

Column 2, CB Column 3, NP Column 1, NP Column 2, NS Column 1, NS Column 2, MT Column 1, RS Column 1, RS Column 2, CC Column 1, CC Column 2, CC Column 3 in the Country Chart Column of the License Requirements section of an ECCN, or classified under ECCNs 1C980, 1C981, 1C982, 1C983, 1C984, 1C997, 5A980, 0A980, 0A982, 0A983, 0A985, and 0E982; however, to avoid duplication, an authorization from OFAC constitutes authorization under the EAR, and no separate BXA authorization is necessary. No person may export or reexport any item subject to both the EAR and OFAC's Iraqi Sanctions Regulations without prior OFAC authorization. Exports and reexports subject to the EAR that are not subject to the Iraqi Sanctions Regulations may require authorization from BXA.

\* \* \* \* \*

15. Section 746.7 is amended by adding a sentence to the end of the introductory paragraph, to read as follows:

**§ 746.7 Iran.**

\* \* \* Exports and reexports subject to the EAR that are not subject to the Iranian Transactions Regulations may require authorization from BXA.

\* \* \* \* \*

**PART 772—[AMENDED]**

16. Section 772.1 is amended by adding the definitions of "agricultural commodities", "medical devices", and "medicines" in alphabetical order, to read as follows:

**§ 772.1 Definitions of terms as used in the Export Administration Regulations (EAR).**

\* \* \* \* \*

*Agricultural commodities.*

Agricultural commodities include food (including processed food); feed; fish; shellfish and fish products; beer, wine and spirits; livestock; fiber including cotton, wool and other fibers; tobacco and tobacco products; wood and wood products; seeds; fertilizer and organic fertilizer; reproductive materials such as fertilized eggs, embryos and semen. For the purposes of the EAR, agricultural commodities do not include furniture made from wood; clothing manufactured from plant or animal materials; agricultural equipment (whether hand tools or motorized equipment); pesticides, insecticides, or herbicides; or cosmetics (unless derived entirely from plant materials).

**Note 1:** This definition of agricultural commodities includes fertilizer and organic fertilizer, as listed in section 775 of the 2001 Agriculture, Rural Development, Food and

Drug Administration, and Related Agencies Appropriations Act (Act) (Public Law 106–387) and commodities listed in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602) as incorporated in section 902 of the Act, as well as commodities determined by the Department of Agriculture to fall within the scope of section 102 of the 1978 Agricultural Trade Act.

**Note 2:** For purposes of License Exception AGR (see § 740.18 of the EAR), agricultural commodities also include vitamins, minerals, food additives and dietary supplements, and bottled water. These items do not fall within the scope of section 102 of the 1978 Agricultural Trade Act, but are treated as agricultural commodities for the purposes of License Exception AGR.

**Note 3:** For purposes of License Exception AGR and export license applications to Iran, Sudan and Libya under the licensing procedures set forth in the appropriate regulations promulgated and administered by Treasury's Office of Foreign Assets Control, agricultural commodities only include those that are classified as EAR99.

\* \* \* \* \*

*Medical devices.* For purposes of the EAR, medical devices are "devices" as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) including medical supplies, instruments, equipment, equipped ambulances, institutional washing machines for sterilization, and vehicles with medical testing equipment. Note that certain component parts and spares to be exported for incorporation into medical devices are on the Commerce Control List. Only items meeting the definition of "medical device" and that are classified as EAR99 are eligible for export to Iran, Libya and Sudan under the licensing procedures set forth in the appropriate regulations promulgated and administered by Treasury's Office of Foreign Assets Control.

*Medicines.* Medicines means "drug" as defined in section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321). For purposes of the EAR, medicines includes prescription and over the counter medicines for humans and animals. Note that certain medicines, such as vaccines and immunotoxins, are on the Commerce Control List. Only items meeting the definition of "medicine" and that are classified as EAR99 are eligible for export to Iran, Libya and Sudan under the licensing procedures set forth in the appropriate regulations promulgated and administered by Treasury's Office of Foreign Assets Control.

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**PART 774—[AMENDED]**

17. In Supplement No. 1 to part 774 (the Commerce Control List), Category 1—Materials, Chemicals, "Microorganisms," and "Toxins" is amended by adding Export Control Classification Number (ECCN) 1C997 to read as follows:

**1C997 Ammonium Nitrate, Including Fertilizers and Fertilizer Blends Containing More Than 15% by Weight Ammonium Nitrate, Except Liquid Fertilizers (Containing Any Amount of Ammonium Nitrate) or Dry Fertilizers Containing Less Than 15% by Weight Ammonium Nitrate**

**License Requirements**

*Reason for Control:* AT.

Control(s)	Country chart
AT applies to entire entry.	AT Column 1 and Iraq

**License Exceptions**

LVS: N/A.  
GBS: N/A.  
CIV: N/A.

**List of Items Controlled**

*Unit:* Kilograms.  
*Related Controls:* N/A.  
*Related Definitions:* N/A.  
*Items:* The list of items controlled is contained in the ECCN heading.

Dated: July 9, 2001.

**James J. Jochum,**

*Assistant Secretary for Export Administration.*

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**DEPARTMENT OF THE TREASURY**

**Office of Foreign Assets Control**

**31 CFR parts 515, 538, 550, and 560**

**Exports of Agricultural Products, Medicines, and Medical Devices to Cuba, Sudan, Libya, and Iran; Cuba Travel-Related Transactions**

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

**ACTION:** Interim rule with request for comments; amendments.

**SUMMARY:** The Office of Foreign Assets Control of the U.S. Department of the Treasury is issuing and amending regulations to implement the Trade Sanctions Reform and Export Enhancement Act of 2000, Title IX of Public Law 106–387 (October 28, 2000). These regulations amend the licensing

provisions of the Cuban Assets Control Regulations, the Sudanese Sanctions Regulations, the Libyan Sanctions Regulations, and the Iranian Transactions Regulations, 31 CFR parts 515, 538, 550, and 560, respectively, as they relate to the exportation and reexportation from the U.S. or by U.S. persons of agricultural commodities, medicine, or medical devices to Cuba, Sudan, Libya, and Iran. These regulations also amend the Cuban Assets Control Regulations with respect to Cuba travel-related transactions.

**DATES:** *Effective Date:* July 26, 2001.

Comments: Written comments must be received no later than September 10, 2001. Comments should be sent to David W. Mills, Chief, Policy Planning and Program Management Division, Room 2176 Main Treasury Annex, 1500 Pennsylvania Ave. N.W., Washington, DC 20220 or via OFAC's website (<http://www.treas.gov/ofac>).

**FOR FURTHER INFORMATION CONTACT:**

Dennis P. Wood, Chief of Compliance Programs, tel.: 202/622-2490, Steven I. Pinter, Acting Chief of Licensing, tel.: 202/622-2480, or Barbara C. Hammerle, Acting Chief Counsel, tel.: 202/622-2410, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

**SUPPLEMENTARY INFORMATION:**

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**Background**

The Trade Sanctions Reform and Export Enhancement Act of 2000, Title IX of Public Law 106-387 (October 28, 2000) (the "TSRA"), provides that the President shall terminate any unilateral agricultural sanction or unilateral medical sanction in effect as of the date

of enactment of the TSRA. The TSRA does not direct the termination of any unilateral agricultural sanction or unilateral medical sanction that prohibits, restricts, or conditions the provision or use of any agricultural commodity, medicine, or medical device that is controlled on the United States Munitions List, controlled on any control list established by the Export Administration Act of 1979 or any successor statute, or used to facilitate the development or production of chemical or biological weapons or weapons of mass destruction. Exporters should consult the Department of Commerce, Bureau of Export Administration ("BXA"), to determine whether a particular item is controlled under specific Export Commodity Control Number ("ECCN") on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1 (the "CCL").

Section 906 of the TSRA further requires that the export of agricultural commodities, medicine, or medical devices to Cuba or to the government of a country that has been determined by the Secretary of State, under Section 620A of the Foreign Assistance Act of 1961 (22 U.S.C. 2371), section 6(j)(1) of the Export Administration Act of 1979 (50 U.S.C. app. 2405(j)(1)), or section 40(d) of the Arms Export Control Act (22 U.S.C. 2780(d)), to have provided support repeatedly for acts of international terrorism, or to any other entity in such a country, shall only be made pursuant to one-year licenses issued by the United States Government. The governments of Cuba, Sudan, Libya, and Iran have been designated as supporting international terrorism pursuant to section 6(j) of the Export Administration Act of 1979.

These regulations amend the Cuban Assets Control Regulations, 31 CFR part 515 ("CACR"), the Sudanese Sanctions Regulations, 31 CFR part 538 (the "SSR"), the Libyan Sanctions Regulations, 31 CFR part 550 (the "LSR"), and the Iranian Transactions Regulations, 31 CFR part 560 (the "ITR"), to implement the TSRA as required. The Department of Treasury's Office of Foreign Assets Control ("OFAC") has endeavored to implement the TSRA in a way that is consistent with both the statutory language and the intent of its drafters and in a manner that also provides exporters with an efficient and expedited process for engaging in authorized exports of agricultural commodities, medicine, and medical devices. Following this approach, OFAC is applying the licensing procedures required by section 906 of the TSRA to all exports and

reexports of agricultural commodities, medicine, and medical devices to Sudan, Libya, and Iran that are within the current scope of OFAC's licensing jurisdiction. Similarly, OFAC is applying this licensing procedure to cover exports to the governments of Sudan, Libya, and Iran, any entities in these countries, and individuals in these countries, as well as to persons in third countries purchasing specifically for resale to any of the foregoing.

*Cuban Assets Control Regulations.*

This rule implements the TSRA with respect to the Cuban Assets Control Regulations, 31 CFR part 515 (the "CACR"), in the following ways:

With respect to exports from the United States to Cuba, § 515.533 of the CACR already provides a general license for transactions incident to exportations that are licensed or otherwise authorized by the Department of Commerce. As was the case prior to enactment of the TSRA, exporters seeking to export items from the United States to Cuba should seek authorization from the Commerce Department, which is also amending its regulations to implement the TSRA.

OFAC is amending § 515.533 to clarify that reexports of U.S.-origin items by persons subject to U.S. jurisdiction are also covered by this general license. Thus, overseas persons subject to U.S. jurisdiction that wish to reexport U.S.-origin items to Cuba are authorized to do so provided the reexport is licensed or otherwise authorized by the Commerce Department.

OFAC is also amending § 515.533 to clarify the general restrictions on financing sales of licensed items to Cuba and to implement the special financing restrictions with respect to licensed agricultural sales to Cuba contained in Section 908(b) of the TSRA. The new language slightly expands the payment and financing terms that may be used in agricultural sales to Cuba from those that previously existed.

Although § 515.207 of the CACR prohibits the entry into U.S. ports by vessels engaged in Cuban commerce, § 515.550 already provides a waiver for those vessels engaged in trade with Cuba that is licensed or otherwise exempt. Thus, vessels carrying exports or reexports of agricultural commodities, medicine, or medical supplies that have been licensed or otherwise authorized by the Commerce Department will be permitted to enter U.S. ports, provided they have not carried unlicensed and non-exempt cargo or persons to or from Cuba and provided they are not currently carrying unauthorized goods in which Cuba or a

Cuban national has an interest. A short note referencing this waiver is added to the end of § 515.207, which contains the prohibition on vessel entry.

Section 1706(a)(1) of the Cuban Democracy Act of 1992, 106 Stat. 2575, prohibits the issuance of licenses authorizing U.S.-owned or controlled foreign firms to engage in transactions related to the exportation to Cuba of commodities produced outside of the United States. OFAC is amending the Note to § 515.559 to make clear that U.S.-owned or controlled foreign firms may, however, be authorized to engage in the reexport of U.S.-origin items to Cuba pursuant to § 515.533. Otherwise, the provisions of § 515.559 remain unchanged.

With respect to section 910(a) of the TSRA, which authorizes Cuba travel-related transactions regarding the commercial sale of agricultural commodities, § 515.533(e) of the CACR already states that specific licenses may be issued on a case-by-case basis authorizing Cuba travel-related transactions directly incident to marketing, sales negotiation, accompanied delivery, and servicing of exports and reexports that appear consistent with the export and reexport licensing policy of the Commerce Department. A prospective exporter does not need to obtain a license from the Commerce Department before applying for such a travel license provided that the proposed exports or reexports clearly fit within current Commerce licensing policy. Section 515.560(b) of the CACR is amended to implement section 910(b) of the TSRA.

*Sudanese Sanctions Regulations (“SSR”), Libyan Sanctions Regulations (“LSR”), Iranian Transaction Regulations (“ITR”).* With respect to the SSR, LSR, and ITR, this rule is intended to establish an expedited process for the issuance of the one-year license required by section 906 of the TSRA. This rule also is intended to clarify the agricultural commodities, medical devices, and medicines covered by the new licensing provisions in these regulations. The Department of Treasury’s Office of Foreign Assets Control (“OFAC”) will put in place expedited procedures to respond to requests for licenses to export agricultural commodities, medicine, and medical devices to Sudan, Libya, and Iran. Exporters of all fertilizers, live horses, western red cedar, and medical devices require commodity classification from the Department of Commerce, Bureau of Export Administration (“BXA”) certifying that the product is EAR 99 included with the exporter’s license request to OFAC. See,

15 CFR 748.3 for instructions for submitting commodity classifications. However, BXA will publish on its website at [www.bxa.doc.gov/Regulations/TradeSanctionsReformExportEnhancementAct.html](http://www.bxa.doc.gov/Regulations/TradeSanctionsReformExportEnhancementAct.html) a list of medical supplies, such as syringes, bandages, gauze and similar items, that *do not* require BXA commodity classification prior to submitting a license application to OFAC. When submitting a license request to OFAC under its expedited review procedures, exporters must indicate to OFAC that their medical supply is on the BXA medical supply list on BXA’s website. Otherwise, exporters must provide OFAC with a copy of the BXA commodity classification for those medical devices that BXA has classified as EAR99. BXA’s website will also include a list of medicines that are not EAR 99 and, therefore, not eligible for exportation under these rules.

The expedited process will include, when appropriate, referral of the one-year license request to other government agencies for guidance in evaluating the request. If no government agency raises an objection to or concern with the application within nine business days from the date of any such referral, OFAC will issue the one-year license, provided that the request otherwise meets the requirements set forth in this rule. If any government agency raises an objection to the request within nine business days from the date of referral, OFAC will deny the request for the one-year license. If any government agency raises a concern short of an objection with the request within nine business days from the date of referral, OFAC will delay its response to the license request for no more than thirty additional days to allow for further review of the request.

The TSRA defines *agricultural commodities* by reference to the meaning given to that term in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602). This definition includes food commodities, feed, fish, shellfish and fish products, beer, wine and spirits, soft drinks, livestock, fiber, including cotton, wool, and other fibers, tobacco and tobacco products, wood and wood products (including lumber and utility poles), seeds, and reproductive materials such as fertilized eggs, embryos, and semen. It also includes certain fertilizers and organic fertilizers that are not otherwise controlled. The term *agricultural commodities* does not include furniture made from wood, clothing manufactured from plant or animal materials, agricultural equipment (whether hand tools or motorized

equipment), pesticides, insecticides, herbicides, or cosmetics (unless derived entirely from plant materials). Exporters may consult the Department of Agriculture website at <http://www.fas.usda.gov> for assistance in determining whether a particular item meets the definition of *agricultural commodities* under the Agricultural Trade Act. Although the definition of *agricultural commodities* under the TSRA does not include vitamins and minerals, food additives or supplements, or bottled drinking water, OFAC will include such items in the definition of *agricultural commodities* for the purposes of this rule. An Official Commodity Classification of EAR 99 obtained from BXA is required to be submitted with the exporter’s request to OFAC for a one-year license to export to Sudan, Libya, or Iran fertilizers, live horses, or western red cedar. An Official Commodity Classification from BXA is *not* required to be submitted with the exporter’s request for a one-year license to export to Sudan, Libya, or Iran any other agricultural commodity. See, 15 CFR 745.3 for instructions for obtaining an Official Commodity Classification of EAR 99 from BXA.

The TSRA defines the terms *medicine* and *medical device* by adopting the definitions of drug and device set forth in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). These definitions include prescription medicines and over-the-counter medicines for humans and animals that are classified as EAR 99. They also include medical supplies, instruments, equipment, and equipped ambulances that are so classified. They do not include general-purpose furniture and equipment (such as desks, tables, lamps, and office computers) used in medical offices and waiting rooms. Exporters may consult with the Food and Drug Administration for assistance in determining whether a particular item meets the definition of drug or device under the Federal Food, Drug, and Cosmetic Act. Although most medicines and medical devices are classified under the Export Administration Regulations, 15 CFR part 774, as EAR 99, certain vaccines, biological and chemical products, medical devices and parts for such devices are listed on the CCL and are not eligible for export under this rule. Exporters must have an Official Commodity Classification of EAR 99 from BXA for all medical devices (including supplies) prior to submitting a license request to OFAC, unless the item is specifically listed on BXA’s website at [www.bxa.doc.gov/Regulations/TradeSanctionsReform](http://www.bxa.doc.gov/Regulations/TradeSanctionsReform)

*Export Enhancement Act.* This list identifies those medical supplies, such as syringes, bandages, gauze and similar items, that *do not* require BXA classification prior to submitting a license application to OFAC. When submitting a license request to OFAC under its expedited review procedures, exporters must indicate to OFAC that their medical supply is listed on the BXA medical supply list on BXA's website. Otherwise, exporters must provide OFAC with a copy of the BXA Official Commodity Classification of EAR 99 for those medical devices not listed on the BXA website. See, 15 CFR 745.3 for instructions for obtaining Official Commodity Classification of EAR 99 from BXA.

In addition, BXA has identified on its website a list of medicines that are on the CCL and not eligible for OFAC's expedited review procedures. When submitting a license application to OFAC under its expedited review procedures, exporters must indicate to OFAC that their medicine is not on the BXA medicine list on BXA's website, in other words, that it is classified as EAR 99. If exporters are unsure of whether their medicine is on the CCL, they should seek an Official Commodity Classification from BXA confirming that their medicine is classified as EAR99 prior to submitting a license request to OFAC under its expedited review procedures. See, 15 CFR 745.3 for instructions for obtaining Official Commodity Classification of EAR 99 from BXA.

Sections 538.523, 550.569, and 560.530 set forth procedures and requirements for requesting and obtaining these one-year licenses. Incomplete requests will be returned to the requestor without action and without prejudice.

These amendments to the SSR, LSR, and ITR also grant by general license the authority for sellers to respond to public tenders on an executory basis, negotiate and sign executory contracts, and make necessary shipping and financing arrangements, not otherwise specifically prohibited by Chapter V of 31 CFR, for the exportation to Libya and the exportation or reexportation to Sudan and Iran of agricultural commodities, medicine, and medical devices. Before the actual exportation to Libya or exportation or reexportation to Sudan or Iran takes place, prospective exporters must obtain a one-year license issued by the Department of the Treasury upon a determination that such exports are covered by the TSRA and are not exports to any entity within Sudan, Libya, or Iran promoting international terrorism.

Specific licenses issued prior to the effective date of this rule authorizing the performance of executory contracts for the sale of agricultural commodities, medicine, or medical equipment shall remain in effect until the expiration date specified in the license or the first anniversary of the effective date of this rule, whichever comes first. However, after the effective date of this rule, new contracts for the exportation of agricultural commodities, medicine, or medical devices may be entered into only pursuant to the terms of, and as authorized by, this new rule.

Specific licenses issued prior to the effective date of this rule authorizing the sale and exportation or reexportation of bulk agricultural commodities listed in Appendix A to 31 CFR parts 538 and 550 and Appendix B to 31 CFR part 560 shall remain in effect solely to permit completion of performance of contracts already entered into prior to the effective date of this rule pursuant to the license. As of the effective date of this rule, new contracts for the exportation of bulk agricultural commodities may be entered into only pursuant to the terms of, and as authorized by, this new rule.

Nothing in this rule, however, affects prohibitions on the exportation of any agricultural commodity, medicine, or medical device listed on the CCL. Moreover, nothing in this rule affects prohibitions on the sale or supply of U.S. equipment, technology, or software used to manufacture agricultural commodities, medicine, or medical devices, such as technology to design or produce biotechnological items or medical devices. This rule does not affect U.S. nonproliferation export controls, including end-user and end-use controls maintained under the Enhanced Proliferation Control Initiative.

This rule amends the SSR, LSR, and ITR in the following ways:

The amendments to §§ 538.523, 550.569, and 560.530 of these regulations implement section 906 of the Act by amending current sanctions against Sudan, Libya, and Iran to require that all exports of covered agricultural products, medicine, and medical devices to the governments of these countries or any entities in these countries be authorized by one-year licenses issued by the Department of the Treasury. These one-year licenses will authorize the exporter to engage in the exportation or reexportation of the licensed products for up to one year from the date of signing of any contract that is entered into during the one-year period of the license.

The amendments to §§ 538.523, 550.569, and 560.530 of these

regulations further implement section 906 of the Act by providing exporters a general license to engage in certain transactions relating to the sale and exportation of covered items to Sudan, Libya, or Iran prior to obtaining the one-year license, such as responding to public tenders on an executory basis, negotiating and signing executory contracts or other agreements capable of acceptance, making shipping arrangements, obtaining insurance, and arranging financing, to the extent not otherwise prohibited by Chapter V of 31 CFR. The one-year licenses will also authorize the performance of executory contracts entered into pursuant to the general license. The amendments specify that any executory contracts entered into prior to obtaining the one-year license will be deemed to have been entered into on the date the one-year license is issued for the purpose of determining the beginning of the 12-month period during which exports may be shipped.

The amendments to §§ 538.523, 550.569, and 560.530 of these regulations also implement section 906 of the Act by providing procedures for requesting, and for the issuance of, the one-year licenses.

Sections 538.526, 550.572, and 560.533 are amended to extend the general license for U.S. persons to broker sales of bulk agricultural commodities by U.S. persons to include the provision of brokerage services on behalf of U.S. persons for sales of all agricultural commodities, medicines, and medical devices as defined by §§ 538.523, 550.569, and 560.530.

Clarifying amendments are made to §§ 538.205, 538.211, 538.405, 550.306, 550.318, 550.405, and 560.405.

Because the Regulations involve a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) (the "APA") requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. However, because of the importance of the issues raised by these regulations, this rule is issued in interim form and comments will be considered in the development of final regulations. Accordingly, the Department encourages interested persons who wish to comment to do so at the earliest possible time to permit the fullest consideration of their views.

The period for submission of comments will close September 10, 2001. The Department will consider all comments received before the close of the comment period in developing final regulations. Comments received after

the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept public comments accompanied by a request that a part or all of the submission be treated confidentially because of its business proprietary nature or for any other reason, and it will return such submission to the originator without considering them in the development of final regulations. In the interest of accuracy and completeness, the Department requires comments in written form.

All public comments on these regulations will be a matter of public record. Copies of the public record concerning these regulations will be made available, not sooner than October 10, 2001 and may be obtained from OFAC's website (<http://www.treas.gov/ofac>). If that service is unavailable, written requests for copies may be sent to: Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Ave., NW Washington, DC 20220, Attn: Merete Evans.

Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601-612) does not apply.

#### Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the "Reporting and Procedures Regulations"). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been previously approved by the Office of Management and Budget ("OMB") under control number 1505-0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

#### List of Subjects

##### 31 CFR Part 515

Administrative practice and procedure, Agricultural commodities, Banks, Banking, Cuba, Drugs, Exports, Foods, Foreign trade, Imports, Information, Investments, Loans, Medical devices, Medicine, Penalties, Reporting and recordkeeping requirements, Services, Specially designated nationals, Terrorism, Transportation.

##### 31 CFR Part 538

Administrative practice and procedure, Agricultural commodities, Banks, Banking, Drugs, Exports, Foods, Foreign trade, Imports, Information,

Investments, Loans, Medical devices, Medicine, Penalties, Reporting and recordkeeping requirements, Services, Specially designated nationals, Sudan, Terrorism, Transportation.

##### 31 CFR Part 550

Administrative practice and procedure, Agricultural commodities, Banks, Banking, Drugs, Exports, Foods, Foreign trade, Imports, Information, Investments, Libya, Loans, Medical devices, Medicine, Penalties, Reporting and recordkeeping requirements, Services, Specially designated nationals, Terrorism, Transportation.

##### 31 CFR Part 560

Administrative practice and procedure, Agricultural commodities, Banks, Banking, Drugs, Exports, Foods, Foreign trade, Imports, Information, Investments, Iran, Loans, Medical devices, Medicine, Penalties, Reporting and recordkeeping requirements, Services, Specially designated nationals, Terrorism, Transportation.

For the reasons set forth in the preamble, 31 CFR chapter V, parts 515, 538, 550, and 560 are amended as follows:

#### PART 515—CUBAN ASSETS CONTROL REGULATIONS

##### Authority

1. Revise the authority citation for 31 CFR part 515 to read as follows:

**Authority:** 18 U.S.C. 2332d; 22 U.S.C. 2370(a), 6001-6010; 31 U.S.C. 321(b); 50 U.S.C. App. 1-44; Pub. L. 101-410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 106-387, 114 Stat. 1549; E.O. 9193, 7 FR 5205, 3 CFR, 1938-1943 Comp., p. 1147; E.O. 9989, 13 FR 4891, 3 CFR, 1943-1948 Comp., p. 748; Proc. 3447, 27 FR 1085, 3 CFR, 1959-1963 Comp., p. 157; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614.

##### Subpart B—Prohibitions

2. Amend § 515.207 by adding a note to the end of the section to read as follows:

##### § 515.207 Entry of vessels engaged in trade with Cuba.

\* \* \* \* \*

**Note to § 515.207:** For the waiver of the prohibitions contained in this section for certain vessels engaged in licensed or exempt trade with Cuba, see § 515.550.

##### Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

3. Revise the heading and paragraphs (a) and (e) and remove paragraph (f) of § 515.533 to read as follow:

##### § 515.533 Transactions incident to exportations from the United States and reexportations of U.S.-origin items to Cuba.

(a) All transactions ordinarily incident to the exportation of goods, wares, and merchandise from the United States, or the reexportation of U.S.-origin goods, wares, and merchandise from a third country, to any person within Cuba are hereby authorized, provided the following terms and conditions are complied with:

(1) The exportation or reexportation is licensed or otherwise authorized by the Department of Commerce under the provisions of the Export Administration Act of 1979, as amended (50 U.S.C. app. 2401-2420) (see the Export Administration Regulations, 15 CFR 730-774); and

(2) Only the following payment or financing terms may be used:

- (i) Payment of cash in advance;
  - (ii) For authorized sales of agricultural items, financing by a banking institution located in a third country provided the banking institution is not a designated national, United States citizen, United States permanent resident alien, or an entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches). Such financing may be confirmed or advised by a United States banking institution; or
  - (iii) For all other authorized sales, financing by a banking institution located in a third country provided the banking institution is not a designated national or a person subject to the jurisdiction of the United States. Such financing may be confirmed or advised by a United States banking institution.
- \* \* \* \* \*

(e) Specific licenses may be issued on a case-by-case basis authorizing the travel-related transactions set forth in § 515.560(c) and other transactions that are directly incident to the marketing, sales negotiation, accompanied delivery, or servicing of exports or reexports that are consistent with the export or reexport licensing policy of the Department of Commerce.

\* \* \* \* \*

4. Revise the heading of § 515.559 and the Note to § 515.559 to read as follows:

##### § 515.559 Certain transactions by U.S.-owned or controlled foreign firms with Cuba.

\* \* \* \* \*

**Note to § 515.559:** For reexportation of U.S.-origin goods, wares, or merchandise by U.S.-owned or controlled foreign firms, see § 515.533. Transactions by U.S.-owned or controlled foreign firms directly incident to the exportation of information or informational materials or the donation of

food to nongovernmental entities or individuals in Cuba are exempt from the prohibitions of this part. See § 515.206. For the waiver of the prohibitions contained in § 515.207 with respect to vessels transporting shipments of goods, wares, or merchandise pursuant to this section, see § 515.550.

5. Revise paragraph (b) of § 515.560 to read as follows:

**§ 515.560 Travel-related transactions to, from, and within Cuba by persons subject to the jurisdiction of the United States.**

\* \* \* \* \*

(b) Effective October 28, 2000, no specific licenses will be issued authorizing the travel-related transactions in paragraph (c) of this section in connection with activities other than those referenced in paragraph (a) of this section.

\* \* \* \* \*

**PART 538—SUDANESE SANCTIONS REGULATIONS**

**Authority**

1. Revise the authority citation for 31 CFR part 538 to read as follows:

**Authority:** 3 U.S.C. 301; 31 U.S.C. 321(b); 18 U.S.C. 2339B, 2332d; 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 106–387, 114 Stat. 1549; E.O. 13067, 62 FR 59989; 3 CFR, 1997 Comp., p. 230.

**Subpart B—Prohibitions**

2. Revise § 538.205 to read as follows:

**§ 538.205 Prohibited exportation and reexportation of goods, technology, or services to Sudan.**

Except as otherwise authorized, the exportation or reexportation, directly or indirectly, to Sudan of any goods, technology (including technical data, software, or other information) or services from the United States or by a United States person, wherever located, or requiring the issuance of a license by a Federal agency, is prohibited.

3. Amend § 538.211 to redesignate paragraphs (b) through (e) as paragraphs (c) through (f) and to add a new paragraph (b) to read as follows:

**§ 538.211 Exempt transactions.**

\* \* \* \* \*

(b) *Humanitarian donations.* The prohibitions of this part do not apply to donations by United States persons of articles, such as food, clothing, and medicine, intended to be used to relieve human suffering.

\* \* \* \* \*

**Subpart D—Interpretations**

4. Amend § 538.405 by revising paragraph (b) to read as follows:

**§ 538.405 Transactions incidental to a licensed transaction authorized.**

\* \* \* \* \*

(b) Provision of any transportation services to or from Sudan not explicitly authorized in or pursuant to this part other than loading, transporting, and discharging licensed or exempt cargo there.

\* \* \* \* \*

**Subpart E—Licenses, Authorizations, and Statements of Licensing Policy**

5. Revise § 538.523 to read as follows:

**§ 538.523 Commercial sales, exportation, and reexportation of agricultural commodities, medicine, and medical devices.**

(a) *One-year license requirement.* The exportation or reexportation of agricultural commodities (including bulk agricultural commodities listed in appendix A to this part 538), medicine, or medical devices to the Government of Sudan, any entity in Sudan, individuals in Sudan, or persons in third countries purchasing specifically for resale to any of the foregoing, shall only be made pursuant to a one-year license issued by the U.S. Department of the Treasury, Office of Foreign Assets Control, for contracts entered into during the one-year period of the license and shipped within the 12-month period beginning on the date of the signing of the contract. No license will be granted for the exportation or reexportation of agricultural commodities, medicine, or medical equipment to any entity or individual in Sudan promoting international terrorism. Executory contracts entered into pursuant to paragraph (b)(2) of this section prior to the issuance of the one-year license described in this paragraph shall be deemed to have been signed on the date of issuance of that one-year license (and, therefore, the exporter is authorized to make shipments under that contract within the 12-month period beginning on the date of issuance of the one-year license).

(b) *General license for arrangement of exportation or reexportation of covered products.*

(1) The making of shipping arrangements, cargo inspection, obtaining of insurance, and arrangement of financing (consistent with § 538.525) for the exportation or reexportation of agricultural commodities, medicine, or medical devices to the Government of Sudan, entities in Sudan, individuals in Sudan, or persons in third countries purchasing specifically for resale to any of the foregoing, is authorized.

(2) If desired, entry into executory contracts (including executory pro

forma invoices, agreements in principle, or executory offers capable of acceptance such as bids in response to public tenders) for the exportation or reexportation of agricultural commodities, medicine, and medical devices to the Government of Sudan, entities in Sudan, individuals in Sudan, or persons in third countries purchasing specifically for resale to any of the foregoing, is authorized, provided that performance of an executory contract is expressly made contingent upon the prior issuance of the one-year license described in paragraph (a) of this section.

(c) *Instructions for obtaining one-year licenses.* In order to obtain the one-year license described in paragraph (a), the exporter must provide to the Office of Foreign Assets Control:

(1) The applicant's full legal name (if the applicant is a business entity, the state or jurisdiction of incorporation and principal place of business).

(2) The applicant's mailing and street address (so that OFAC may reach a responsible point of contact, the applicant should also include the name of the individual(s) responsible for the application and related commercial transactions along with their telephone and fax numbers and, if available, email addresses).

(3) The names, mailing addresses, and if available, fax and telephone numbers of all parties with an interest in the transaction. If the goods are being exported or reexported to a purchasing agent in Sudan, the exporter must identify the agent's principals at the wholesale level for whom the purchase is being made. If the goods are being exported or reexported to an individual, the exporter must identify any organizations or entities with which the individual is affiliated that have an interest in the transaction.

(4) A description of all items to be exported or reexported pursuant to the requested one-year license, including a statement that the item is classified as EAR 99, and, if necessary, documentation sufficient to verify that the items to be exported or reexported are classified as EAR 99 and do not fall within any of the limitations contained in paragraph (d) of this section.

(5) An Official Commodity Classification of EAR 99 issued by the Department of Commerce, Bureau of Export Administration ("BXA"), certifying that the product is EAR 99 is required to be submitted to OFAC with the request for a license authorizing the exportation or reexportation of all fertilizers, live horses, western red cedar, and medical devices other than basic medical supplies, such as

syringes, bandages, gauze and similar items, that are specifically listed on BXA's website, [www.bxa.doc.gov/Regulations/TradeSanctionsReformExportEnhancementAct.html](http://www.bxa.doc.gov/Regulations/TradeSanctionsReformExportEnhancementAct.html). Medical supplies that are specifically listed on BXA's website do not require an Official Commodity Classification of EAR 99 from BXA. BXA will also provide a list on its website of medicines that are ineligible for a one-year license under these procedures. If an exporter is uncertain whether the medicine to be exported is eligible, they should seek an Official Commodity Classification of EAR 99 from BXA and submit a copy to OFAC. See, 15 CFR 745.3 for instructions for obtaining Official Commodity Classification of EAR 99 from BXA.

(d) *Limitations.*

(1) Nothing in this section or in any license issued pursuant to paragraph (a) of this section relieves the exporter from compliance with the export license application requirements of another Federal agency.

(2) Nothing in this section or in any license issued pursuant to paragraph (a) of this section authorizes the exportation or reexportation of any agricultural commodity, medicine, or medical device controlled on the United States Munitions List established under section 38 of the Arms Export Control Act (22 U.S.C. 2778); controlled on any control list established under the Export Administration Act of 1979 or any successor statute (50 U.S.C. App. 2401 et seq.); or used to facilitate the development or production of a chemical or biological weapon or weapon of mass destruction.

(3) Nothing in this section or in any license issued pursuant to paragraph (a) of this section affects prohibitions on the sale or supply of U.S. technology or software used to manufacture agricultural commodities, medicine, or medical devices, such as technology to design or produce biotechnological items or medical devices.

(4) Nothing in this section or in any license issued pursuant to paragraph (a) of this section affects U.S. nonproliferation export controls, including end-user and end-use controls maintained under the Enhanced Proliferation Control Initiative.

(5) This section does not apply to any transaction or dealing involving property blocked pursuant to this chapter or to any other activity prohibited by this chapter that is not otherwise authorized in this part.

(e) *Covered items.* For the purposes of this part, agricultural commodities, medicine, and medical devices are defined below.

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that are not listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1, and that fall within the term "agricultural commodity" as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) Products not listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1, that are intended for ultimate use in Sudan as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, the term medicine has the same meaning given the term "drug" in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) but does not include any item listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1 (excluding items classified as EAR 99).

(3) *Medical device.* For the purposes of this section, the term medical device has the meaning given the term "device" in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) but does not include any item listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1 (excluding items classified as EAR 99).

(f) *Transition period.*

(1) Specific licenses issued prior to July 26, 2001 authorizing the performance of executory contracts for the sale of agricultural commodities, medicine, or medical equipment shall remain in effect until the expiration date specified in the license or July 26, 2002, whichever comes first. However, after July 26, 2001, new contracts for the exportation of agricultural commodities, medicine, or medical devices may be entered into only pursuant to the terms of, and as authorized by, this part.

(2) Specific licenses issued prior to July 26, 2001 authorizing the sale and exportation or reexportation of bulk agricultural commodities listed in Appendix A to 31 CFR parts 538 and 550 and Appendix B to 31 CFR part 560 shall remain in effect solely to permit

completion of performance of contracts already entered into prior to July 26, 2001 pursuant to the license. As of July 26, 2001, new contracts for the exportation of bulk agricultural commodities may be entered into only pursuant to the terms of, and as authorized by, this part.

**§ 538.524 [removed and reserved]**

6. Remove and reserve § 538.524.

7. Amend § 538.525 to revise the heading and paragraph (d) and to add a new paragraph (e) to read as follows:

**§ 538.525 Payment for and financing of commercial sales of agricultural commodities, medicine, and medical equipment.**

\* \* \* \* \*

(d) *Transfers through the U.S. financial system.* Before a United States financial institution initiates a payment on behalf of any customer, or credits a transfer to the account on its books of the ultimate beneficiary, the United States financial institution must determine that the underlying transaction is not prohibited by this part. Any payment relating to a transaction authorized in or pursuant to § 538.523 or § 538.526 that is routed through the U.S. financial system must reference the relevant Office of Foreign Assets Control license authorizing the payment to avoid the blocking or rejection of the transfer.

(e) Notwithstanding any other provision of this part, no commercial exportation to Sudan may be made with United States Government assistance, including United States foreign assistance, United States export assistance, and any United States credit or guarantees absent a Presidential waiver.

8. Amend § 538.526 to revise the heading and paragraphs (a), (b) introductory text, (b)(1) and (b)(2) to read as follows:

**§ 538.526 Brokering sales of agricultural commodities, medicine, and medical devices.**

(a) *General license for brokering sales by U.S. persons.* United States persons are authorized to provide brokerage services on behalf of U.S. persons for the sale and exportation or reexportation by United States persons of agricultural commodities, medicine, and medical devices, provided that the sale and exportation or reexportation is authorized by a one-year license issued pursuant to § 538.523.

(b) *Specific licensing for brokering sales by non-U.S. persons of bulk agricultural commodities.* Specific licenses may be issued on a case-by-case

basis to permit United States persons to provide brokerage services on behalf of non-United States, non-Sudanese persons for the sale and exportation or reexportation of bulk agricultural commodities to the Government of Sudan, entities in Sudan or individuals in Sudan. Specific licenses issued pursuant to this section will authorize the brokering only of sales that:

- (1) Are limited to the bulk agricultural commodities listed in appendix A to this part 538;
- (2) Are to purchasers permitted pursuant to § 538.523;

**Note to paragraph (b)(2):** Requests for specific licenses to provide brokerage services under this paragraph must include all of the information described in § 538.523(c).

\* \* \* \* \*

**PART 550—LIBYAN SANCTIONS REGULATIONS**

**Authority**

1. Revise the authority citation for 31 CFR part 550 to read as follows:

**Authority:** 3 U.S.C. 301; 18 U.S.C. 2339B, 2332d; 22 U.S.C. 287c, 2349aa-8 and 2349aa-9; 31 U.S.C. 321(b); 49 U.S.C. 40106(b); 50 U.S.C. 1601-1651, 1701-1706; Pub. L. 101-410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 106-387, 114 Stat. 1549; E.O. 12543, 51 FR 875; 3 CFR, 1986 Comp., p. 181; E.O. 12544, 51 FR 1235, 3 CFR, 1986 Comp., p. 183; E.O. 12801, 57 FR 14319 3 CFR, 1992 Comp., p. 294.

**Subpart C—Definitions**

2. Revise § 550.206 to read as follows:

**§ 550.306 Person.**

The term *person* means an individual or entity.

3. Revise § 550.308 to read as follows:

**§ 550.308 United States person.**

The term *United States person*, or as abbreviated, *U.S. person*, means any United States citizen, permanent resident alien, juridical person authorized under the laws of the United States (including foreign branches), or any person in the United States.

4. Revise § 550.318 to read as follows:

**§ 550.318 Entity.**

The term *entity* means a partnership, association, trust, joint venture, corporation, or other organization.

**Subpart D—Interpretations**

5. Amend § 550.405 to revise paragraph (b) to read as follows:

**§ 550.405 Transactions incidental to a licensed transaction authorized.**

\* \* \* \* \*

(b) Provision of any transportation services to or from Libya not explicitly authorized in or pursuant to this part other than loading, transporting, and discharging licensed or exempt cargo there.

\* \* \* \* \*

**Subpart E—Licenses, Authorizations, and Statements of Licensing Policy**

6. Revise § 550.569 to read as follows:

**§ 550.569 Commercial sales and exportation of agricultural commodities, medicine, and medical devices.**

(a) *One-year license requirement.* The exportation of agricultural commodities (including bulk agricultural commodities listed in appendix A to this part 550), medicine, or medical devices to the Government of Libya, any entity in Libya, individuals in Libya, or persons in third countries purchasing specifically for resale to any of the foregoing, shall only be made pursuant to a one-year license issued by the United States Department of the Treasury, Office of Foreign Assets Control, for contracts entered into during the one-year period of the license and shipped within the 12-month period beginning on the date of the signing of the contract. No license will be granted for the exportation of agricultural commodities, medicine, or medical equipment to any entity or individual in Libya promoting international terrorism. Executory contracts entered into pursuant to paragraph (b)(2) of this section prior to the issuance of the one-year license described in this paragraph shall be deemed to have been signed on the date of issuance of that one-year license (and, therefore, the exporter is authorized to make shipments under that contract within the 12-month period beginning on the date of issuance of the one-year license).

(b) *General license for arrangement of exportation of covered products.*

(1) The making of shipping arrangements, cargo inspection, obtaining of insurance, and arrangement of financing (consistent with § 550.571) for the exportation of agricultural commodities, medicine, and medical devices to the Government of Libya, entities in Libya, individuals in Libya, or persons in third countries purchasing specifically for resale to any of the foregoing, is authorized.

(2) If desired, entry into executory contracts (including executory pro forma invoices, agreements in principle, or executory offers capable of acceptance such as bids in response to public tenders) for the exportation of

agricultural commodities, medicine, and medical devices to the Government of Libya, entities in Libya, individuals in Libya, or persons in third countries purchasing specifically for resale to any of the foregoing, is authorized, provided that performance of an executory contract is expressly made contingent upon the prior issuance of the one-year license described in paragraph (a) of this section.

(c) *Instructions for obtaining one-year licenses.* In order to obtain the one-year license described in paragraph (a), the exporter must provide to the Office of Foreign Assets Control:

(1) The applicant's full legal name (if the applicant is a business entity, the state or jurisdiction of incorporation and principal place of business).

(2) The applicant's mailing and street address (so that OFAC may reach a responsible point of contact, the applicant should also include the name of the individual(s) responsible for the application and related commercial transactions along with their telephone and fax numbers and, if available, email addresses).

(3) The names and addresses and, if available, fax and phone numbers of all parties with an interest in the transaction. If the goods are being exported to a purchasing agent in Libya, the exporter must identify the agent's principals at the wholesale level for whom the purchase is being made. If the goods are being exported to an individual, the exporter must identify any organizations or entities with which the individual is affiliated that have an interest in the transaction.

(4) A description of all items to be exported pursuant to the requested one-year license, including a statement that the item is classified as EAR 99, and, if necessary, documentation sufficient to verify that the items to be exported are classified as EAR 99 and do not fall within any of the limitations contained in paragraph (d) of this section.

(5) An Official Commodity Classification of EAR 99 issued by the Department of Commerce, Bureau of Export Administration ("BXA"), certifying that the product is EAR 99 is required to be submitted to OFAC with the request for a license authorizing the exportation or reexportation of all fertilizers, live horses, western red cedar, and medical devices other than basic medical supplies, such as syringes, bandages, gauze and similar items, that are specifically listed on BXA's website, [www.bxa.doc.gov/Regulations/TradeSanctionsReformExportEnhancementAct.html](http://www.bxa.doc.gov/Regulations/TradeSanctionsReformExportEnhancementAct.html). Medical supplies that are specifically listed on BXA's website do not require an Official



Commodity Classification of EAR 99 from BXA. BXA will also provide a list on its website of medicines that are ineligible for a one-year license under these procedures. If an exporter is uncertain whether the medicine to be exported is eligible, they should seek an Official Commodity Classification of EAR 99 from BXA and submit a copy to OFAC. See, 15 CFR 745.3 for instructions for obtaining Official Commodity Classification of EAR 99 from BXA.

(d) *Limitations.*

(1) Nothing in this section or in any license issued pursuant to paragraph (a) of this section relieves the exporter from compliance with the export license application requirements of another Federal agency.

(2) Nothing in this section or in any license issued pursuant to paragraph (a) of this section authorizes the exportation or reexportation of any agricultural commodity, medicine, or medical device controlled on the United States Munitions List established under section 38 of the Arms Export Control Act (22 U.S.C. 2778); controlled on any control list established under the Export Administration Act of 1979 or any successor statute (50 U.S.C. App. 2401 *et seq.*); or used to facilitate the development or production of a chemical or biological weapon or weapon of mass destruction.

(3) Nothing in this section or in any license issued pursuant to paragraph (a) of this section affects prohibitions on the sale or supply of U.S. technology or software used to manufacture agricultural commodities, medicine, or medical devices, such as technology to design or produce biotechnological items or medical devices.

(4) Nothing in this section or in any license issued pursuant to paragraph (a) of this section affects U.S. nonproliferation export controls, including end-user and end-use controls maintained under the Enhanced Proliferation Control Initiative.

(5) This section does not apply to any transaction or dealing involving property blocked pursuant to this chapter or any other activity prohibited by this chapter not otherwise authorized in this part.

(e) *Covered items.* For the purposes of this part, agricultural commodities, medicine, and medical devices are defined below.

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products that are not listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1, and that fall

within the term "agricultural commodity" as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) Products not listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1, that are intended for ultimate use in Libya as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, the term *medicine* has the same meaning given the term "drug" in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) but does not include any item listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1 (excluding items classified as EAR 99).

(3) *Medical device.* For the purposes of this section, the term *medical device* has the meaning given the term "device" in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) but does not include any item listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1 (excluding items classified as EAR 99).

(f) *Transition period.*

(1) Specific licenses issued prior to July 26, 2001 authorizing the performance of executory contracts for the sale of agricultural commodities, medicine, or medical equipment shall remain in effect until the expiration date specified in the license or July 26, 2002, whichever comes first. However, after July 26, 2001, new contracts for the exportation of agricultural commodities, medicine, or medical devices may be entered into only pursuant to the terms of, and as authorized by, this part.

(2) Specific licenses issued prior to July 26, 2001 authorizing the sale and exportation or reexportation of bulk agricultural commodities listed in Appendix A to 31 CFR parts 538 and 550 and Appendix B to 31 CFR part 560 shall remain in effect solely to permit completion of performance of contracts already entered into prior to July 26, 2001 pursuant to the license. As of July 26, 2001, new contracts for the exportation of bulk agricultural commodities may be entered into only

pursuant to the terms of, and as authorized by, this part.

7. Remove and reserve § 550.570.

**§ 550.570 [Removed and reserved]**

8. Amend § 550.571 to revise the heading and paragraph (d) and to add a new paragraph (e) to read as follows:

**§ 550.571 Payment for and financing of exports of agricultural commodities, medicine, and medical equipment.**

\* \* \* \* \*

(d) *Transfers through the U.S. financial system.* Before a United States financial institution initiates a payment on behalf of any customer, or credits a transfer to the account on its books of the ultimate beneficiary, the United States financial institution must determine that the underlying transaction is not prohibited by this part. Any payment relating to a transaction authorized in or pursuant to § 550.569 or § 550.572 that is routed through the U.S. financial system must reference the relevant Office of Foreign Assets Control license authorizing the payment to avoid the blocking or rejection of the transfer.

(e) Notwithstanding any other provision of this part, no commercial exportation to Libya may be made with United States Government assistance, including United States foreign assistance, United States export assistance, and any United States credit or guarantees absent a Presidential waiver.

9. Amend § 550.572 to revise the heading and paragraphs (a), (b) introductory text, (b)(1) and (b)(2) to read as follows:

**§ 550.572 Brokering sales of agricultural commodities, medicine, and medical devices.**

(a) *General license for brokering sales by U.S. persons.* United States persons are authorized to provide brokerage services on behalf of U.S. persons for the sale and exportation or reexportation by United States persons of agricultural commodities, medicine, and medical devices, provided that the sale and exportation or reexportation is authorized by a one-year license issued pursuant to § 550.569.

(b) *Specific licensing for brokering sales by non-U.S. persons of bulk agricultural commodities.* Specific licenses may be issued on a case-by-case basis to permit United States persons to provide brokerage services on behalf of non-United States, non-Libyan persons for the sale and exportation or reexportation of bulk agricultural commodities to the Government of Libya, entities in Libya or individuals in

Libya. Specific licenses issued pursuant to this section will authorize the brokering only of sales that:

(1) Are limited to the bulk agricultural commodities listed in appendix A to this part 550;

(2) Are to purchasers permitted pursuant to § 550.569;

**Note to paragraph (b)(2):** Requests for specific licenses to provide brokerage services under this paragraph must include all of the information described in § 550.569(c).

\* \* \* \* \*

10. Revise § 550.573 to read as follows:

**§ 550.573 Travel transactions in connection with the exportation of agricultural commodities, medicine, and medical devices.**

Travel transactions to, from, and within Libya for the sole purpose of engaging in transactions authorized by § 550.569 are authorized. Travel transactions related to installation or servicing of medical equipment sold pursuant to § 550.569 must be authorized by specific license. See § 501.801(b) of this chapter for specific licensing procedures.

**Note to § 550.573:** U.S. passports must be validated by the U.S. Department of State for travel to Libya.

**PART 560—IRAN TRANSACTION REGULATIONS**

**Authority**

1. Revise the authority citation for part 560 to read as follows:

**Authority:** 3 U.S.C. 301; 18 U.S.C. 2339B, 2332d; 22 U.S.C. 2349aa–9; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 106–387, 114 Stat. 1549; E.O. 12613, 52 FR 41940, 3 CFR, 1987 Comp., p. 256; E.O. 12957, 60 FR 14615, 3 CFR, 1995 Comp., p. 332; E.O. 12959, 60 FR 24757, 3 CFR, 1995 Comp., p. 356; E.O. 13059, 62 FR 44531, 3 CFR, 1997 Comp., p. 217.

**Subpart D—Interpretations**

2. Amend § 560.405 to revise paragraph (b) to read as follows:

**§ 560.405 Transactions incidental to a licensed transaction authorized.**

\* \* \* \* \*

(b) Provision of any transportation services to or from Iran not explicitly authorized in or pursuant to this part other than loading, transporting, and discharging licensed or exempt cargo there.

\* \* \* \* \*

**Subpart E—Licenses, Authorizations and Statements of Licensing Policy**

3. Amend § 560.520 to revise the heading to read as follows:

**§ 560.520 Exportation of agricultural commodities on contracts entered into prior to May 7, 1995.**

\* \* \* \* \*

4. Revise § 560.530 to read as follows:

**§ 560.530 Commercial sales, exportation, and reexportation of agricultural commodities, medicine, and medical devices.**

(a) *One-year license requirement.* The exportation or reexportation of agricultural commodities (including bulk agricultural commodities listed in appendix B to this part 560), medicine, or medical devices to the Government of Iran, any entity in Iran, individuals in Iran, or persons in third countries purchasing specifically for resale to any of the foregoing, shall only be made pursuant to a one-year license issued by the United States Department of the Treasury, Office of Foreign Assets Control, for contracts entered into during the one-year period of the license and shipped within the 12-month period beginning on the date of the signing of the contract. No license will be granted for the exportation or reexportation of agricultural commodities, medicine, or medical equipment to any entity or individual in Iran promoting international terrorism. Executory contracts entered into pursuant to paragraph (b)(2) of this section prior to the issuance of the one-year license described in this paragraph shall be deemed to have been signed on the date of issuance of that one-year license (and, therefore, the exporter is authorized to make shipments under that contract within the 12-month period beginning on the date of issuance of the one-year license).

(b) *General license for arrangement of exportation and reexportation of covered products.*

(1) The making of shipping arrangements, cargo inspections, obtaining of insurance, and arrangement of financing (consistent with § 560.532) for the exportation or reexportation of agricultural commodities, medicine, and medical devices to the Government of Iran, entities in Iran, individuals in Iran, or persons in third countries purchasing specifically for resale to any of the foregoing, is authorized.

(2) If desired, entry into executory contracts (including executory pro forma invoices, agreements in principle, or executory offers capable of acceptance such as bids in response to public tenders) for the exportation or

reexportation of agricultural commodities, medicine, and medical devices to the Government of Iran, entities in Iran, individuals in Iran, or persons in third countries purchasing specifically for resale to any of the foregoing, is authorized, provided that performance of an executory contract is expressly made contingent upon the prior issuance of the one-year license described in paragraph (a) of this section.

(c) *Instructions for obtaining one-year licenses.* In order to obtain the one-year license described in paragraph (a), the exporter must provide to the Office of Foreign Assets Control:

(1) The applicant's full legal name (if the applicant is a business entity, the state or jurisdiction of incorporation and principal place of business).

(2) The applicant's mailing and street address (so that OFAC may reach a responsible point of contact, the applicant should also include the name of the individual(s) responsible for the application and related commercial transactions along with their telephone and fax numbers and, if available, email addresses).

(3) The names, mailing addresses, and, if available, fax and telephone numbers of all parties with an interest in the transaction. If the goods are being exported or reexported to a purchasing agent in Iran, the exporter must identify the agent's principals at the wholesale level for whom the purchase is being made. If the goods are being exported or reexported to an individual, the exporter must identify any organizations or entities with which the individual is affiliated that have an interest in the transaction.

(4) A description of all items to be exported or reexported pursuant to the requested one-year license, including a statement that the item is classified as EAR 99, and, if necessary, documentation sufficient to verify that the items to be exported or reexported are classified as EAR 99 and do not fall within any of the limitations contained in paragraph (d) of this section.

(5) An Official Commodity Classification of EAR 99 issued by the Department of Commerce, Bureau of Export Administration ("BXA"), certifying that the product is EAR 99 is required to be submitted to OFAC with the request for a license authorizing the exportation or reexportation of all fertilizers, live horses, western red cedar, and medical devices other than basic medical supplies, such as syringes, bandages, gauze and similar items, that are specifically listed on BXA's website, [www.bxa.doc.gov/Regulations/TradeSanctions](http://www.bxa.doc.gov/Regulations/TradeSanctions)

*ReformExport EnhancementAct.html*. Medical supplies that are specifically listed on BXA's website do not require an Official Commodity Classification of EAR 99 from BXA. BXA will also provide a list on its website of medicines that are ineligible for a one-year license under these procedures. If an exporter is uncertain whether the medicine to be exported is eligible, they should seek an Official Commodity Classification of EAR 99 from BXA and submit a copy to OFAC. See, 15 CFR 745.3 for instructions for obtaining Official Commodity Classification of EAR 99 from BXA.

(d) *Limitations.*

(1) Nothing in this section or in any license issued pursuant to paragraph (a) of this section relieves the exporter from compliance with the export license application requirements of another Federal agency.

(2) Nothing in this section or in any license issued pursuant to paragraph (a) of this section authorizes the exportation or reexportation of any agricultural commodity, medicine, or medical device controlled on the United States Munitions List established under section 38 of the Arms Export Control Act (22 U.S.C. 2778); controlled on any control list established under the Export Administration Act of 1979 or any successor statute (50 U.S.C. App. 2401 *et seq.*); or used to facilitate the development or production of a chemical or biological weapon or weapon of mass destruction.

(3) Nothing in this section or in any license issued pursuant to paragraph (a) of this section affects prohibitions on the sale or supply of U.S. technology or software used to manufacture agricultural commodities, medicine, or medical devices, such as technology to design or produce biotechnological items or medical devices.

(4) Nothing in this section or in any license issued pursuant to paragraph (a) of this section affects U.S. nonproliferation export controls, including end-user and end-use controls maintained under the Enhanced Proliferation Control Initiative.

(5) This section does not apply to any transaction or dealing involving property blocked pursuant to this chapter or any other activity prohibited by this chapter not otherwise authorized in this part.

(e) *Covered items.* For the purposes of this part, agricultural commodities, medicine, and medical devices are defined below.

(1) *Agricultural commodities.* For the purposes of this section, agricultural commodities are:

(i) Products not listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1, and that fall within the term "agricultural commodity" as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602); and

(ii) Products not listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1, that are intended for ultimate use in Iran as:

(A) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(B) Seeds for food crops;

(C) Fertilizers or organic fertilizers; or

(D) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this section, the term medicine has the same meaning given the term "drug" in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) but does not include any item listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1 (excluding items classified as EAR 99).

(3) *Medical device.* For the purposes of this section, the term medical device has the meaning given the term "device" in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) but does not include any item listed on the Commerce Control List in the Export Administration Regulations, 15 CFR part 774, supplement no. 1 (excluding items classified as EAR 99).

(f) *Transition period.*

(1) Specific licenses issued prior to July 26, 2001 authorizing the performance of executory contracts for the sale of agricultural commodities, medicine, or medical equipment shall remain in effect until the expiration date specified in the license or July 26, 2002, whichever comes first. However, after July 26, 2001, new contracts for the exportation of agricultural commodities, medicine, or medical devices may be entered into only pursuant to the terms of, and as authorized by, this new part.

(2) Specific licenses issued prior to July 26, 2001 authorizing the sale and exportation or reexportation of bulk agricultural commodities listed in Appendix A to 31 CFR parts 538 and 550 and Appendix B to 31 CFR part 560 shall remain in effect solely to permit completion of performance of contracts already entered into prior to July 26, 2001 pursuant to the license. As of July

26, 2001, new contracts for the exportation of bulk agricultural commodities may be entered into only pursuant to the terms of, and as authorized by, this part.

**§ 560.531 [Removed and reserved]**

5. Remove and reserve § 560.531.

6. Amend § 560.532 to revise the heading and paragraph (d) and to add a new paragraph (e) to read as follows:

**§ 560.532 Payment for and financing of exports and reexports of commercial commodities, medicine, and medical devices.**

\* \* \* \* \*

(d) *Transfers through the U.S. financial system.* Any payment relating to a transaction authorized in or pursuant to § 560.530 or § 560.533 that is routed through the U.S. financial system must reference the relevant Office of Foreign Assets Control license authorizing the payment to avoid the rejection of the transfer. See § 560.516(b).

(e) Notwithstanding any other provision of this part, no commercial exportation to Iran may be made with United States Government assistance, including United States foreign assistance, United States export assistance, and any United States credit or guarantees absent a Presidential waiver.

7. Amend § 560.533 to revise the heading and paragraphs (a), (b) introductory text, (b)(1), and (b)(2) to read as follows:

**§ 560.533 Brokering sales of agricultural commodities, medicine, and medical devices.**

(a) *General license for brokering sales by U.S. persons.* United States persons are authorized to provide brokerage services on behalf of U.S. persons for the sale and exportation or reexportation by United States persons of agricultural commodities, medicine, and medical devices, provided that the sale and exportation or reexportation is authorized by a one-year license issued pursuant to § 560.530.

(b) *Specific licensing for brokering sales by non-U.S. persons of bulk agricultural commodities.* Specific licenses may be issued on a case-by-case basis to permit United States persons to provide brokerage services on behalf of non-United States, non-Iranian persons for the sale and exportation or reexportation of bulk agricultural commodities to the Government of Iran, entities in Iran or individuals in Iran. Specific licenses issued pursuant to this section will authorize the brokering only of sales that:

(1) Are limited to the bulk agricultural commodities listed in appendix B to this part 560;

(2) Are to purchasers permitted pursuant to § 560.530;

\* \* \* \* \*

**Note to § 560.533(b)(2):** Requests for specific licenses to provide brokerage services under this paragraph must include all of the information described in § 560.530(c).

Dated: June 6, 2001.

**Loren L. Dohm,**  
*Acting Director, Office of Foreign Assets Control.*

Approved: June 14, 2001.

**James F. Sloan,**  
*Acting Under Secretary (Enforcement),  
Department of the Treasury.*

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