

ECCN DETAILS

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You selected ECCN **1C351** for Commerce Control List details.

*For this HTML, tabular columns are approximated with fixed spaces.
We regret some horizontal alignments may not be exact.*

License exception Strategic Trade Authorization (STA) prohibitions or limits apply to this ECCN, or parts of the ECCN, as detailed in License Exceptions below, or as defined in § 740.20(2) or § 740.20(3) for "600 series" items.

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 entire entry CB Column 1

CW applies to 1C351.d.11 and d.12

and a license is required for CW reasons

for all destinations, including Canada,

as follows: CW applies to 1C351.d.11

for ricin in the form of (1) Ricinus

Communis AgglutininII (RCAII), also

known as ricin D or Ricinus Communis

LectinIII (RCLIII) and (2) Ricinus

Communis LectinIV (RCLIV), also known

as ricin E. CW applies to 1C351.d.12

for saxitoxin identified by CAS

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.

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 paragraph (d) of this entry, with the exception of toxins controlled for CW

reasons under d.11 and d.12, 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 paragraph d.12; 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 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, or the Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, 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

CIV: N/A

Special Conditions for STA

STA: (1) Paragraph (c)(1) of License

Exception STA (§ 740.20(c)(1)) may be used for items in 1C351.d.1 through 1C351.d.10 and 1C351.d.13 through 1C351.d.19. See § 740.20(b)(2)(vi) for restrictions on the quantity of any one toxin that may be exported in a single shipment and the number of shipments that may be made to any one end user in a single calendar year. Also see the Automated Export System (AES) requirements in § 758.1(b)(4) of the EAR.

(2) Paragraph (c)(2) of License Exception STA (§ 740.20(c)(2) of the EAR) may not be used for any items in 1C351.

Items Controlled

Related Controls: (1) Certain forms of ricin

and saxitoxin in 1C351.d.11. and d.12 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: (1) For the purposes of
this entry "immunotoxin" is defined as an
antibody-toxin conjugate intended to destroy
specific target cells (e.g., tumor cells) that
bear antigens homologous to the antibody.
(2) For the purposes of this entry "subunit"
is defined as a portion of the "toxin".

Items:

- a. Viruses 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 (HAO).
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. Monkeypox virus;
- a.31. Murray Valley encephalitis virus;
- a.32. Newcastle disease virus;
- a.33. Nipah virus;
- a.34. Omsk hemorrhagic fever virus;
- a.35. Oropouche virus;
- a.36. Peste-des-petits ruminants virus;
- a.37. Porcine Teschovirus;
- a.38. Powassan virus;
- a.39. Rabies virus and all other members of the Lyssavirus genus;
- a.40. Reconstructed 1918 influenza virus;
 Technical Note: 1C351.a.40 includes reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments.
- a.41. Rift Valley fever virus;
- a.42. Rinderpest virus;
- a.43. Rocio virus;
- a.44. Sabia virus;
- a.45. Seoul virus;
- a.46. Severe acute respiratory syndromerelated coronavirus (SARS-related coronavirus);
- a.47. Sheeppox virus;
- a.48. Sin Nombre virus;
- a.49. St. Louis encephalitis virus;
- a.50. Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease);
- a.51. Swine vesicular disease virus;
- a.52. Tick-borne encephalitis virus (Far Eastern subtype, formerly known as Russian Spring-Summer encephalitis virus – see 1C351.b.3 for Siberian subtype);
- a.53. Variola virus;

- a.54. Venezuelan equine encephalitis virus;
- a.55. Vesicular stomatitis virus;
- a.56. Western equine encephalitis virus; or
- a.57. 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.52 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. *Clostridium 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, and "subunits" thereof:
 - d.1. Abrin;
 - d.2. Aflatoxins;
 - d.3. Botulinum toxins;
 - d.4. Cholera toxin;
 - d.5. *Clostridium perfringens* alpha, beta 1, beta 2, epsilon and iota toxins;
 - d.6. Conotoxins;
 - d.7. Diacetoxyscirpenol;
 - d.8. HT-2 toxin;
 - d.9. Microcystins (Cyanginosins);
 - d.10. Modeccin;
 - d.11. Ricin;
 - d.12. Saxitoxin;
 - d.13. Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins);
 - d.14. *Staphylococcus aureus* enterotoxins, hemolysin alpha toxin, and toxic shock syndrome toxin (formerly known as *Staphylococcus enterotoxin F*);
 - d.15. T-2 toxin;
 - d.16. Tetrodotoxin;
 - d.17. Viscumin (*Viscum album* lectin 1); or
 - d.18. Volkensin.
- e. "Fungi", as follows:
 - e.1. *Coccidioides immitis*; or
 - e.2. *Coccidioides posadasii*.