

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. For the purposes of this entry, only saxitoxin is controlled under paragraph d.6; other members of the paralytic shellfish poison family (e.g. neosaxitoxin) are classified as EAR99.

**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, as follows:

- a.1. Chikungunya virus;
- a.2. Congo-Crimean haemorrhagic fever virus;
- a.3. Dengue fever virus;
- a.4. Eastern equine encephalitis virus;
- a.5. Ebola virus;
- a.6. Hantaan virus;
- a.7. Japanese encephalitis virus;
- a.8. Junin virus;
- a.9. Lassa fever virus
- a.10. Lymphocytic choriomeningitis virus;
- a.11. Machupo virus;
- a.12. Marburg virus;
- a.13. Monkey pox virus;
- a.14. Rift Valley fever virus;
- a.15. Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus);
- a.16. Variola virus;
- a.17. Venezuelan equine encephalitis virus;
- a.18. Western equine encephalitis virus;
- a.19. White pox; or
- a.20. Yellow fever virus.

b. Rickettsiae, as follows:

- b.1. Bartonella quintana (Rochalimea quintana, Rickettsia quintana);
- b.2. Coxiella burnetii;
- b.3. Rickettsia prowasecki; or
- b.4. Rickettsia rickettsii.

c. Bacteria, as follows:

- c.1. Bacillus anthracis;
- c.2. Brucella abortus;
- c.3. Brucella melitensis;
- c.4. Brucella suis;
- c.5. Burkholderia mallei (Pseudomonas mallei);
- c.6. Burkholderia pseudomallei (Pseudomonas pseudomallei);
- c.7. Chlamydia psittaci;
- c.8. Clostridium botulinum;
- c.9. Francisella tularensis;
- c.10. Salmonella typhi;
- c.11. Shigella dysenteriae;
- c.12. Vibrio cholerae; or
- c.13. Yersinia pestis.

d. "Toxins", as follows, and "subunits" thereof:

- d.1. Botulinum toxins;
- d.2. Clostridium perfringens toxins;
- d.3. Conotoxin;
- d.4. Microcystin (Cyanginosin);
- d.5. Ricin;
- d.6. Saxitoxin;
- d.7. Shiga toxin;
- d.8. Staphylococcus aureus toxins;
- d.9. Tetrodotoxin;
- d.10. Verotoxin;
- d.11. Aflatoxins;
- d.12. Abrin;
- d.13. Cholera toxin;
- d.14. Diacetoxyscirpenol toxin;
- d.15. T-2 toxin;
- d.16. HT-2 toxin;
- d.17. Modeccin toxin;
- d.18. Volkensin toxin; or
- d.19. Viscum Album Lectin 1 (Viscumin).

8. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, "Microorganisms" & "Toxins," ECCN 1C353 is amended by revising the ECCN heading and the List of Items Controlled to read as follows:

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

\* \* \* \* \*

**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 the pathogenicity of microorganisms 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 "subunits 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 the pathogenicity of microorganisms 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 "subunits of toxins" thereof.

■ 9. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 1—

Materials, Chemicals, "Microorganisms" & "Toxins," ECCN 1C991 is amended by revising the List of Items Controlled to read as follows:

**1C991 Vaccines, immunotoxins, medical products, diagnostic and food testing kits, as follows (see List of Items Controlled).**

\* \* \* \* \*

**List of Items Controlled**

**Unit:** \$ value.

**Related Controls:** Medical products containing ricin or saxitoxin, as follows, are controlled for CW reasons under ECCN 1C351:

- (1) Ricinus Communis Agglutinin<sub>II</sub> (RCA<sub>II</sub>), also known as ricin D, or Ricinus Communis Lectin<sub>III</sub> (RCL<sub>III</sub>);
- (2) Ricinus Communis Lectin<sub>IV</sub> (RCL<sub>IV</sub>), also known as ricin E; or
- (3) Saxitoxin identified by C.A.S.

#35523–89–8.

**Related Definitions:** For the purpose 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. For the purpose of this entry, "medical products" are: (1) pharmaceutical formulations designed for human administration in the treatment of medical conditions, (2) prepackaged for distribution as medical products, and (3) approved by the U.S. Food and Drug Administration to be marketed as medical products. For the purpose of this entry, "diagnostic and food testing kits" are specifically developed, packaged and marketed for diagnostic or public health purposes. Biological toxins in any other configuration, including bulk shipments, or for any other end-uses are controlled by ECCN 1C351. For the purpose of this entry, "vaccine" is defined as a medicinal (or veterinary) product in a pharmaceutical formulation, approved by the U.S. Food and Drug Administration or the U.S. Department of Agriculture to be marketed as a medical (or veterinary) product or for use in clinical trials, that is intended to stimulate a protective immunological response in humans or animals in order to prevent disease in those to whom or to which it is administered.

**Items:**

- a. Vaccines against items controlled by ECCN 1C351, 1C352, 1C353, or 1C354;
- b. Immunotoxins containing items controlled by 1C351.d;
- c. Medical products containing botulinum toxins controlled by ECCN 1C351.d.1;
- d. Medical products containing items controlled by ECCN 1C351.d, except