

(2) A license requirement applies to all exports and reexports to an SDT of any item subject to the EAR on the Commerce Control List (CCL).

(3) To avoid duplication, U.S. persons are not required to seek separate authorization for an export or reexport subject both to the EAR and to OFAC's Terrorism Sanctions Regulations. Therefore, if OFAC authorizes an export or reexport by a U.S. person to a SDT, no separate authorization from BXA is necessary.

(4) Any export or reexport by a U.S. person of any item subject to both the EAR and OFAC's Terrorism Sanctions Regulations and not authorized by OFAC is a violation of the EAR. Any export from abroad or reexport by a non-U.S. person of items requiring a license pursuant to this section and not authorized by BXA is a violation of the EAR.

(5) These licensing requirements supplement any other requirements set forth elsewhere in the EAR.

(b) *Exceptions.* No License Exceptions or other BXA authorization for items described by paragraph (a) of this section are available for exports or reexports to SDTs.

(c) *Licensing policy.* Applications for licenses required by paragraph (a) of this section generally will be denied. You should consult with OFAC concerning transactions subject to OFAC licensing requirements.

(d) *Contract sanctity.* Contract sanctity provisions are not available for license applications reviewed under this section.

4. A new section 744.14 is added to read as follows:

**§ 744.14 Restrictions on exports and certain reexports to designated foreign terrorist organizations.**

Consistent with the objectives of sections 302 and 303 of the Anti-Terrorism and Effective Death Penalty Act (Anti-Terrorism Act) (Pub.L. 104-132, 110 Stat. 1214-1319), BXA maintains restrictions on exports and certain reexports to designated Foreign Terrorist Organizations. The Secretary of State has designated certain designated Foreign Terrorist Organizations pursuant to section 302 of the Anti-Terrorism Act. Also pursuant to section 302 of the Anti-Terrorism Act, the Department of the Treasury, Office of Foreign Assets Control, maintains 31 CFR part 597, the Foreign Terrorist Organizations Sanctions Regulations, requiring U.S. financial institutions to block all financial transactions involving assets of designated Foreign Terrorist Organizations within the possession or control of such U.S.

financial institutions. Section 303 of the Anti-Terrorism Act prohibits persons within the United States or subject to U.S. jurisdiction from knowingly providing material support or resources to a designated Foreign Terrorist Organization and makes violations punishable by criminal penalties under title 18, United States Code. These designated Foreign Terrorist Organizations are listed in the Appendices to 31 CFR Chapter V and identified by the bracketed suffix initials [FTO]. The export control requirements set forth below further the objectives of the Anti-Terrorism Act.

(a) *License requirement(s).* A license requirement applies to:

(1) All exports and reexports to an FTO of any item subject to the EAR on the Commerce Control List (CCL); and

(2) All exports and reexports to an FTO by a U.S. person of any item subject to the EAR.

(3) Any export or reexport by a U.S. person prohibited by the EAR and not authorized by BXA is a violation of the EAR. Any export from abroad or reexport by a non-U.S. person of items requiring a license pursuant to this section and not authorized by BXA is a violation of the EAR.

(4) These licensing requirements supplement any other requirements set forth elsewhere in the EAR.

(b) *Exceptions.* No License Exceptions or other BXA authorization for items described by paragraph (a) of this section are available for exports or reexports to FTOs.

(c) *Licensing policy.* Applications for exports and reexports to FTOs of all items identified by paragraphs (a)(1) and (a)(2) of this section will generally be denied, to the extent they constitute material support or resources, as defined in 18 U.S.C. 2339A(b).

(d) *Contract sanctity.* Contract sanctity provisions are not available for license applications reviewed under this section.

**Note to § 744.14.** This section does not implement, construe, or limit the scope of any criminal statute, including (but not limited to) 18 U.S.C. 2339B(a)(1) and 2339A, and does not excuse any person from complying with any criminal statute, including (but not limited to) 18 U.S.C. 2339B(a)(1) and 18 U.S.C. 2339A.

**PART 772—[AMENDED]**

5. Part 772 is amended:

a. By adding a definition for foreign terrorist organization;

b. By revising the heading for the definition of Specially Designated Terrorist; and

c. By revising the introductory text of paragraph (a) for the definition of "U.S. person" to read as follows:

**PART 772—DEFINITIONS OF TERMS**

\* \* \* \* \*

*Foreign Terrorist Organizations (FTO).* Any organization that is determined by the Secretary of the Treasury to be a foreign terrorist organization under notices or regulations issued by the Office of Foreign Assets Control (see 31 CFR chapter V).

\* \* \* \* \*

*Specially Designated Terrorist (SDT).*

\* \* \*

\* \* \* \* \*

*U.S. person.* (a) For purposes of §§ 744.6, 744.10, and 744.11 of the EAR, the term U.S. person includes:

\* \* \* \* \*

Dated: December 29, 1998.

**R. Roger Majak,**

*Assistant Secretary for Export Administration.*

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**DEPARTMENT OF THE TREASURY**

**Customs Service**

**19 CFR Part 162**

[T.D. 99-4]

RIN 1515-AC33

**Mandatory Seizure of Certain Plastic Explosives**

**AGENCY:** Customs Service, Department of the Treasury.

**ACTION:** Final rule.

**SUMMARY:** This document amends the Customs Regulations regarding the types of merchandise that are required to be seized and forfeited if introduced or attempted to be introduced into the United States contrary to law. The Customs Regulations reflect the statutory list of such merchandise set forth in 19 U.S.C. 1595a(c)(1). That statute was amended to add plastic explosives not containing a detection agent to the list of merchandise required to be seized and forfeited. This document conforms the Customs Regulations to that statutory change.

**EFFECTIVE DATE:** January 8, 1999.

**FOR FURTHER INFORMATION CONTACT:** Todd J. Schneider, Penalties Branch, 202-927-1694.

**SUPPLEMENTARY INFORMATION:**

## Background

Section 596(c)(1) of the Tariff Act of 1930 (19 U.S.C. 1595a(c)(1)) sets forth a list of merchandise which, if introduced or attempted to be introduced into the United States contrary to law, are required to be seized and forfeited.

Section 162.23(a), Customs Regulations (19 CFR 162.23(a)), reflects the list of merchandise that must be mandatorily seized if introduced or attempted to be introduced into the United States contrary to law as set forth in 19 U.S.C. 1595a(c).

Title VI, section 606 of Pub. L. 104-132, the "Antiterrorism and Effective Death Penalty Act of 1996," amended 19 U.S.C. 1595a(c)(1), effective April 24, 1997, to add to the list of merchandise required to be seized, merchandise that "is a plastic explosive, as defined in section 841(q) of Title 18, United States Code, which does not contain a detection agent, as defined in section 841(p) of such title." This amendment was made to implement the Convention on the Marking of Plastic Explosives for the Purpose of Detection, which the United States entered into at Montreal, Canada, in 1991.

This document amends § 162.23(a), Customs Regulations, to reflect that amendment to 19 U.S.C. 1595a(c)(1).

## Inapplicability of Public Notice and Comment Requirements and Delayed Effective Date Requirements

Inasmuch as this amendment merely conforms the Customs Regulations to existing law, pursuant to 5 U.S.C. 553(b)(3)(B), good cause exists for dispensing with notice and public procedure for this amendment as they are unnecessary. For the same reason, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

## Regulatory Flexibility Act and Executive Order 12866

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

This document does not meet the criteria for a significant regulatory action under Executive Order 12866.

Drafting Information: The principal author of this document was Janet Johnson, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

## List of Subjects in 19 CFR Part 162

Customs duties and inspection, Imports, Inspection, Law enforcement, Prohibited merchandise, Restricted merchandise, Seizures and forfeitures.

## Amendment to the Regulations

For the reasons set forth in the preamble, part 162 of the Customs Regulations (19 CFR part 162) is amended as set forth below.

### PART 162—INSPECTION, SEARCH AND SEIZURE

1. The general authority citation for part 162 and the specific authority citation for § 162.23 continue to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1624.

\* \* \* \* \*

Section 162.23 also issued under 19 U.S.C. 1595a(c).

\* \* \* \* \*

2. Section 162.23(a) is amended by removing the word "or" at the end of paragraph (a)(2); by removing the period at the end of paragraph (a)(3) and adding "; or" in its place; and by adding a new paragraph (a)(4) to read as follows:

**§ 162.23 Seizure under section 596(c) Tariff Act of 1930, as amended (19 U.S.C. 1595a(c)).**

(a) *Mandatory seizures.* \* \* \*

\* \* \* \* \*

(4) A plastic explosive, as defined in section 841(q) of title 18, United States Code, which does not contain a detection agent, as defined in section 841(p) of that title.

\* \* \* \* \*

Approved: December 1, 1998.

**Raymond W. Kelly,**

*Commissioner of Customs.*

**Dennis M. O'Connell,**

*Acting Deputy Assistant Secretary of the Treasury.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 862 and 892

[Docket Nos. 98P-0506 and 98P-0621]

#### Medical Devices; Exemptions From Premarket Notification; Class II Devices

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing an order granting petitions requesting exemption from the premarket

notification requirements for certain class II devices. FDA is publishing this order in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**EFFECTIVE DATE:** January 8, 1999.

#### FOR FURTHER INFORMATION CONTACT:

Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

#### SUPPLEMENTARY INFORMATION:

#### I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Pub. L. 94-295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Pub. L. 101-629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part