

of Food and Drugs, 21 CFR part 866 is amended as follows:

## **PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES**

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.3305 is revised to read as follows:

### **§ 866.3305 Herpes simplex virus serological assays.**

(a) *Identification.* Herpes simplex virus serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum. Additionally, some of the assays consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from a mild infection to a severe generalized disease with a fatal outcome.

(b) *Classification.* (1) *Class II (special controls).* The device is classified as class II (special controls) if the herpes simplex virus serological assay is type 1 and/or 2. The special control for the device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays." For availability of the guidance document, see § 866.1(e).

(2) *Class III (premarket approval).* The device is classified as class III if the herpes simplex virus serological assay is a type other than type 1 and/or 2.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established for the requirement for premarket approval for the devices described in paragraph (b)(2) of this section. See § 866.3.

Dated: March 23, 2007.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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## **DEPARTMENT OF STATE**

### **22 CFR Part 126**

**[Public Notice: 5740]**

### **Amendment of the International Traffic in Arms Regulations: Policy With Respect to Vietnam**

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** Notice is hereby given that the Department of State is amending the International Traffic in Arms Regulations (ITAR) regarding Vietnam at 22 CFR 126.1 to make it United States policy to consider on a case-by-case basis licenses, other approvals, exports or imports of non-lethal defense articles and defense services destined for or originating in Vietnam. The United States will deny licenses, other approvals, exports or imports of lethal defense articles and services destined for or originating in Vietnam. Under this policy, the exports of lethal-end items, components of lethal-end items (unless those components are non-lethal, safety-of-use spare parts for lethal-end items), non-lethal crowd control defense articles and defense services, and night vision devices to end-users with a role in ground security will not be approved.

**DATES:** *Effective Date:* This rule is effective April 3, 2007.

**ADDRESSES:** Interested parties may submit comments at any time by any of the following methods:

- *E-mail:*

*DDTCResponseTeam@state.gov* with an appropriate subject line.

- *Mail:* Department of State, Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTN: Regulatory Change, 12th Floor, SA-1, Washington, DC 20522-0112.

- *Fax:* 202-261-8199.

- *Hand Delivery or Courier (regular work hours only):* Department of State, Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTENTION: Regulatory Change, SA-1, 12th Floor, 2401 E Street, NW., Washington, DC 20037.

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:** Ann K. Ganzer, Office of Defense Trade Controls Policy, Department of State, 12th Floor, SA-1, Washington DC 20522-0112; Telephone 202-663-2792 or FAX 202-261-8199; e-mail: *DDTCResponseTeam@state.gov*. ATTN: Regulatory Change.

**SUPPLEMENTARY INFORMATION:** On November 2, 2006, the Secretary of State

modified the U.S. arms transfer policy toward Vietnam allowing the sale, lease, export, or other transfer of non-lethal defense articles and defense services to the country. Subsequently, the President issued a determination December 29, 2006 that the furnishing of defense articles and services to Vietnam would strengthen the security of the United States and promote world peace.

The new policy will not permit the export or other transfer to Vietnam of: (a) Lethal end items, (b) components of lethal end items, unless those components are non-lethal, safety-of-use spare parts for lethal end items, (c) non-lethal crowd control defense articles and defense services, and (d) night vision devices to end-users with a role in ground security.

### **Regulatory Analysis and Notices**

#### *Administrative Procedure Act*

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.

#### *Regulatory Flexibility Act*

This rule does not require analysis under the Regulatory Flexibility Act.

#### *Unfunded Mandates Act of 1995*

This rule does not require analysis under the Unfunded Mandates Reform Act.

#### *Small Business Regulatory Enforcement Fairness Act of 1996*

This amendment has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness 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.

#### *Executive Orders 12372 and 13132*

It is determined that this rule does not have sufficient federalism implications to warrant application of the consultation provisions of Executive Orders 12372 and 13132.

#### *Executive Order 12866*

This amendment 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.

#### *Paperwork Reduction Act*

This rule does not impose any new reporting or recordkeeping requirements

subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

#### List of Subjects in 22 CFR Part 126

Arms and munitions, Exports.

■ Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 126 is amended as follows:

#### PART 126—GENERAL POLICIES AND PRACTICES

■ 1. The authority citation for part 126 continues to read as follows:

**Authority:** Secs. 2, 38, 40, 42, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); E.O. 11958, 42 FR 4311; 3 CFR, 1977 Comp., p. 79; 22 U.S.C. 2651a; 22 U.S.C. 287c; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; Sec. 1225, Pub. L. 108–375.

■ 2. Section 126.1 is amended by revising paragraph (a) and adding paragraph (l) to read as follows:

##### § 126.1 Prohibited exports and sales to certain countries.

(a) *General.* It is the policy of the United States to deny licenses and other approvals for exports and imports of defense articles and defense services, destined for or originating in certain countries. This policy applies to Belarus, Cuba, Iran, North Korea, Syria, and Venezuela. This policy also applies to countries with respect to which the United States maintains an arms embargo (e.g., Burma, China, Liberia, Somalia, and Sudan) or whenever an export would not otherwise be in furtherance of world peace and the security and foreign policy of the United States. Information regarding certain other embargoes appears elsewhere in this section. Comprehensive arms embargoes are normally the subject of a State Department notice published in the **Federal Register**. The exemptions provided in the regulations in this subchapter, except § 123.17 of this subchapter, do not apply with respect to articles originating in or for export to any proscribed countries, areas, or persons in this § 126.1.

\* \* \* \* \*

(l) *Vietnam.* It is the policy of the United States to deny licenses, other approvals, exports or imports of defense articles and defense services destined for or originating in Vietnam except, on a case-by-case basis, for:

- (1) Non-lethal defense articles and defense services, and
- (2) Non-lethal, safety-of-use defense articles (e.g., cartridge actuated devices, propellant actuated devices and technical manuals for military aircraft for purposes of enhancing the safety of the aircraft crew) for lethal end-items.

For non-lethal defense end-items, no distinction will be made between Vietnam's existing and new inventory.

Dated: March 13, 2007.

**Stephen D. Mull,**

*Acting Assistant Secretary for Political-Military Affairs, Department of State.*

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#### DEPARTMENT OF THE TREASURY

##### Office of Foreign Assets Control

##### 31 CFR Parts 538 and 560

##### Sudanese Sanctions Regulations; Iranian Transactions Regulations

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Office of Foreign Assets Control of the U.S. Department of the Treasury is amending the Sudanese Sanctions Regulations, 31 CFR part 538, and the Iranian Transactions Regulations, 31 CFR part 560, to authorize the exportation or reexportation, directly or indirectly, from the United States or by a U.S. person, wherever located, of any goods or technology to a third-country government, or to its contractors or agents, for shipment to, respectively, Sudan or Iran via a diplomatic pouch.

**DATES:** *Effective Date:* April 3, 2007.

**FOR FURTHER INFORMATION CONTACT:** Assistant Director for Compliance Outreach & Implementation, tel.: 202/622–2490, Assistant Director for Licensing, tel.: 202/622–2480, Assistant Director for Policy, tel.: 202/622–4855, or Chief Counsel, tel.: 202/622–2410, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

##### SUPPLEMENTARY INFORMATION:

##### Electronic and Facsimile Availability

This document and additional information concerning the Office of Foreign Assets Control are available from OFAC's Web site (<http://www.treas.gov/ofac>) or via facsimile through a 24-hour fax-on demand service, tel.: (202) 622–0077.

##### Background

The Sudanese Sanctions Regulations, 31 CFR part 538 (the “SSR”), were promulgated to implement Executive Order 13067 of November 3, 1997 (“E.O. 13067”), in which the President declared a national emergency with respect to the policies and actions of the

Government of Sudan. To deal with that emergency, E.O. 13067 imposed comprehensive trade sanctions with respect to Sudan and blocked all property and interests in property of the Government of Sudan in the United States or within the possession or control of United States persons. Subsequently, the President issued Executive Order 13412 of October 13, 2006 (“E.O. 13412”), to take additional steps with respect to the emergency declared in E.O. 13067. While it exempted specific areas of Sudan from certain prohibitions in E.O. 13067, E.O. 13412 continued the blocking of the Government of Sudan's property and interests in property and imposed a prohibition on transactions relating to Sudan's petroleum or petrochemical industries. E.O. 13412 also removed the regional government of Southern Sudan from the definition of the Government of Sudan.

Existing § 538.516 of the SSR authorizes all transactions in connection with the importation into the United States from Sudan, or the exportation from the United States to Sudan, of diplomatic pouches and their contents. OFAC is amending this general license to expand the scope of authorized transactions relating to the importation and exportation of diplomatic pouches and their contents. Specifically, OFAC is revising § 538.516 of the SSR by redesignating the original section as § 538.516(a) and by adding a new paragraph (b). New § 538.516(b) authorizes the exportation or reexportation, directly or indirectly, from the United States or by a U.S. person, wherever located, of any goods or technology to a third-country government, or to its contractors or agents, for shipment to Sudan via a diplomatic pouch. In addition, § 538.516(b) clarifies that, to the extent necessary, the shipment by a third-country government to Sudan of U.S.-origin goods or technology in a diplomatic pouch is authorized.

The Iranian Transactions Regulations, 31 CFR part 560 (the “ITR”), implement a series of Executive orders, beginning with Executive Order 12957 of March 15, 1995, in which the President declared a national emergency with respect to the actions and policies of the Government of Iran. To deal with that threat, Executive Order 12957 imposed prohibitions on certain transactions with respect to the development of Iranian petroleum resources. On May 6, 1995, the President issued Executive Order 12959 imposing comprehensive trade sanctions to further respond to the threat, and on August 19, 1997, the President issued Executive Order 13059