conspicuous means in a reasonably understandable form and readily noticeable to the consumer. As to type size, disclosures in 12-point type are deemed to be readily noticeable for purposes of § 226.5a. Disclosures printed in less than 12-point type do not automatically violate the standard; however, disclosures in less than 8-point type would likely be too small to satisfy the standard. Disclosures that are transmitted by electronic communication are judged for purposes of the clear and conspicuous standard based on the form in which they are provided even though they may be viewed by the consumer in a different form.

2. *Prominent location.* i. *Generally.* Certain of the required disclosures provided on or with an application or solicitation must be prominently located. Disclosures are deemed to be prominently located, for example, if the disclosures are on the same page as an application or solicitation reply form. If the disclosures appear elsewhere, they are deemed to be prominently located if the application or solicitation reply form contains a clear and conspicuous reference to the location of the disclosures and indicates that they contain rate, fee, and other cost information, as applicable. Disclosures required by § 226.5a(b) that are placed outside the table must begin on the same page as the table but need not end on the same page.

ii. *Electronic disclosures.* Electronic disclosures are deemed to be prominently located if:

A. They are posted on a web site and the application or solicitation reply form is linked to the disclosures in a manner that prevents the consumer from by-passing the disclosures before submitting the application or reply form; or

B. They are located on the same page as an application or solicitation reply form, that contains a clear and conspicuous reference to the location of the disclosures and indicates that they contain rate, fee, and other cost information, as applicable.

* * * * *

5a(b) Required Disclosures

5a(b)(1) Annual Percentage Rate

* * * * *

6. *Introductory rates—premium rates.* If the initial rate is temporary and is higher than the permanently applicable rate, the card issuer must disclose the initial rate in the table. The initial rate must be in at least 18-point type unless the issuer also discloses in the table the permanently applicable rate. The issuer may disclose in the table the permanently applicable rate that would otherwise apply if the issuer also discloses the time period during which the initial rate will remain in effect. In that case, the permanently applicable rate must be in at least 18-point type.

7. *Increased penalty rates.* If the initial rate may increase upon the occurrence of one or more specific events, such as a late payment or an extension of credit that exceeds the credit limit, the card issuer must disclose in the table the initial rate and the increased penalty rate that may apply. If the penalty rate is based on an index and an increased margin, the issuer must also disclose in the table the index and the margin as well as the specific event or events that may result in the increased rate, such as ''applies to accounts 60 days late.'' If the penalty rate cannot be determined at the time disclosures are given, the issuer must provide an explanation of the specific event or events that may result in imposing an increased rate. In describing the specific event or events that may result in an increased rate, issuers need not be as detailed as for the disclosures required under § 226.6(a)(2). For issuers using a tabular format, the specific event or events must be placed outside the table and an asterisk or other means shall be used to direct the consumer to the additional information. At its option, the issuer may include in the explanation of the penalty rate the period for which the increased rate will remain in effect, such as ''until you make three timely payments.'' The issuer need not disclose an increased rate that is imposed when credit privileges are permanently terminated.

* * * * *

Appendices G and H—Open-End and Closed-End Model Forms and Clauses

1. *Permissible changes.* * * * (But see Appendix G comment 5 for special rules concerning certain disclosures required under § 226.5a for credit and charge card applications and solicitations). * * *

* * * * *

APPENDIX G—OPEN-END MODEL FORMS AND CLAUSES

* * * * *

5. Model G–10(A), Sample G–10(B) and Model G–10(C). i. Model G–10(A) and Sample G–10(B) illustrate, in the tabular format, all of the disclosures required under § 226.5a for applications and solicitations for credit cards other than charge cards. Model G–10(B) is a sample disclosure illustrating an account with a lower introductory rate and penalty rate. Model G–10(C) illustrates the tabular format disclosure for charge card applications and solicitations and reflects all of the disclosures in the table.

ii. Except as otherwise permitted, disclosures must be substantially similar in sequence and format to model forms G–10(A) and (C). The disclosures may, however, be arranged vertically or horizontally and need not be highlighted aside from being included in the table. While proper use of the model forms will be deemed in compliance with the regulation, card issuers are permitted to use headings and disclosures other than those in the forms (with an exception relating to the use of ''grace period'') if they are clear and concise and are substantially similar to the headings and disclosures contained in model forms. For further discussion of requirements relating to form, see the commentary to § 226.5a(a)(2).

* * * * *

By order of the Board of Governors of the Federal Reserve System, September 27, 2000.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 00–25316 Filed 10–2–00; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 742 and 774

[Docket No. 000920265–0265–01]

RIN 0694–AC13

Revisions and Clarifications to the Commerce Control List; Chemical and Biological Weapons Controls; Australia Group

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: This final rule amends the Commerce Control List (CCL) of the Export Administration Regulations to implement an October 1999 Australia Group agreement to clarify the scope of controls on saxitoxin, toxic gas monitoring systems, and cross-flow filtration equipment, as well as clarifying the application of the rule for mixtures containing Australia Group (AG) chemicals that are also identified as Schedule 1 chemicals under the Chemical Weapons Convention. The final rule also amends the CCL to authorize, without a license, exports of certain medical products containing botulinum toxin, and certain diagnostic and food testing kits that contain AG-controlled toxins. Finally, this final rule amends the CCL to add titanium carbide and silicon carbide to the list of construction materials for heat exchangers. Restrictions on chemicals and toxins that are also controlled for CW (Chemical Weapons Convention) purposes continue to apply. This rule will result in an overall decreased licensing burden on U.S. industry.

EFFECTIVE DATE: This rule is effective: October 3, 2000.

FOR FURTHER INFORMATION CONTACT: James Seevaratnam, Director, Chemical and Biological Controls Division, Bureau of Export Administration, (202) 501–7900.

SUPPLEMENTARY INFORMATION:

Background

On October 7, 1999, the Bureau of Export Administration (BXA) published a final rule amending the Export Administration Regulations (EAR) to implement the October 1998 Australia Group agreement to amend controls on toxic gas monitoring systems and to amend the CCL to authorize, without a license, exports of medical products containing controlled biological toxins that are developed, packaged and sold for medical treatment.

The Australia Group (AG), a multilateral forum that coordinates export controls to curtail the proliferation of chemical and biological weapons, held its annual consultations in Paris, October 4–8, 1999. The 30 AG participating countries agreed to maintain export controls on a list of chemicals, biological agents, relevant equipment and technology that could be used in the production of chemical or biological weapons. The AG reviews items on its control list periodically to enhance the effectiveness and achieve greater harmonization of participating governments' national controls.

At the October 1999 Australia Group consultations, participants agreed to further revise the control list entry for toxic gas monitoring systems to clarify the scope of controls. To implement this agreement, this final rule amends the Commerce Control List (CCL) of the Export Administration Regulations (EAR) by revising Export Control Classification Number (ECCN) 2B351. Specifically, this rule clarifies that the control of toxic gas monitoring systems under ECCN 2B351 applies only to such systems that operate on line without any requirement for human intervention. The AG agreed that the intent of this control is to control systems capable of detecting toxic gases in environments such as a chemical plant rather than batch-mode operation equipment that is normally used in a laboratory. While not changing the scope of the control in any way, this rule also clarifies the description of cross-flow filtration equipment in ECCN 2B352 by describing it as cross (tangential) flow filtration equipment. In an expansion of controls, the Australia Group agreed to add titanium carbide and silicon carbide to the list of materials describing heat exchangers subject to control in ECCN 2B350.

The Department of Commerce also maintains controls on exports of biological agents that could be used in the production of biological weapons. These materials require a license under ECCN 1C351 for export and reexport for CB (chemical and biological weapons) reasons to all destinations, except Canada. These controls are implemented in accordance with the export control provisions of the Australia Group. Note that two biological agents, ricin and saxitoxin, classified as ECCN 1C351.d.5 and .d.6, respectively, are Schedule 1 chemicals under the Chemical Weapons Convention and are also controlled for CW reasons to all destinations, including Canada.

As agreed by the AG, medical products that contain the AG-controlled botulinum toxin that are pharmaceutical formulations designed for human administration in the treatment of medical conditions have broad medical applications while posing no significant proliferation concerns. Such products are controlled under ECCN 1C991 and may be exported and reexported without a license to all destinations and entities, except terrorist supporting countries (Cuba, Iran, Iraq, Libya, North Korea, Sudan, Syria) and Serbia, and except as provided in Parts 736 and 744 of the EAR. This further liberalization of licensing requirements for the botulinum toxin does not apply if the botulinum toxin is to be exported in any other configuration, including bulk shipments, or for any other end-uses, in which case it is still controlled under ECCN 1C351.

In addition, this final rule further amends ECCN 1C991 to clarify the criteria for defining an item containing botulinum toxin as a medical product when approved by the Food and Drug Administration (FDA) for distribution in interstate commerce as a medical product. Specifically, the medical product must be: (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 Food and Drug Administration to be marketed as medical products.

Further, this rule removes controls on certain diagnostic and food testing kits that contain toxins controlled by the AG. Specifically, this final rule amends ECCN 1C991 to include diagnostic and food testing kits containing AG-controlled toxins controlled under ECCN 1C351. Such testing kits may be exported and reexported without a license to all destinations and entities, except to terrorist supporting countries and Serbia, and except as provided in Parts 736 and 744 of the EAR, when the kits are specifically developed, packaged, and marketed for diagnostic or public health purposes. Diagnostic and food testing kits containing CW-controlled toxins continue to be controlled under ECCN 1C351 to all destinations, including Canada.

This rule clarifies that the scope of AG-controls on saxitoxin under 1C351.d.6 applies only to saxitoxin and not the entire family of paralytic shellfish poisons (*e.g.*, neosaxitoxin) which, other than saxitoxin, are classified under EAR99. This rule also clarifies the forms of saxitoxin and ricin that are controlled for CW reasons under ECCN 1C351.

Finally, the AG agreed to the development of a rounding rule for mixtures that contain trace and unintended quantities of AG-controlled chemicals that are also on CWC Schedule 1 listed in ECCN 1C350. The United States is providing a ''round to zero'' rule for Schedule 1 chemicals similar to that agreed by the AG. This rule, currently set forth in section 712.1 of the Chemical Weapons Convention Regulations, is now added to the note under 1C350 on mixtures. The licensing requirements do not apply to mixtures containing less than 0.5% aggregate quantities of Schedule 1 chemicals as unavoidable by-products or impurities, and the Schedule 1 chemicals are not intentionally produced or added.

Exporters are reminded that although license requirements have been removed for shipments of the medical products and test kits for CB reasons as described above, these items continue to require a license under 1C991 for export or reexport to terrorist supporting and embargoed destinations and entities. Exporters may also need to consult with the Department of the Treasury's Office of Foreign Assets Control, which administers economic sanctions against certain countries and entities, including the Taliban controlled areas of Afghanistan.

Although the EAA expired on August 20, 1994, the President invoked the International Emergency Economic Powers Act and continued in effect the Export Administration Regulations and, to the extent permitted by law, the provisions of the EAA in Executive Order 12924 of August 19, 1994, as extended by the President's notices of August 15, 1995 (60 FR 42767), August 14, 1996 (61 FR 42527), August 13, 1997 (62 FR 43629), August 13, 1998 (63 FR 44121), August 10, 1999 (64 FR 44101) and August 8, 2000 (65 FR 48347).

Rulemaking Requirements

1. This final 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 Office of Management and Budget Control Number. This rule involves a collection of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control numbers 0694–0088, ''Multi-Purpose Application,'' which carries a burden hour estimate of 45 minutes for a

manual submission and 40 minutes for an electronic submission.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Kirsten Mortimer, Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects in 15 CFR Parts 742 and 774

Exports, foreign trade.

Accordingly, 15 CFR Chapter 7, Subchapter C, is amended as follows:

1. The authority citation for 15 CFR part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 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. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of November 12, 1998, 63 FR 63589, 3 CFR, 1998 Comp., p. 305; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

2. The authority citation for 15 CFR part 774 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*, 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

PART 742—[AMENDED]

3. Section 742.18 is amended by revising paragraph (a)(1) as follows:

§ 742.18 Chemical Weapons Convention (CWC or Convention)

* * * * *

(a) * * *

(1) Schedule 1 chemicals identified in ECCNs 1C350 and 1C351. A license is required for CW reasons for exports and reexports of Schedule 1 chemicals identified under ECCN 1C350.a.20, a.24, and a.31 and ECCN 1C351.d.5 and d.6 to all destinations *including* Canada. CW applies to 1C351.d.5 for ricin in the form of Ricinus Communis Agglutinin $_{II}$ (RCA_{II}), also known as ricin D or Ricinus Communis Lectin $_{III}$ (RCL_{III}); and Ricinus Communis Lectin $_{IV}$ (RCL_{IV}), also known as ricin E. CW applies to 1C351.d.6 for saxitoxin identified by C.A.S. #35523–89–8. Also see the advance notification procedures and annual reporting requirements described in § 745.1 of the EAR.

* * * * *

PART 774—[AMENDED]

4. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, ''Microorganisms,'' and ''Toxins'', Export Control Classification Numbers (ECCNs) are amended:

a. By revising the License Requirements section for ECCN 1C350;

b. By revising ECCN 1C351; and

c. By revising ECCN 1C991, 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.2, a.3, a.5, a.6, a.7, a.8, a.10, a.11, a.12, a.13, a.15, a.16, a.17, a.20, a.21, a.22, a.23, a.24, a.28, a.29, a.30, a.31, a.32, a.33, a.35, a.37, a.41, a.47, a.48, a.49, a.50, a.51, a.53, or a.54. For 1C350.a.20, a.24 and a.31, a license is required for CW reasons for all destinations, including Canada. For all other chemicals controlled for CW reasons, a license is a required for export to countries not listed in Supplement No. 2 to part 745, except for Schedule 3 chemicals which do not require a license for CW reasons if an End-Use Certificate has been obtained from the government of the importing country. See § 742.18 of the EAR. Also, see § 745.2 of the EAR for End-Use Certificate requirements. 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. *SAMPLE SHIPMENTS:* Certain sample shipments of chemicals controlled under ECCN 1C350 may be made without a license, as provided by the following:

a. *Chemicals Not Eligible:* No CWC Schedule 1 chemical is eligible for sample shipment without a license. Therefore, the following chemicals are *not* eligible for sample shipments: 0-Ethyl-2-diisopropylaminoethyl methylphosphonite (QL) (C.A.S. #57856–11–8), Ethylphosphonyl difluoride (C.A.S. #753–98–0), and Methylphosphonyl difluoride (C.A.S. #676–99–3).

b. *Countries Not Eligible:* The following countries are not eligible to receive any sample shipments: Cuba, Iran, Iraq, Libya, North Korea, Sudan, Syria.

c. *Sample Shipments:* 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 each chemical to any one consignee per calendar year. Multiple sample shipments, in any quantity, not exceeding the totals indicated in this paragraph may be exported without a license, in accordance with the provisions of this Note 1. 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. However, a sample shipment exported and received under this exclusion remains subject to all General Prohibitions including the end-use restriction described in § 744.4 of the EAR. Sample shipments of chemicals included in CWC Schedule 2 and controlled for CW reasons to non-CWC States Parties (destinations not listed in Supplement No. 2 to part 745 of the EAR) may not be made without a license. Sample shipments of chemicals listed in Schedule 3 and controlled for CW reasons to non-States Parties may not be made without first obtaining an End-Use Certificate, as described in § 745.2 of the EAR. If no End-Use Certificate is obtained pursuant to § 745.2 of the EAR, a license is required for sample shipments to non-

CWC States Parties of Schedule 3 chemicals controlled under ECCN 1C350 for CW reasons.

d. 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 Export Administration, P.O. Box 273, Washington, DC 20044, Attn: ''Report of Sample Shipments of Chemical Precursors''.

2. *MIXTURES:* Mixtures controlled by this entry that contain certain concentrations of precursor and intermediate chemicals are subject to the following licensing requirements:

a. A license is required, regardless of the concentrations in the mixture, for the following chemicals: 0-Ethyl-2-diisopropylaminoethyl methylphosphonite (QL) (C.A.S.#57856–11–8), Ethylphosphonyl difluoride (C.A.S.#753–98–0) and Methylphosphonyl difluoride (C.A.S.#676–99–3), unless the mixture contains less than 0.5% aggregate quantities of Schedule 1 chemicals as unavoidable by-products or impurities, and the Schedule 1 chemicals are not intentionally produced or added.

b. A license is required when at least one of the following chemicals constitutes more than 10 percent of the weight of the mixture: Arsenic trichloride (C.A.S.#7784–34–1), Benzilic acid (C.A.S.#76–93–7), Diethyl ethylphosphonate (C.A.S.#78–38–6), Diethyl methylphosphonite (C.A.S.#15715–41–0),Diethyl-N,N-dimethylphosphoroamidate (C.A.S.#2404–03–7), N,N-Diisopropyl-beta-aminoethane thiol (C.A.S.#5842–07–9), N,N-Diisopropyl-2-aminoethyl chloride hydrochloride (C.A.S.#4261–68–1), N,N-Diisopropyl-beta-aminoethanol (C.A.S.#96–80–0), N,N-Diisopropyl-beta-aminoethyl chloride (C.A.S.#96–79–7), Dimethyl ethylphosphonate (C.A.S.#6163–75–3), Dimethyl methylphosphonate (C.A.S.#756–79–6), Ethylphosphonous dichloride [Ethylphosphinyl dichloride] (C.A.S.#1498–40–4), Ethylphosphonus difluoride [Ethylphosphinyl difluoride] (C.A.S.#430–78–4), Ethylphosphonyl dichloride (C.A.S.#1066–50–8), Methylphosphonous dichloride [Methylphosphinyl dichloride] (C.A.S.#676–83–5), Methylphosphonous difluoride [Methylphosphinyl difluoride] (C.A.S.#753–59–3), Methylphosphonyl dichloride (C.A.S.#676–97–1), Pinacolyl alcohol (C.A.S.#464–07–3), 3-Quinuclidinol (C.A.S.#1619–34–7), and Thiodiglycol (C.A.S.#111–48–8) (Related ECCN: 1C995);

c. A license is required when at least one of all other chemicals in the List of Items Controlled under ECCN 1C350 constitutes more than 25 percent of the weight of the mixture (related ECCN: 1C995); *and*

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

Note to Mixtures: Calculation of concentrations of AG-controlled chemicals:

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

b. *Absolute 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;

c. *Example.*

11% chemical listed in paragraph b. of Note 2.
39% chemical not listed in Note 2
50% Solvent
100% Mixture
11/100=11% chemical listed in paragraph b. of Note 2.

In this example, a license is required because a chemical listed in paragraph b. of Note 2 constitutes more than 10 percent of the weight of the mixture.

3. *COMPOUNDS.* A license is not required under this entry for chemical compounds created with any chemicals identified in this entry, unless those compounds are also identified in this entry.

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 (Item 25 in List of Items Controlled) includes its liquid, gaseous, and aqueous phases, and hydrates.

LIST OF ITEMS CONTROLLED

* * * * *

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

License Requirements

Reason for Control: CB, CW, AT

Control(s)	Country chart
CB applies to entire entry ..	CB Column 1

CW applies to 1C351.d.5 and d.6 and a license is required for CW reasons for all destinations, including Canada, as follows: CW applies to 1C351.d.5 for ricin in the form of (1) Ricinus Communis Agglutinin$_{II}$ (RCA$_{II}$), also known as ricin D or Ricinus Communis Lectin$_{III}$ (RCL$_{III}$); and (2) Ricinus Communis Lectin$_{IV}$ (RCL$_{IV}$), also known as ricin E. CW applies to 1C351d.6 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.

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: Certain forms of ricin and saxitoxin in 1C351.d.5. and d.6 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 additional CWC Schedule 1 chemicals controlled by the Department of State. 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.5 and d.6, 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. 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;

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; *or*

d.11. Aflatoxins.

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

License Requirements

Reason for Control: CB, AT.

Control(s)	Country Chart
CB applies to 1C991.d	CB Column 3
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: Medical products containing ricin in the form of (1) Ricinus Communis $Agglutinin_{II}$ (RCA_{II}), also known as ricin D or Ricinus Communis $Lectin_{III}$ (RCL_{III}); and (2) Ricinus Communis $Lectin_{IV}$ (RCL_{IV}), also known as ricin E; and saxitoxin identified by C.A.S. #35523–89–8, are controlled for CW reasons under 1C351.

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 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.

Items:

a. Vaccines containing items controlled by ECCNs 1C351, 1C352, 1C353 and 1C354;

b. Immunotoxins;

c. Medical products containing botulinum toxins controlled by ECCN 1C351.d.1;

d. Medical products containing biological toxins controlled by ECCN 1C351.d.2 through d.11, except biological toxins controlled for CW reasons under 1C351.d.5 and d.6; *and*

e. Diagnostic and food testing kits containing biological toxins controlled by ECCN 1C351.d, except biological toxins controlled for CW reasons under ECCN 1C351.d.5 and d.6.

5. In Supplement No. 1 to part 774 (the Commerce Control List), Category 2—Materials Processing, Export Control Classification Numbers (ECCNs) are amended:

a. By revising the List of Items Controlled section for 2B350;

b. By revising the entry heading and List of Items Controlled section for ECCN 2B351; and

c. By revising the List of Items Controlled section for ECCN 2B352, 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^3 (100 liters) and less than 20 m^3 (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 where all surfaces of the agitator 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^3 (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^2, 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;
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, 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;
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. Multiple seal valves incorporating a leak detection port, bellows-seal valves, non-return (check) valves or diaphragm valves, in which all surfaces that come into direct contact with the chemical(s) being processed or contained are made from any of the following materials:
g.1. Alloys with more than 25% nickel and 20% chromium by weight;
g.2. Fluoropolymers;
g.3. Glass (including vitrified or enamelled coatings or glass lining);
g.4. Nickel or alloys with more than 40% nickel by weight;
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;
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^3/hour, or vacuum pumps with manufacturer's specified maximum flow-rate greater than 5 m^3/hour (under standard temperature (273 K (0° C)) and pressure (101.3 kPa) conditions), 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;
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, or chemical weapons precursors controlled by 1C350, 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.

2B351 Toxic gas monitoring systems that operate on-line and dedicated detectors therefor.

* * * * *

List of Items Controlled

Unit: Equipment in number.
Related Controls: N/A.
Related Definitions: For the purposes of this entry, the term ''continuous operation'' describes the capability of the equipment to operate on line without human intervention. The intent of this entry is to control toxic gas monitoring systems capable of collection and detection of samples in environments such as chemical plants, rather than those used for batch-mode operation in laboratories.
Items:
a. Designed for continuous operation and usable for the detection of chemical warfare agents or chemicals controlled by 1C350 at concentrations of less than 0.3mg/m^3 (see technical note below); *or*
b. Designed for the detection of cholinesterase-inhibiting activity.

Technical Note: Toxic Gas Monitoring Systems, controlled under 2B351.a., include those with detection capability for chemicals containing phosphorus, sulfur, fluorine or chlorine, other than those specified in 1C350.

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. A flow rate greater than 100 liters per hour;

c.2. Components of polished stainless steel or titanium;

c.3. Double or multiple sealing joints within the steam containment area; *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 greater than 50 kgs of ice in 24 hours but less than 1,000 kgs;

f. Equipment that incorporates or is contained in P3 or P4 containment housing, as follows:

f.1. Independently ventilated protective full or half suits;

f.2. Class III biological safety cabinets or isolators with similar performance standards;

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

Dated: September 22, 2000.

R. Roger Majak,

Assistant Secretary for Export Administration.

[FR Doc. 00–25068 Filed 10–2–00; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 91N–0101, 91N–0098, 91N–0103, and 91N–100H]

RIN 0910–AA19

Food Labeling: Health Claims and Labeling Statements; Dietary Fiber and Cancer; Antioxidant Vitamins and Cancer; Omega-3 Fatty Acids and Coronary Heart Disease; Folate and Neural Tube Defects; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its regulations codifying the agency's decision not to authorize the use of health claims for four substance-disease relationships in the labeling of foods, including dietary supplements: Dietary fiber and cancer, antioxidant vitamins and cancer, omega-3 fatty acids and coronary heart disease, and the claim that 0.8 milligram (mg) of folate in dietary supplement form is more effective in reducing the risk of neural tube defects than a lower amount in conventional food. This action is being taken in response to a decision of the U.S. Court of Appeals for the D.C. Circuit invalidating these regulations and directing FDA to reconsider whether to authorize the four health claims. This action will result in the removal of the regulations but does not constitute FDA authorization of the four claims. FDA is completing its reconsideration of the claims and expects to issue decisions on all four claims by October 10, 2000.

DATES: This rule is effective October 3, 2000.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS–832), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5429.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 6, 1993, FDA issued final rules announcing its decision not to authorize the use of health claims for four substance-disease relationships in the labeling of conventional foods. (See 58 FR 2537 (dietary fiber and cancer); 58 FR 2622 (antioxidant vitamins and cancer); 58 FR 2682 (omega-3 fatty acids and coronary heart disease); and 58 FR 2606 (folic acid [1] and neural tube defects[2])). Soon after, FDA proposed in the **Federal Register** of October 14, 1993 (58 FR 53296), not to authorize use of three of the four claims in the labeling of dietary supplements. In October 1993, after further review of evidence on the relationship between folate and reduced risk of neural tube defects, FDA proposed to authorize a health claim for this relationship (58 FR 53254, October 14, 1993); however, the agency proposed not to allow such claims to include a statement that folate from one source is more effective in reducing the risk of neural tube defects than folate from another source. Both proposals became final by operation of law on December 31, 1993. (See 59 FR 395, January 4, 1994 (dietary fiber and cancer, antioxidant vitamins and cancer, and omega-3 fatty acids and coronary heart disease); 59 FR 433, January 4, 1994 (folate and neural tube defects).) FDA's decisions not to authorize these four claims are codified in § 101.71(a) (21 CFR 101.71(a)) (dietary fiber and cancer); § 101.71(c) (antioxidant vitamins and cancer); § 101.71(e) (omega-3 fatty acids and coronary heart disease); and § 101.79(c)(2)(i)(G) (21 CFR 101.79(c)(2)(i)(G)) (claims comparing effectiveness of folate from different sources).

Several dietary supplement marketers and nonprofit organizations that had submitted comments during FDA's health claims rulemakings filed suit in Federal district court on constitutional and statutory grounds seeking, among other things, authorization to make the following health claims for use in the labeling of dietary supplements: ''Consumption of fiber may reduce the risk of colorectal cancer,'' ''Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer,'' ''Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease,'' and ''0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.'' The district court ruled for FDA in all respects

[1] In its original health claim evaluation, FDA used the term ''folic acid'' to describe this B vitamin. Later, the agency decided that the broader term ''folate'' was more scientifically accurate because that term encompasses both synthetic and naturally occurring forms of the vitamin, whereas folic acid refers only to the synthetic form (see 58 FR 53254 at 53257 through 53258 and 53280, October 14, 1993). Accordingly, this rule uses the term ''folate.'' The two terms may be used interchangeably in food labeling.

[2] Neural tube defects are birth defects of the brain or spinal cord. Spina bifida and anencephaly are the most common types of neural tube defects.