or material, including living material that has been deliberately inoculated or contaminated with the agent. Isolated live cultures of a pathogen agent include live cultures in dormant form or in dried preparations, whether the agent is natural, enhanced or modified.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) Certain forms of ricin and saxitoxin in 1C351.d.14 and .d.15 are CWC Schedule 1 chemicals (see § 742.18 of the EAR). The U.S. Government must provide advance notification and annual reports to the OPCW of all exports of Schedule 1 chemicals. See § 745.1 of the EAR for notification procedures. See 22 CFR part 121, Category XIV and § 121.7 for CWC Schedule 1 chemicals that are "subject to the ITAR." (2) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (for APHIS, see 7 CFR 331.3(b), 9 CFR 121.3(b), and 9 CFR 121.4(b); for CDC, see 42 CFR 73.3(b) and 42 CFR 73.4(b)). (3) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are "subject to the ITAR."

Related Definitions: For the purposes of this entry, 'immunotoxins' are monoclonal antibodies linked to a toxin with the intention of destroying a specific target cell while leaving adjacent cells intact.

Items:

a. Viruses identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows:

a.1. African horse sickness virus;

a.2. African swine fever virus;

a.3. Andes virus;

a.4. Avian influenza (AI) viruses identified as having high pathogenicity (HP), as follows:

a.4.a. AI viruses that have an intravenous pathogenicity index (IVPI) in 6-week-old chickens greater than 1.2; *or*

a.4.b. AI viruses that cause at least 75% mortality in 4- to 8-week-old chickens infected intravenously.

Note: *Avian influenza (AI) viruses of the H5 or H7 subtype that do not have either of the characteristics described in 1C351.a.4 (specifically, 1C351.a.4.a or .a.4.b) should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0). If the amino acid motif is similar to that observed for other HPAI isolates, then the isolate being tested should be considered as HPAI and the virus is controlled under 1C351.a.4.*

a.5. Bluetongue virus;

a.6. Chapare virus;

a.7. Chikungunya virus;

a.8. Choclo virus;

a.9. Classical swine fever virus (Hog cholera virus);

a.10. Crimean-Congo hemorrhagic fever virus;

a.11. Dobrava-Belgrade virus;

a.12. Eastern equine encephalitis virus;

a.13. Ebolavirus (includes all members of the Ebolavirus genus);

a.14. Foot-and-mouth disease virus;

a.15. Goatpox virus;

a.16. Guanarito virus;

a.17. Hantaan virus;

a.18. Hendra virus (Equine morbillivirus);

a.19. Japanese encephalitis virus;

a.20. Junin virus;

a.21. Kyasanur Forest disease virus;

a.22. Laguna Negra virus;

a.23. Lassa virus;

a.24. Louping ill virus;

a.25. Lujo virus;

a.26. Lumpy skin disease virus;

a.27. Lymphocytic choriomeningitis virus;

a.28. Machupo virus;

a.29. Marburgvirus (includes all members of the Marburgvirus genus);

a.30. Middle East respiratory syndrome-related coronavirus (MERS-related coronavirus);

a.31. Monkeypox virus;

a.32. Murray Valley encephalitis virus;

a.33. Newcastle disease virus;

a.34. Nipah virus;

a.35. Omsk hemorrhagic fever virus;

a.36. Oropouche virus;

a.37. Peste-des-petits ruminants virus;

a.38. Porcine Teschovirus;

a.39. Powassan virus;

a.40. Rabies virus and all other members of the Lyssavirus genus;

a.41. Reconstructed 1918 influenza virus;

Technical Note: *1C351.a.41 includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments*.

a.42. Rift Valley fever virus;

a.43. Rinderpest virus;

a.44. Rocio virus;

a.45. Sabia virus;

a.46. Seoul virus;

a.47. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);

a.48. Sheeppox virus;

a.49. Sin Nombre virus;

a.50. St. Louis encephalitis virus;

a.51. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);

a.52. Swine vesicular disease virus;

a.53. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus - see 1C351.b.3 for Siberian subtype);

a.54. Variola virus;

a.55. Venezuelan equine encephalitis virus;

a.56. Vesicular stomatitis virus;

a.57. Western equine encephalitis virus; *or*

a.58. Yellow fever virus.

b. Viruses identified on the APHIS/CDC "select agents" lists (see Related Controls paragraph #2 for this ECCN), but not identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows:

b.1. [Reserved];

b.2. [Reserved]; *or*

b.3. Tick-borne encephalitis virus (Siberian subtype, formerly West Siberian virus - see 1C351.a.53 for Far Eastern subtype).

c. Bacteria identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows:

c.1. Bacillus anthracis;

c.2. Brucella abortus;

c.3. Brucella melitensis;

c.4. Brucella suis;

c.5. Burkholderia mallei (Pseudomonas mallei);

c.6. Burkholderia pseudomallei (Pseudomonas pseudomallei);

c.7. Chlamydia psittaci (Chlamydophila psittaci);

c.8. Clostriduim argentinense (formerly known as Clostridium botulinum Type G), botulinum neurotoxin producing strains;

c.9. Clostridium baratii, botulinum neurotoxin producing strains;

c.10. Clostridium botulinum;

c.11. Clostridium butyricum, botulinum neurotoxin producing strains;

c.12. Clostridium perfringens, epsilon toxin producing types;

c.13. Coxiella burnetii;

c.14. Francisella tularensis;

c.15. Mycoplasma capricolum subspecies capripneumoniae ("strain F38");

c.16. Mycoplasma mycoides subspecies mycoides SC (small colony) (a.k.a. contagious bovine pleuropneumonia);

c.17. Rickettsia prowazekii;

c.18. Salmonella enterica subspecies enterica serovar Typhi (Salmonella typhi);

c.19. Shiga toxin producing Escherichia coli (STEC) of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups;

Note: *Shiga toxin producing Escherichia coli (STEC) includes, inter alia, enterohaemorrhagic E. coli (EHEC), verotoxin producing E. coli (VTEC) or verocytotoxin producing E. coli (VTEC).*

c.20. Shigella dysenteriae;

c.21. Vibrio cholerae; *or*

c.22. Yersinia pestis.

d. "Toxins" identified on the Australia Group (AG) "List of Human and Animal Pathogens and Toxins for Export Control," as follows, or their subunits:

d.1. Abrin;

d.2. Aflatoxins;

d.3. Botulinum toxins;

d.4. Brevetoxins;

d.5. Clostridium perfringens alpha, beta 1, beta 2, epsilon and iota toxins;

d.6. Conotoxins;

d.7. Diacetoxyscirpenol;

d.8. Gonyautoxins;

d.9. HT-2 toxin;

d.10. Microcystins (Cyanginosins);

d.11. Modeccin;

d.12. Nodularins;

d.13. Palytoxin;

d.14. Ricin;

d.15. Saxitoxin;

d.16. Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);

d.17. Staphylococcus aureus enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as Staphylococcus enterotoxin F);

d.18. T-2 toxin;

d.19. Tetrodotoxin;

d.20. Viscumin (Viscum album lectin 1); *or*

d.21. Volkensin.

e. “Fungi”, as follows:

e.1. Coccidioides immitis; *or*

e.2. Coccidioides posadasii.

* * * * *

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

License Requirements

Reason for Control: CB, AT

Control(s)	**Country Chart (See Supp. No. 1 to part 738)**
CB applies to genetic elements of items controlled by 1C351.d.14 and .15	CB Column 1
CB applies to entire entry	CB Column 2
AT applies to entire entry	AT Column 1

License Requirements Notes:

1. Vaccines that contain genetic elements or genetically modified organisms identified in this ECCN are controlled by ECCN 1C991.

2. Unless specified elsewhere in this ECCN 1C353 (e.g., in License Requirement Note 1), this ECCN controls genetic elements or genetically modified organisms for all biological agents and “toxins,” regardless of quantity or attenuation, that are identified in the List of Items Controlled for

this ECCN, including genetic elements or genetically modified organisms for attenuated strains of select biological agents or "toxins" that are excluded from the lists of select biological agents or "toxins" by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, in accordance with the APHIS regulations in 7 CFR part 331 and 9 CFR part 121 and the CDC regulations in 42 CFR part 73.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, and the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, maintain controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN, including (but not limited to) certain genetic elements, recombinant nucleic acids, and recombinant organisms associated with the agents or toxins in ECCN 1C351 or 1C354 (for APHIS, see 7 CFR 331.3(c), 9 CFR 121.3(c), and 9 CFR 121.4(c); for CDC, see 42 CFR 73.3(c) and 42 CFR 73.4(c)). (2) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are subject to the export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.

Related Definition: N/A

Items:

a. Any genetically modified organism that contains, or any genetic element that codes for, any of the following:

a.1. Any gene, genes, translated product or translated products specific to any virus controlled by 1C351.a or .b or 1C354.c;

a.2. Any gene or genes specific to any bacterium controlled by 1C351.c or 1C354.a, or any fungus controlled by 1C351.e or 1C354.b, and which;

a.2.a. In itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health; *or*

a.2.b. Could endow or enhance pathogenicity; *or*

a.3. Any toxins, or their subunits, controlled by 1C351.d.

b. [Reserved].

Technical Notes:

1. Genetically modified organisms include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation.

2. “Genetic elements” include, inter alia, chromosomes, genomes, plasmids, transposons, vectors, and inactivated organisms containing recoverable nucleic acid fragments, whether genetically modified or unmodified, or chemically synthesized in whole or in part. For the purposes of this ECCN 1C353, nucleic acids from an inactivated organism, virus, or sample are considered to be ‘recoverable’ if the inactivation and preparation of the material is intended or known to facilitate isolation, purification, amplification, detection, or identification of nucleic acids.

3. This ECCN does not control nucleic acid sequences of shiga toxin producing Escherichia coli of serogroups O26, O45, O103, O104, O111, O121, O145, O157, and other shiga toxin producing serogroups, other than those genetic elements coding for shiga toxin, or for its subunits.

4. ‘Endow or enhance pathogenicity’ is defined as when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism's ability to be

used to deliberately cause disease or death. This might include alterations to, *inter alia*: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability.

* * * * *

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

License Requirements

Reason for Control: CB, AT

Control(s)	**Country Chart (See Supp. No. 1 to part 738)**
CB applies to entire entry	CB Column 2
AT applies to entire entry	AT Column 1

***License Requirements Notes*:**

1. All vaccines are excluded from the scope of this ECCN. See ECCN 1C991 for vaccines.

2. Unless specified elsewhere in this ECCN 1C354 (e.g., in License Requirement Note 1), this ECCN controls all biological agents, regardless of quantity or attenuation, that are identified in the List of Items Controlled for this ECCN, including small quantities or attenuated strains of select biological agents that are excluded from the list of PPQ select agents and "toxins" by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, in accordance with their regulations in 7 CFR part 331.

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A

GBS: N/A

List of Items Controlled

Related Controls: (1) The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, maintains controls on the possession, use, and transfer within the United States of certain items controlled by this ECCN (see 7 CFR 331.3(c), 9 CFR 121.3(c), and 9 CFR 121.4(c)). (2) See 22 CFR part 121, Category XIV(b), for modified biological agents and biologically derived substances that are subject to the export licensing jurisdiction of the U.S. Department of State, Directorate of Defense Trade Controls.

Related Definitions: N/A

Items:

a. Bacteria, as follows:

a.1. *Xanthomonas albilineans*;

a.2. *Xanthomonas citri pv. citri (Xanthomonas axonopodis* pv. *citri, Xanthomonas campestris* pv. *citri)*;

a.3. *Xanthomonas oryzae* [this species of proteobacteria is identified on the APHIS "select agents" list (see Related Controls paragraph for this ECCN), but only the pathovar *Xanthomonas oryzae* pv. *oryzae* (syn. *Pseudomonas campestris* pv. *oryzae*) is identified on the Australia Group (AG) "List of Plant Pathogens for Export Control"];

a.4. *Clavibacter michiganensis* subsp. *sepedonicus* (*Clavibacter sepedonicus*, *Clavibacter michiganense* subsp. *sepedonicus*, *Corynebacterium michiganensis* subsp. *sepedonicum*, *Corynebacterium sepedonicum*);

a.5. *Ralstonia solanacearum*, race 3, biovar 2;

a.6. *Raythayibactor toxicus* [this bacterium is identified on the APHIS "select agents" list (see the Related Controls paragraph for this ECCN), but is not identified on the Australia Group (AG) "List of Plant Pathogens for Export Control"].

b. Fungi, as follows:

b.1. *Bipolaris oryzae* (*Cochliobolus miyabeanus*, *Helminthosporium oryzae*);

b.2. *Colletotrichum kahawae* (*Colletotrichum coffeanum* var. *virulans*);

b.3. *Pseudocercospora ulei* (*Microcyclus ulei, Dothidella ulei*);

b.4. *Puccinnia graminis* ssp. *graminis* var. *graminis/Puccinia graminis* ssp. *graminis* var. *stakmanii* (*Puccinia graminis* [syn. *Puccinia graminis* f. sp. *tritici*]);

b.5. *Puccinia striiformis* (syn. *Puccinia glumarum*);

b.6. *Magnaporthe oryzae* (Pyricularia oryzae);

b.7. *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*);

b.8. *Sclerophthora rayssiae* var. *zeae*;

b.9. *Synchytrium endobioticum*;

b.10. *Tilletia indica*;

b.11. *Thecaphora solani*;

b.12. *Phoma glycinicola* (formerly *Pyrenochaeta glycines*) [this fungus is identified on the APHIS "select agents" list (see the Related Controls paragraph for this ECCN), but is not identified on the Australia Group (AG) "List of Plant Pathogens for Export Control"].

c. Viruses, as follows:

c.1. Andean potato latent virus (Potato Andean latent tymovirus);

c.2. Potato spindle tuber viroid.

* * * * *

E. "TECHNOLOGY"

* * * * *

1E001 "Technology" according to the General Technology Note for the "development" or "production" of items controlled by 1A002, 1A003, 1A004, 1A005, 1A006.b, 1A007, 1A008 1A101, 1A231, 1B (except 1B608, 1B613 or 1B999), or 1C (except 1C355, 1C608, 1C980 to 1C984, 1C988, 1C990, 1C991, 1C995 to 1C999).

License Requirements

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

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
NS applies to "technology" for items controlled by 1A002, 1A003, 1A005, 1A006.b, 1A007, 1B001 to 1B003, 1B018, 1C001 to 1C011, or 1C018	NS Column 1.
NS applies to "technology" for items controlled by 1A004	NS Column 2.

MT applies to “technology” for items controlled by 1A101, 1B001, 1B101, 1B102, 1B115 to 1B119, 1C001, 1C007, 1C011, 1C101, 1C102, 1C107, 1C111, 1C116, 1C117, or 1C118 for MT reasons	MT Column 1.
NP applies to “technology” for items controlled by 1A002, 1A007, 1A231, 1B001, 1B101, 1B201, 1B225, 1B226, 1B228 to 1B234, 1C002, 1C010, 1C111, 1C116, 1C202, 1C210, 1C216, 1C225 to 1C237, or 1C239 to 1C241 for NP reasons	NP Column 1.
CB applies to “technology” for items controlled by 1C351.d.14 and .15 and the 1C353 genetic elements of toxins in ECCN 1C351.d.14 and .15	CB Column 1.
CB applies to “technology” for items controlled by 1C351, 1C353, or 1C354; and CB applies to “technology” for materials controlled by 1C350	CB Column 2.

and for chemical detection systems and dedicated detectors therefor, in 1A004.c, that also have the technical characteristics described in 2B351.a	
RS applies to technology for equipment controlled in 1A004.d	RS Column 2.
AT applies to entire entry	AT Column 1.

Reporting Requirements

See § 743.1 of the EAR for reporting requirements for exports under License Exceptions, and Validated End-User authorizations.

List Based License Exceptions (See Part 740 for a description of all license exceptions)

TSR: Yes, except for the following:

1) Items controlled for MT reasons; or

2) Exports and reexports to destinations outside of those countries listed in Country Group A:5 (See Supplement No. 1 to part 740 of the EAR) of "technology" for the "development" or production" of the following:

(a) Items controlled by 1C001; or

(b) Items controlled by 1A002.a which are composite structures or laminates having an organic "matrix" and being made from materials listed under 1C010.c or 1C010.d.

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit "technology" according to the General Technology Note for the "development" or "production" of equipment and materials specified by ECCNs 1A002, 1C001, 1C007.c , 1C010.c or d or 1C012 to any of the destinations listed in Country Group A:6 (See Supplement No.1 to part 740 of the EAR).

List of Items Controlled

Related Controls (1) Also see ECCNs 1E101, 1E201, and 1E202. (2) See ECCN 1E608 for "technology" for items classified under ECCN 1B608 or 1C608 that, immediately prior to July 1, 2014, were classified under ECCN 1B018.a or 1C018.b through .m (note that ECCN 1E001 controls "development" and "production" "technology" for chlorine trifluoride controlled by ECCN 1C111.a.3.f – see ECCN 1E101 for controls on "use" "technology" for chlorine trifluoride). (3) See ECCN 1E002.g for control libraries (parametric technical databases) "specially designed" or modified to enable equipment to perform the functions of equipment controlled under ECCN 1A004.c (Nuclear, biological and chemical (NBC) detection systems) or ECCN 1A004.d (Equipment for detecting or identifying explosives residues). (4) "Technology" for lithium isotope separation (see related ECCN 1B233) and "technology" for items described in ECCN 1C012 are subject to the export licensing authority of the Department of Energy (see 10 CFR part 810). (5) "Technology" for items described in ECCN 1A102 is "subject to the ITAR" (see 22 CFR parts 120 through 130).

Related Definitions: N/A

Items:

The list of items controlled is contained in the ECCN heading.

* * * * *

1E351 "Technology" according to the "General Technology Note" for the disposal of chemicals or microbiological materials controlled by 1C350, 1C351, 1C353, or 1C354.

License Requirements

Reason for Control: CB, AT

Control(s)	*Country Chart (See Supp. No. 1 to part 738)*
CB applies to "technology" for the disposal of items controlled by 1C351.d.14 and .15 and the 1C353 genetic elements of toxins in ECCN 1C351.d.14 and .15	CB Column 1
CB applies to "technology" for the disposal of items controlled by 1C351, 1C353, or 1C354; and CB applies to "technology" for the disposal of items controlled by 1C350	CB Column 2

AT applies to entire entry	AT Column 1

List Based License Exceptions (See Part 740 for a description of all license exceptions)

TSR: N/A

List of Items Controlled

Related Controls: N/A

Related Definitions: N/A

Items:

The list of items controlled is contained in the ECCN heading.

* * * * *

Thea D. Rozman Kendler

Assistant Secretary for Export Administration

[FR Doc. 2023-26532 Filed: 12/7/2023 8:45 am; Publication Date: 12/8/2023]