hazards (such as the presence of *Listeria monocytogenes* in ready-to-eat foods).

In responding to the questions set out in this document, please address, to the extent you are able, each of the three types of hazards discussed in the previous paragraph. FDA is particularly interested in receiving comments about food manufacturing practices and other controls used by small food manufacturing and processing entities.

II. Questions

In general, how should the CGMP regulations in part 110 be revised or otherwise modernized? Please describe, generally, the short comings of the current regulations.

1. Which practices specified in current part 110 are most effective at preventing each type of food hazard? Which practices are least effective at such prevention?

2. In today's food manufacturing environment, what conditions, practices, or other factors are the principal contributors to each type of food hazard?

3. If the CGMP regulations were revised, which type or types of food hazards could be most readily prevented through CGMP-type controls?

4. Are there preventive controls, in addition to those set out in part 110, needed to reduce, control, or eliminate each of the three types of food hazards? If yes, please identify the specific hazard and the particular controls, that would reduce, control, or eliminate the hazard.

5. What concepts or underlying principles should guide FDA's adoption of new preventive controls?

6. How should the effectiveness of preventive controls for each of the three types of hazards be most accurately measured?

7. In today's food manufacturing environment, what are the principal contributors to the presence of undeclared allergens in food? For example, do labeling errors or cross-contamination contribute? Which preventive controls could help reduce, control, or eliminate the presence of undeclared allergens in food?

8. Are there existing quality systems or standards (such as international standards) that FDA should consider as part of the agency's exploration of food CGMP modernization? Please identify these systems or standards and explain what their consideration might contribute to this effort.

9. There is a broad variation within the food manufacturing and processing industry, including variations in size of establishments, the nature of the food produced, the degree to which the food is processed, and the vulnerability of a particular operation to physical, chemical, or microbial hazards. How, if at all, should the CGMP regulations be revised to take into account such variation? For example, should there be different sets of preventive controls for identifiable segments of the food industry, such as different storage temperature limits?

10. There are a number of measures, procedures, and programs that help to ensure that preventive controls are carried out adequately. These include the following items:

- Training programs for managers and/or workers;
- Audit programs;
- Written records, e.g., batch records, sanitation records;
- Validation of control measures;
- Written sanitation standard operating procedures;
- Food label review and control program; and
- Testing of incoming raw materials, in process materials, or finished products.

Which (if any) of these should be required practices for food and manufacturers and why? Which (if any) of these should be recommended practices for food manufacturers and processors and why?

11. Are there preventive controls in addition to those already set out in part 110 for food distributors, wholesalers, and warehousers that are needed to help ensure the safe and sanitary holding of food? If yes, please identify the controls by hazard and sector of the industry.

III. Registration

You should register for any of the meetings by fax or e-mail (see **FOR FURTHER INFORMATION CONTACT**). For security reasons and due to space limitations, we recommend that you register at least 5 days prior to the meeting you wish to attend. Registration will be accepted on a space-available basis. You may register until close of business on July 14, 2004, for the College Park meeting, close of business on July 16, 2004, for the Chicago meeting, and close of business on July 30, 2004, for the San Jose meeting. If you need special accommodations due to a disability, please inform the contact person at least 7 days in advance (see **FOR FURTHER INFORMATION CONTACT**). Please include your name, title, firm name, address, telephone number, and e-mail address (if available) when you register. FDA encourages individuals or firms with relevant data or information to present such information at the meeting or in written comments to the record. If you would like to make oral comments at one of the meetings, please specify your interest in speaking when you register. The amount of time for each oral presentation may be limited due to the number of requests to speak.

IV. Transcripts

A transcript will be made of the proceedings of each meeting. You may request a copy of a meeting transcript in writing from FDA's Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 30 working days after the public meetings at a cost of 10 cents per page. The transcript of each public meeting and all comments submitted will be available for public examination at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Comments

In addition to presenting oral comments at a public meeting, interested persons may submit (see **ADDRESSES**) written or electronic comments on the subject of these meetings. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15197 Filed 6–30–04; 1:38 pm]

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DEPARTMENT OF STATE

22 CFR Parts 121 and 123

[Public Notice 4754]

Z–RIN 1400–ZA–11

Amendment to the International Traffic in Arms Regulations: United States Munitions List and Part 123

AGENCY: Department of State.

ACTION: Final Rule.

SUMMARY. The Department of State, in consultation with the Departments of Defense and Commerce, is amending the text of Category XIV of the United States Munitions List (USML) as published in the **Federal Register** on November 27, 2002 to clarify the continuity of coverage for equipment and its

components, parts, accessories, and attachments specifically designed or modified for military operations and compatibility with military equipment and employed for the dissemination, dispersion or testing of agents controlled by the category.

In addition, to reflect the March 29, 2004 accession to the North Atlantic Treaty Organization (NATO) of seven European countries, section 123.27 of the International traffic in Arms Regulations (ITAR) is being amended to add Bulgaria, Estonia, Latvia, Lithuania, Romania, Slovakia, and Slovenia.

DATES: *Effective:* July 2, 2004.

ADDRESSES: Interested parties are invited to submit written comments to the Department of State, Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTN: Regulatory Change, USML Part 121, Category XIV, 12th Floor, SA–1, Washington DC 20522–0112. E-mail comments may be sent to: *DTCPResponseTeam@state.gov.* Comments will be accepted at any time. Persons with access to the Internet may also view this notice by going to the regulations.gov Web site at: *http://www.regulations.gov/index.cfm.*

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Tomchik, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663–2799 or FAX (202) 261–8199. ATTN: Regulatory Change, USML Part 121, Category XIV.

SUPPLEMENTARY INFORMATION:

1. *Category XIV.* Since the publication on November 27, 2002 (67 FR 70839) of the revision to this category of the USML (22 CFR Part 121), questions have arisen regarding continuity of coverage for equipment and its components, parts, accessories, and attachments specifically designed or modified for military operations and compatibility with military equipment and employed for the dissemination, dispersion, or testing of agents controlled by the category. The text published on November 27 could be misconstrued as a diminution in the scope of controls for such equipment. To clarify that coverage under the USML for such equipment was and remains continuous, paragraph (f)(1) is amended to specify that the control embraces the tear gases and riot control agents specified in paragraph (d) and the defoliants specified in paragraph (e) of Category XIV.

2. *Section 123.* On March 29, 2004 seven European countries deposited in Washington, DC the instruments of accession by which those countries became formal members of the North Atlantic Treaty Organization (NATO). The seven countries in question are Bulgaria, Estonia, Latvia, Lithuania, Romania, Slovakia, and Slovenia. Accordingly, ITAR section 123.27 (22 CFR 123.27) is being amended to add these countries to the enumerated list of NATO allies of the United States.

Regulatory Analysis and Notices

This amendment involves a foreign affairs function of the United States and, therefore, is not subject to the procedures required by 5 U.S.C. 553 and 554. It is exempt from review under Executive Order 12866 but has been reviewed internally by the Department of State to ensure consistency with the purposes thereof. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. It has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Act of 1996. It will not have substantial direct effects on the States, the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this rule does not have sufficient federalism implications to warrant application of consultation provisions of Executive Orders 12372 and 13132.

List of Subjects in 22 CFR Parts 121 and 123

Arms and munitions, Exports.

■ Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, Parts 121 and 123 are amended as follows:

PART 121—THE UNITED STATES MUNITIONS LIST

■ 1. The authority citation for Part 121 continues to read as follows:

Authority: Sec. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2278, 2797); E.O. 11958, 42 FR 4311; 3 CFR 1977 Comp. p. 79; 22 U.S.C. 2658; Pub. L. 105–261, 112 Stat. 1920.

■ 2. In § 121.1, Category XIV—Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment is amended by revising paragraphs (f) introductory text and (f)(1) to read as follows:

§ 121.1 General. The United States Munitions List.

* * * * *

Category XIV—Toxicological Agents, Including Chemical Agents, Biological Agents, and Associated Equipment

* * * * *

*(f) Equipment and its components, parts, accessories, and attachments specifically designed or modified for military operations and compatibility with military equipment as follows:

(1) The dissemination, dispersion or testing of the chemical agents, biological agents, tear gases and riot control agents, and defoliants listed in paragraphs (a), (b), (d), and (e), respectively, of this category;

* * * * *

PART 123—LICENSES FOR THE EXPORT OF DEFENSE ARTICLES

■ 3. The authority citation for part 123 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, and 2797); 22 U.S.C. 2753; E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp. p. 79; 22 U.S.C. 2658; Pub. L. 105–261, 112 Stat. 1920.

■ 4. Section 123.27 is amended by revising paragraph (a)(1) to read as follows:

§ 123.27 Special licensing regime for export to U.S. allies of commercial communications satellite components, systems, parts, accessories, attachments and associated technical data.

(a) * * *

(1) The proposed exports or re-exports concern exclusively one or more countries of the North Atlantic Treaty Organization (Belgium, Bulgaria, Canada, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Turkey, United Kingdom, and the United States) and/or one or more countries which have been designated in accordance with section 517 of the Foreign Assistance Act of 1961 as a major non-NATO ally (and as defined further in section 644(q) of that Act) for purposes of that Act and the Arms Export Control Act (Argentina, Australia, Bahrain, Egypt, Israel, Japan, Jordan, Kuwait, New Zealand, the Philippines, Thailand, and the Republic of Korea).

* * * * *

Dated: June 14, 2004.

John R. Bolton,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 04–15097 Filed 7–1–04; 8:45 am]

BILLING CODE 4710–25–P