

DEPARTMENT OF COMMERCE**Bureau of Export Administration****15 CFR Parts 740, 742, 746, 772 and 774**

[Docket No. 010612152-1152-01]

RIN 0694-AC37

Exports of Agricultural Commodities, Medicines and Medical Devices**AGENCY:** Bureau of Export Administration, Commerce.**ACTION:** Interim final rule with request for comments.

SUMMARY: This rule amends the Export Administration Regulations (EAR) to implement certain provisions of the Trade Sanctions Reform and Export Enhancement Act (TSRA) of 2000. The TSRA requires the President to terminate existing U.S. unilateral agricultural and medical sanctions and also provides that the export of agricultural commodities, medicines and medical devices to designated terrorist countries be made in accordance with the licensing regime described in that Act. The Department of Commerce is implementing TSRA as it relates to exports of agricultural commodities to Cuba. This rule establishes License Exception Agricultural Commodities (AGR) to permit exports and reexports to Cuba of agricultural commodities that are not specifically identified on the Commerce Control List (CCL) and are classified as EAR99. The Department of the Treasury's Office of Foreign Assets Control (OFAC) is implementing TSRA as it relates to exports to Iran, Libya, and Sudan of agricultural commodities, medicines and medical devices that are not specifically identified on the CCL and are classified as EAR99.

DATES: This rule is effective July 26, 2001. Comments must be received by September 10, 2001.

ADDRESSES: Written comments should be sent to Kirsten Mortimer, Regulatory Policy Division, Bureau of Export Administration, Department of Commerce, Room 2705, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Brian Nilsson, Office of Strategic Trade and Foreign Policy Controls, Bureau of Export Administration, Telephone: (202) 482-4196, E-mail: bnilsson@bxa.doc.gov.

SUPPLEMENTARY INFORMATION:**Background**

On October 28, 2000, the President signed the Trade Sanctions Reform and Export Enhancement Act (TSRA) (Title IX of Pub. L. 106-387) which 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, except that exports of agricultural commodities, medicines and medical devices to designated terrorist countries are subject to the export requirements described in the TSRA. A designated terrorist country is a country that has been determined by the Secretary of State to have repeatedly provided support for acts of international terrorism under section 620A of the Foreign Assistance Act of 1961, section 6(j)(1) of the Export Administration Act of 1979, or section 40(d) of the Arms Export Control Act.

The TSRA does not require the President to terminate 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.

This rule amends the EAR to create a new License Exception AGR for exports of agricultural commodities classified as EAR99 from the United States to Cuba and reexports of U.S. origin agricultural commodities classified as EAR99 to Cuba. The Department of the Treasury's Office of Foreign Assets Control is also taking action to implement the TSRA requirements, notably with respect to agricultural and medical exports classified as EAR99 to Iran, Sudan and Libya.

I. License Exception Agricultural Commodities (AGR) to Cuba

This rule establishes a new License Exception Agricultural Commodities (AGR) in § 740.18 of the EAR. License Exception AGR authorizes exports and certain reexports of agricultural commodities provided that they are classified as EAR99 and meet all the other criteria of License Exception AGR, including the prior notification requirements described below. License Exception AGR is not applicable for items controlled under a specific Export Control Classification Number (ECCN) on the Commerce Control List (CCL). To be eligible for AGR, shipments of

agricultural commodities must be made pursuant to a written contract and must take place within one year of the signing of a contract, unless the shipment is a commercial sample or donation in which case the contract requirement does not apply. Agricultural commodities are defined in part 772 (Definitions of Terms) of the EAR and must be classified as EAR99 to be eligible for License Exception AGR. Transactions that do not satisfy all the criteria of License Exception AGR require a license from BXA.

Prior Notification Requirement

As noted above, to be eligible for License Exception AGR, exporters must also provide prior notification by completing the Multipurpose Application Form (BXA-748P) or its electronic equivalent and including certain information requested on the BXA-748P form. The following blocks must be completed, as appropriate, on the Multipurpose Application Form: Blocks 1, 2, 3, 4, 5, 14, 16, 17, 18, 19, 21, 22 (a), (e), (f), (g), (h), (i), (j), 23, and 25. If your commodity is fertilizer, western red cedar or live horses, you must confirm that BXA has previously classified your commodity as EAR99 by placing the Commodity Classification Automatic Tracking System (CCATS) number in block 22(d). The box "other" must be selected as the type of application. This designator will automatically place the notification into a special review track. BXA will not initiate the registration of the notice unless all the required information is complete. BXA will refer notifications to interested reviewing agencies within two business days of registration. The application control number will allow exporters and reexporters to track their notices by calling the System for Tracking Export License Applications (STELA) at (202) 482-2752. STELA will provide the date of registration of the notification and a notification number. If no reviewing agencies raise objections within nine business days, STELA will confirm that you may proceed with the transaction, provided you satisfy all other requirements of License Exception AGR, including the requirement to have a written contract prior to any shipment. BXA will issue subsequent written confirmation. STELA will also advise if a license is required, in which case BXA will process the notification as a license application in accordance with the procedures described in part 750 and the licensing policies set forth in the EAR. BXA will change the notification number to a license application number. At this time, BXA may request additional information to complete the

processing of the license application. These procedures implement section 906(a)(1) of the Trade Sanctions Reform and Export Enhancement Act which requires that procedures be in place to deny exports of agricultural commodities to any entity in Cuba that promotes international terrorism.

Donations of Agricultural Commodities to Cuba

Donations of agricultural commodities are eligible for export and reexport to Cuba under License Exception AGR, provided the transaction meets the requirements and procedures of this license exception, except the contract requirement does not apply. Donations of food items to non-governmental organizations (NGOs) and individuals in Cuba may also be eligible for License Exception GFT. See § 740.12 for eligibility requirements of gift parcels and humanitarian donations under License Exception GFT.

Exports of Medicines and Medical Devices to Cuba

Exports of medicines and medical devices are not eligible for export or reexport to Cuba under TSRA procedures and, therefore, License Exception AGR is not available. Such items continue to require authorization for export to Cuba under the provisions of the Cuban Democracy Act (CDA) (22 U.S.C. 6004). BXA reviews applications for such exports on a case-by-case basis and will generally approve such exports unless one of the restrictions set forth in the CDA and in section 746.2 of the EAR applies. As is the standard licensing practice under the EAR, licenses issued have a twenty-four month validity period. Exporters are not required to have a written contract to apply for an export license.

II. OFAC Authorization for Agricultural Commodities, Medicines and Medical Devices to Iran, Libya and Sudan

The Department of the Treasury's Office of Foreign Assets Control (OFAC) is implementing the provisions of TSRA as they relate to exports of agricultural commodities, medicines and medical devices that are classified as EAR99 to Iran, Libya and Sudan. Exporters should review OFAC's regulations for the requirements relating to exports of agricultural commodities, medicines and medical devices to Iran, Libya and Sudan.

As explained in the OFAC regulations, exporters must have an official commodity classification of EAR99 from BXA for all medical devices (including supplies) prior to submitting an application to OFAC,

unless the item is specifically listed on BXA's website at www.bxa.doc.gov/Regulations/TradeSanctionsReformExportEnhancementAct.html. This list identifies those medical supplies, such as syringes, bandages, gauze and similar items, that *do not* require BXA classification prior to OFAC review. When submitting a license application 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. Exporters who are unable to access BXA's website may contact BXA at 202-482-4811 to obtain BXA's medical supplies list.

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. As explained in the OFAC regulations, 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. If exporters are unsure if 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 submission of an application to OFAC under its expedited review procedures. Exporters who are unable to access BXA's website may contact BXA at 202-482-4811 to obtain BXA's list of medicines that are on the CCL.

For agricultural commodities, an official commodity classification of EAR99 from BXA is only required for fertilizers, western red cedar, and live horses. See section 748.3 of the EAR for instructions for submitting commodity classification requests.

III. Definitions and Procedures for Classifying Agricultural and Medical Commodities

This rule establishes new definitional entries for "agricultural commodities", "medicines" and "medical devices" in part 772 of the EAR. Commodities included within these definitions must be classified as EAR99 to be eligible for License Exception AGR or OFAC authorization. Exporters should review OFAC's regulations for the requirements relating to exports of agricultural commodities, medicines and medical devices to Iran, Libya and Sudan.

Agricultural Commodities

Agricultural commodity is defined in § 902 of the Trade Sanctions Reform and Export Enhancement Act of 2000 (TSRA) (§ 902 of Public Law 106-387), which incorporates by reference the definition of agricultural commodity in section 102 of the Agriculture Trade Act of 1978 (7 U.S.C. 5602). Section 775 of Public Law 106-387 also provides that, for purposes of administering Title IX of the TSRA, the term agricultural commodity also includes fertilizer and organic fertilizer.

Under this rule, agricultural commodities include 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. A list of these commodities is available for review at the U.S. Department of Agriculture website at <http://www.fas.usda.gov/itp/sanctions.html>. If you have questions regarding whether an item is defined by section 102 of the Agriculture Trade Act of 1978 (7 U.S.C. § 5602), you should consult with the Department of Agriculture.

Consistent with section 775 of Pub. L. 106-387, this rule also includes fertilizers and organic fertilizers in the scope of agricultural commodities. Although items in this paragraph may not be specifically identified as agricultural commodities on the Department of Agriculture website, they are considered agricultural commodities under the EAR and for purposes of implementation of the TSRA.

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

Under this rule, 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, however, that certain items that meet the definition of agricultural commodity are controlled on the CCL

and are not eligible for BXA's License Exception AGR for Cuba or OFAC's revised export procedures for Iran, Libya and Sudan. These include certain fertilizer products controlled under new ECCN 1C997, western red cedar controlled under ECCN 1C988, and live horses (if to be exported by sea) controlled under ECCN 0A980. For other fertilizer products, western red cedar and live horses that are not controlled on the CCL, exporters must have an official commodity classification of EAR99 from BXA prior to submission of a notification under License Exception AGR to BXA (for Cuba) or submission of a request for authorization to OFAC (for Iran, Libya, and Sudan). Exporters should review OFAC's regulations for the requirements relating to exports of agricultural commodities to Iran, Libya and Sudan.

In sum, two specific determinations are required prior to qualifying for BXA or OFAC authorization under the TSRA procedures: that the product is an agricultural commodity as defined in part 772 of the EAR; and that it is classified as EAR99 under the EAR.

For Cuba, items that are not agricultural commodities, as well as items that are agricultural commodities but that are on the CCL, will require a license from BXA. BXA will review such applications under the licensing policies set forth in § 746.2 (15 CFR 746.2).

Medicines and Medical Devices

Medicines and medical devices are not eligible under License Exception AGR to Cuba, but are eligible for OFAC authorization to Iran, Libya and Sudan. For the purposes of TSRA, medicines are drugs as defined in section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321). Pursuant to the Act, BXA has determined that for the purposes of this rule, medicines include prescription medicines and over the counter medicines for humans and animals. Medical devices are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) under the term "device". Pursuant to the Act, BXA has determined that for the purposes of this rule, medical devices include medical supplies, instruments, equipment, equipped ambulances, institutional washing machines capable of sterilizing hospital clothing and bedding, and vehicles with installed medical testing equipment. Medical devices do not include general purpose furniture such as desks, tables, or lamps used in hospital offices and waiting rooms. Exporters should consult with the Food and Drug Administration for guidance on whether an item meets the

definition of medicine or medical device under the Federal Food, Drug and Cosmetic Act. Although most medicines and medical devices are classified as EAR99, certain vaccines, biological and chemical products, and parts for medical devices are controlled under specific ECCNs on the CCL.

For exports of medicines and medical devices to Iran, Libya, and Sudan, two specific determinations are required prior to submitting a request for OFAC authorization: that the product is a medicine or medical device as defined in part 772 of the EAR; and that it is classified as EAR99 under the EAR.

Exporters should review OFAC's regulations for the requirements relating to exports of medical devices to Iran, Libya and Sudan. As explained in the OFAC regulations, prior to submitting an application to OFAC, exporters must have an official commodity classification of EAR99 from BXA for all medical devices (including supplies), unless the item is specifically listed on BXA's website at [www.bxa.doc.gov/Regulations/Trade Sanctions Reform Export EnhancementAct.html](http://www.bxa.doc.gov/Regulations/Trade%20Sanctions%20Reform%20Export%20EnhancementAct.html). This list identifies those medical supplies, such as syringes, bandages, gauze and similar items, that *do not* require BXA classification prior to OFAC review. When submitting a license application 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.

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. As explained in the OFAC regulations, 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. If exporters are unsure if 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 submission of an application to OFAC under its expedited review procedures. Exporters should review OFAC's regulations for the requirements relating to exports of medicines to Iran, Libya and Sudan.

As noted above, exports of medicines and medical devices are not eligible for export or reexport to Cuba under TSRA procedures. Such items continue to require authorization for export to Cuba under the provisions of the Cuban

Democracy Act (CDA) (22 U.S.C. 6004). For clarity and conformity, however, the term "medical devices" defined under TSRA is determined to be coextensive with the terms "medical supplies, instruments and equipment" used in section 1705 of the CDA. This rule also defines the term "medicines" for the purposes of the TSRA and will also apply this definition to "medicines" as that term is used in the CDA.

IV. Commodity Classification Requirements

As explained in the OFAC regulations, for exports of medical devices to Iran, Libya, and Sudan, exporters must have an official commodity classification of EAR99 from BXA prior to submission of a request for authorization under OFAC's expedited review procedures, unless the medical supply is specifically listed on BXA's website. The medical supply list identifies those medical supplies that *do not* require BXA classification prior to OFAC review. For exports of medicines to Iran, Libya, and Sudan, exporters must confirm that their item is *not* described on BXA's medicines list on BXA's website. The medicines list identifies medicines that are not eligible for OFAC's expedited review procedures. For exports of fertilizers, western red cedar, and live horses, a BXA commodity classification is required prior to submission of a notification for Cuba under License Exception AGR or prior to submission of a request to OFAC under its expedited review procedures for Iran, Libya or Sudan.

V. Continuing Controls

This rule also does not affect controls on any agricultural commodity, medicine or medical device classified under a specific ECCN on the CCL. In addition, this rule does not affect U.S. controls on technology or software used to manufacture agricultural commodities or on technology to design or produce biotechnological items, or medical devices.

Except for the creation of new License Exception AGR in section 740.18, this rule does not make any other license exception available for exports to Cuba, nor does it change the availability or non-availability of any other License Exception. Note that License Exception AVS does not authorize the export of vessels from the United States on temporary sojourn. Consistent with the 1992 Cuban Democracy Act, License Exception AVS does not authorize the export of ship stores, equipment or spares for use on a vessel, bunkering fuel, petroleum and petroleum items

and dunnage for use on any vessel carrying goods or passengers to or from Cuba. Therefore, a specific license is required from BXA for all such exports.

Also in continuation of current rules, aircraft that are on temporary sojourn to Cuba that are carrying items eligible for export under License Exception AGR and that satisfy all the requirements of License Exception AVS (§ 740.15(a) of the EAR) do not need a specific license from BXA. Aircraft that do not satisfy all requirements of License Exception AVS will require a specific license from the BXA and license applications will be reviewed on a case-by-case basis and favorably considered when carrying commodities authorized under the EAR. OFAC also is responsible for licensing family remittances and the financial transactions of persons traveling to Cuba, including travel associated with sales of agricultural commodities to Cuba and persons that accompany cargo on aircraft authorized by BXA.

Finally, this rule does not affect U.S. nonproliferation export controls, including end-use controls (known as the Enhanced Proliferation Control Initiative or EPCI). This rule does not relieve exporters or reexporters of their obligations under General Prohibition 5 in § 736.2(b)(5) of the EAR which provides that you may not, without a license, knowingly export or reexport any item subject to the EAR for use in an activity that is prohibited by part 744 of the EAR. BXA strongly urges the use of Supplement No. 3 to part 732 of the EAR, BXA's "Know Your Customer" Guidance and Red Flags.

VI. New Controls

Consistent with the provisions of the Export Administration Act (EAA), as amended, and after consultation with the Secretary of State, BXA submitted a foreign policy report to the Congress providing notice of its intent to impose new foreign policy controls on 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. These items are now classified as ECCN 1C997, and require a license for anti-terrorism reasons. This foreign policy report was sent to Congress on June 15, 2001. In the development of a final rule, BXA may further amend the EAR to add certain medicines and medical devices to the CCL.

VII. Technical Changes

This rule amends sections 746.3 and 746.7 to clarify the requirements for exports and reexports to Iran and Iraq.

This rule amends the EAR in the following ways:

Part 740 (License Exceptions)

New License Exception Agricultural Commodities (AGR) is established in § 740.18 of the EAR for exports of agricultural commodities classified as EAR99. License Exception AGR authorizes the export of agricultural commodities from the United States and reexport of U.S. origin agricultural commodities to Cuba provided that the notification requirements and other provisions of License Exception AGR are met.

For purpose of transparency, this rule also restates in section 740.2 (Restrictions on All License Exceptions) that license exceptions may not be used for exports or reexports to a destination subject to a comprehensive embargo, unless specifically authorized in the section dealing with a particular embargoed country in part 746 (Embargoes and Other Special Controls) of the EAR.

Part 742 (Control Policy: CCL Based Controls)

In § 742.8, § 742.9, § 742.10, § 742.19, and Supplement No. 1 to Part 742, references are added to reflect the new control status and licensing policy for ammonium nitrate, including certain fertilizers containing ammonium nitrate, under ECCN 1C997. Licenses are required under the EAR for the export and reexport of fertilizers controlled by ECCN 1C997 to Cuba, Iran, Iraq, Libya, North Korea, Sudan and Syria. Applications for items controlled under new ECCN 1C997 are subject to a case-by-case review with general policy of denial to all end-users.

Part 746 (Embargoes and Other Special Controls)

Section 746.2 Cuba

In § 746.2 (Cuba), License Exception AGR eligibility is established for exports and certain reexports of agricultural commodities classified as EAR99 to Cuba. The licensing review policy in § 746.2 is revised to apply to exports and reexports of agricultural commodities subject to the EAR that do not meet the eligibility requirements of License Exception AGR and to other agricultural items (e.g. insecticides, pesticides and herbicides).

Medicines and medical devices continue to require an export license to Cuba under the provisions of the CDA.

Note that the definition of medical devices under TSRA is determined to be coextensive with the terms "medical supplies", "instruments" and "equipment" under the CDA and § 746.2 is revised to use the terms medicines and medical devices, which are defined in part 772.

Section 746.3 Iraq

§ 746.3 is revised to reflect new controls on certain fertilizer products under new ECCN 1C997. This section also clarifies that no person may export or reexport any item subject to both the EAR and OFAC's Iraqi Sanctions Regulations without prior OFAC authorization and that exports and reexports subject to the EAR that are not subject to the Iraqi Sanctions Regulations may require authorization from BXA.

Section 746.7 Iran

This section is revised to clarify that exports and reexports subject to the EAR that are not subject to the Iranian Transactions Regulations may require authorization from BXA.

Part 772 Definitions of Terms

In part 772, this rule adds definitions for the terms "agricultural commodities", "medicines", and "medical devices" consistent with Sections 902 and 775 of Pub. L. 106-387.

Part 774 The Commerce Control List

In Supplement No. 1 to part 774, ECCN 1C997 is added to the CCL. A license is required for the export or reexport of ammonium nitrate, including fertilizers which contain certain concentrations of ammonium nitrate, to terrorist supporting countries.

Rulemaking Requirements

1. This interim final rule has been determined to be not significant for purposes of E.O. 12866.

2. Notwithstanding any other provision of law, no person is required to respond nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB Control Number. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0694-0088, "Multi-Purpose Application," which carries a burden hour estimate of 40 minutes to prepare and submit electronically and

45 minutes to submit manually on multipurpose Application Form (BXA-748P). This rule contains a new information collection requirement that has been submitted for emergency approval under control number 0694-XXXX, "Prior Notification for Exports under License Exception AGR". Prior notification using existing form BXA-748P requires burden hour estimate of 40 minutes to prepare and submit electronically and 45 minutes to submit manually.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States. See 5 U.S.C. 553(a)(1). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this interim rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 5 U.S.C. 553 or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

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 material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the person submitting the comments and will not consider them in the development of final regulations. All public comments on these regulations will be a matter of public record and

will be available for public inspection and copying. In the interest of accuracy and completeness, the Department requires comments in written form.

Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying. Communications from agencies of the United States Government or foreign governments will not be made available for public inspection.

Copies of the public record concerning these regulations may be requested from: Bureau of Export Administration, Office of Administration, U.S. Department of Commerce, Room 6883, 14th and Constitution Avenue, NW, Washington, DC 20230; (202) 482-0637. This component does not maintain a separate public inspection facility. Requesters should first view BXA's website (which can be reached through www.bxa.doc.gov). If requesters cannot access BXA's website, please call the number above for assistance.

List of Subjects

15 CFR Part 740

Administrative practice and procedure, Exports, Foreign trade, Reporting and recordkeeping requirements.

15 CFR Parts 742, 772 and 774

Exports, Foreign trade.

15 CFR Part 746

Embargoes, Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, parts 740, 742, 746, 772, and 774 of the Export Administration Regulations (15 CFR parts 730-799) are amended as follows:

1. The authority citations for parts 740 and 772 are revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106-387; Pub. L. No. 106-508; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13206 (66 F.R. 18397, April 9, 2001).

2. The authority citation for part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106-387; Pub. L. No. 106-508; 50 U.S.C. 1701 *et seq.*; 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of November 9, 2000 (65 F.R. 68063, November 13, 2000); E.O. 13206 (66 F.R. 18397, April 9, 2001).

3. The authority citation for part 746 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106-387; Pub. L. No. 106-508; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 287c; 22 U.S.C. 6004; E.O. 12854, 58 FR 36587, 3 CFR 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13088, 63 FR 32109, 3 CFR, 1998 Comp., p. 191; E.O. 13121 of April 30, 1999, 64 FR 24021 (May 5, 1999); E.O. 13206 (66 F.R. 18397, April 9, 2001).

4. The authority citation for parts 774 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106-387; Pub. L. No. 106-508; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13206 (66 F.R. 18397, April 9, 2001).

PART 740—[AMENDED]

5. Section 740.1 is amended by revising paragraph (a) to read as follows:

§ 740.1 Introduction.

* * * * *

(a) *Scope.* A "License Exception" is an authorization contained in this part that allows you to export or reexport under stated conditions, items subject to the Export Administration Regulations (EAR) that would otherwise require a license under General Prohibition One, Two, or Three, as indicated under one or more of the Export Control Classification Numbers (ECCNs) in the Commerce Control List (CCL) in Supplement No. 1 to part 774 of the EAR and items subject to the EAR that would require a license based on the embargo policies described in part 746 of the EAR. If your export or reexport is subject to General Prohibition Six for embargoed destinations, refer to part 746 of the EAR to determine the availability of any License Exceptions. Special commodity controls apply to short supply items. License Exceptions for items listed on the CCL as controlled for Short Supply reasons are found in part 754 of the EAR. If your export or reexport is subject to General Prohibition Five, consult part 744 of the EAR. If your export or reexport is subject to General Prohibitions Four, Seven, Eight, Nine, or Ten, then no License Exceptions apply.

* * * * *

6. Section 740.2 is amended by adding paragraph (a)(6) to read as follows:

§ 740.2 Restrictions on all License Exceptions.

(a) * * *

(6) The export or reexport is to an embargoed destination (Cuba, Iran, Iraq, and Libya), unless a license exception or portion thereof is specifically listed in the license exceptions paragraph pertaining to a particular embargoed country in part 746 of the EAR.

* * * * *

7. Section 740.18 is added to read as follows:

§ 740.18 Agricultural commodities (AGR).

(a) *Eligibility requirements.* License Exception AGR permits the export of agricultural commodities to Cuba, as well as the reexport of U.S. origin agricultural commodities to Cuba, provided your transaction meets *all* of the following criteria:

(1) The commodity meets the definition of "agricultural commodities" in part 772 of the EAR;

(2) The commodity is EAR99. You must have an official commodity classification of EAR99 from BXA for fertilizers, western red cedar and live horses before you submit a notification under this license exception. See § 748.3 of the EAR for information on how to submit a commodity classification request;

(3) The export or reexport is made pursuant to a written contract, except for donations and commercial samples which are not subject to this contract requirement;

(4) The export or reexport is made within 12 months of the signing of the contract or within 12 months of notification that no objections were raised (if no contract is required). In the case of multiple partial shipments, all such shipments must be made within the 12 months of the signing of the contract or within 12 months of notification that no objections were raised (if no contract is required); and

(5) You notify BXA prior to exporting or reexporting according to the procedures set forth in paragraph (c) of this section. If you intend to engage in multiple shipments during the one-year period after the signing of the contract, you need only notify BXA prior to the first shipment.

(b) *Restrictions.* (1) No export or reexport to any individual or entity designated as a Specially Designated Terrorist or Foreign Terrorist Organization may be made under License Exception AGR (see part 744 of the EAR).

(2) No export or reexport to or for use in biological, chemical, nuclear warfare or missile proliferation activities may be

made under License Exception AGR (see part 744 of the EAR).

(3) No U.S.-owned or controlled foreign firm may export from abroad to Cuba a foreign produced agricultural commodity containing more than 10% U.S.-origin content. Such U.S.-owned or controlled foreign firms require a specific license from BXA as well as the Department of the Treasury's Office of Foreign Assets Control (OFAC). Transactions not subject to the EAR (under 10% U.S.-origin content) require a license from OFAC.

(c) *Prior notification.* (1) *General requirement.* You must notify BXA prior to any export or reexport (or prior to the first of multiple shipments) under License Exception AGR.

(2) *Procedures.* You must provide prior notification of exports and reexports under License Exception AGR by submitting a completed Multipurpose Application Form (BXA-748P) or its electronic equivalent. The following blocks must be completed, as appropriate, on the Multipurpose Application Form: Blocks 1, 2, 3, 4, 5 (by marking box 5 "Other"), 14, 16, 17, 18, 19, 21, 22 (a), (e), (f), (g), (h), (i), (j), 23, and 25 according to the instructions described in Supplement No. 1 to part 748 of the EAR. If your commodity is fertilizer, western red cedar or live horses, you must confirm that BXA has previously classified your commodity as EAR99 by placing the Commodity Classification Automatic Tracking System (CCATS) number in block 22(d). BXA will not initiate the registration of an AGR notification unless all requested information on the Multipurpose Application form is complete.

(3) *Action by BXA.* Within two business days of the registration of the AGR notification, BXA will refer the notification for interagency review, or if necessary return the notification without action (e.g., if the information provided is incomplete). Registration is defined as the point at which the notification is entered into BXA's electronic system.

(4) *Review by other departments or agencies.* The Departments of Defense, State, and other agencies, as appropriate, may review the AGR notification. BXA must receive department or agency objections within nine business days of the referral. Unlike the provisions described in § 750.4(b) of the EAR, there are no provisions for stopping the processing time of the AGR notification. If, within 11 business days after the date of registration, any reviewing agency provides a written objection that the recipient may promote international terrorism or the transaction raises

nonproliferation concerns, you may not use License Exception AGR. In such cases, BXA will notify you that a license is required for the export or reexport. BXA will then process the AGR notification as a license application in accordance with the provisions described in § 750.4 of the EAR, and the licensing policies set forth in the EAR. At this time, BXA may request additional information. When BXA confirms that no agency has raised an objection within eleven business days (as described in paragraph (c)(5) of this section), you may proceed with the transaction provided that you satisfy all other requirements of License Exception AGR, including the requirement to have a written contract prior to any shipment (unless a donation or commercial sample). (Note that the fact that you have been advised that no agency has objected to the transaction does not exempt you from other licensing requirements under the EAR, such as those based on knowledge of a prohibited end-use or end-user as referenced in general prohibition five (part 736 of the EAR) and set forth in part 744 of the EAR.)

(5) *Status of pending AGR notification requests.* You must contact BXA's System for Tracking Export License Applications ("STELA") at (202) 482-2752 for status of your pending AGR notification. (See § 750.5 of the EAR for procedures to access information on STELA.) STELA will provide the date of registration of the AGR notification. If no department or agency objection is raised within 11 business days, STELA will, on the twelfth business day following the date of registration, provide you with confirmation of that fact. You may not proceed with your shipment unless you confirm with STELA that no objection has been raised. BXA will subsequently issue written confirmation to you. If an objection is raised, STELA will indicate that a license is required. The AGR notification will then be processed as a license application. In addition, BXA may provide notice of an objection by telephone, fax, courier service, or other means.

(d) *Donations.* (1) Donations of agricultural commodities are eligible for export and reexport to Cuba under License Exception AGR, provided the transaction meets the requirements and procedures of this license exception (except the written contract requirement).

(2) Donations of food items to non-governmental organizations (NGOs) and individuals in Cuba may also be eligible for License Exception GFT. See § 740.12 for eligibility requirements of gift

parcels and humanitarian donations under License Exception GFT.

PART 742—[AMENDED]

8. § 742.8 is amended by revising the phrase “(c)(6) through (c)(41)” in paragraph (a)(4)(ii) to read “(c)(6) through (c)(43)”.

9. § 742.9 is amended by revising the phrase “(c)(22) through (c)(41)” in paragraph (a)(3)(ii) to read “(c)(22) through (c)(43)” and by adding new paragraph (b)(1)(viii) to read as follows:

§ 742.9 Anti-terrorism: Syria.

* * * * *

- (b) * * *
- (1) * * *

(viii) Ammonium nitrate, including certain fertilizers containing ammonium nitrate, controlled under ECCN 1C997.

* * * * *

10. § 742.10 is amended by revising the phrase “(c)(16) through (c)(41)” in paragraph (a)(4)(ii) to read “(c)(16) through (c)(43)” and by adding new paragraph (b)(1)(ix) to read as follows:

§ 742.10 Anti-terrorism: Sudan.

* * * * *

- (b) * * *
- (1) * * *

(ix) Ammonium nitrate, including certain fertilizers containing ammonium nitrate, controlled under ECCN 1C997.

* * * * *

11. § 742.19 is amended by adding new paragraph (b)(1)(xviii) to read as follows:

§ 742.19 Anti-terrorism: North Korea.

* * * * *

- (b) * * *
- (1) * * *

(xviii) Ammonium nitrate, including certain fertilizers containing ammonium nitrate, controlled under ECCN 1C997.

* * * * *

12. Supplement No. 2 to Part 742 is amended by revising paragraph (b)(3)(ii) and adding paragraph (c)(43) to read as follows:

Supplement No. 2 to Part 742—Anti-Terrorism Controls: Iran, North Korea, Syria and Sudan Contract Sanctity Dates and Related Policies

* * * * *

- (b) * * *
- (3) * * *

(ii) The following items to all end-users: for Iran, items in paragraphs (c)(6) through (c)(43) of this Supplement; for North Korea, items in paragraph (c)(6) through (c)(44) of this Supplement; for Sudan, items in paragraphs (c)(6) through (c)(14), and (c)(16) through

(c)(43) of this Supplement; and for Syria, items in paragraphs (c)(6) through (c)(8), (c)(10) through (c)(14), (c)(16) through (c)(19), and (c)(22) through (c)(43) of this Supplement.

(c) * * *

(43) Ammonium nitrate, including certain fertilizers containing ammonium nitrate, under ECCN 1C997 on the CCL.

(i) *Iran*. Applications for all end-users in Iran of these items will generally be denied.

(ii) *Syria*. Applications for all end-users in Syria of these items will generally be denied. Contract sanctity date: June 15, 2001.

(iii) *Sudan*. Applications for all end-users in Sudan of these items will generally be denied.

(iv) *North Korea*. Applications for all end-users in North Korea of these items will generally be denied. Contract sanctity date: June 15, 2001.

* * * * *

PART 746—[AMENDED]

13. Section 746.2 is amended by adding paragraph (a)(1)(xii), by revising paragraphs (b)(1) introductory text, (b)(3)(iii)(B), (b)(3)(iii)(D) and (b)(4)(iii), by redesignating paragraph (d) as (e), and by adding new paragraph (d), and by revising redesignated paragraph (e) to read as follows:

§ 746.2 Cuba.

(a) * * *

(1) * * *

(xii) Exports of agricultural commodities, classified as EAR99, under License Exception Agricultural Commodities (AGR) and certain reexports of U.S. origin agricultural commodities, classified as EAR99, under License Exception AGR (see § 740.18 of the EAR).

* * * * *

(b) * * *

(1) *Medicines and Medical Devices*. Applications to export medicines and medical devices as defined in part 772 of the EAR will generally be approved, except:

* * * * *

(3) * * *

(iii) * * *

(B) Your transaction involves the export of foreign-produced medicines or medical devices incorporating U.S. origin parts, components or materials, in which case the application will be reviewed according to the provisions of paragraph (b)(1) of this section.

(C) * * *

(D) Your transaction is for the export of donated food to individuals or non-governmental organizations in Cuba and does not qualify as a humanitarian

donation under License Exception GFT (§ 740.12 of the EAR) or License Exception AGR (§ 740.18 of the EAR).

(4) * * *

(iii) Exports of agricultural items, which are outside the scope of agricultural commodities as defined in part 772 of the EAR, such as insecticides, pesticides and herbicides, as well as agricultural commodities not eligible for License Exception AGR, require a license and will be reviewed on a case-by-case basis.

* * * * *

(d) *Definitions*. For purposes of this section, “U.S. person” means any person subject to the jurisdiction of the United States, as described in § 515.329 of the Cuban Assets Control Regulations (31 CFR 515.329).

(e) *Related controls*. OFAC maintains controls on the activities of persons subject to U.S. jurisdiction, wherever located, involving transactions with Cuba or any specially designated Cuban national, as provided in 31 CFR part 515. OFAC’s Terrorism List Government Sanctions Regulations in 31 CFR part 596 prohibit U.S. persons from engaging in a financial transaction with the government of a designated state sponsor of international terrorism without OFAC authorization. The Department of State also implements sanctions on countries that are designated state sponsors of international terrorism. Exporters and reexporters should consult with those agencies for further guidance on these related controls.

14. Section 746.3 is amended by revising paragraph (a) introductory text to read as follows:

§ 746.3 Iraq.

(a) *License requirements*. OFAC administers an embargo against Iraq under the authority of the International Emergency Economic Powers Act of 1977, as amended, and the United Nations Participation Act of 1945, as amended, and in conformance with United Nations Security Council Resolutions. The applicable OFAC regulations, the Iraqi Sanctions Regulations, are found in 31 CFR part 575. You should consult with OFAC for authorization to export or reexport items subject to U.S. jurisdiction to Iraq, or to any entity owned or controlled by, or specially designated as acting for or on behalf of, the Government of Iraq. Please note that such applications will generally be denied by OFAC, absent a published policy stating otherwise. Under the EAR, you need a license to export or reexport to Iraq any item on the CCL containing a CB Column 1, CB

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.

* * * * *

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