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the form and mailing the form to the Marketing Order Administration Branch within two days of receipt of the exempt lot, that such lot has been received and will be utilized in the exempt outlet.

(c) It is the responsibility of the importer to notify the Marketing Order Administration Branch of any lot of exempt commodity rejected by a receiver, shipped to an alternative exempt receiver, exported, or otherwise disposed of. In such cases, a second "Importer's Exempt Commodity Form" must be filed by the importer providing sufficient information to determine ultimate disposition of the exempt lot and such disposition shall be so certified by the final receiver.

(d) All FV-6 forms and other correspondence regarding entry of 8e commodities must be submitted online, mailed or faxed to the Marketing Order and Agreement Division, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250-0237; Telephone (202) 720-4607; or FAX (202) 720-5698. FV-6 forms submitted by FAX must be followed by a mailed, original copy of the FV-6.

 $[61~{\rm FR}$ 13060, Mar. 26, 1996, as amended at 77 FR 51690, Aug. 27, 2012]

§999.600 Regulation governing the importation of pistachios.

(a) *Definitions*. As used in this part:

(1) Aflatoxin is one of a group of mycotoxins produced by the molds Aspergillus flavus and Aspergillus parasiticus. Aflatoxins are naturally occurring compounds produced by molds, which can be spread in improperly processed and stored nuts, dried fruits, and grains.

(2) Aflatoxin inspection certificate means a certificate issued by a USDA or USDA-accredited laboratory.

(3) *Certified lots of pistachios* are those for which aflatoxin inspection certificates have been issued.

(4) *Customs* means the U.S. Customs and Border Protection.

(5) *Importation of pistachios* means the release of pistachios from the custody of U.S. Customs and Border Protection.

(6) *Importer* means a person who engages in the importation of pistachios into the United States. (7) *Inshell pistachios* means pistachios that have shells that have not been removed.

(8) Inspection Service means the Federal Inspection Service, Fruit and Vegetable Programs, Agricultural Marketing Service, USDA, or the Federal-State Inspection Programs.

(9) *Inspector* means any inspector authorized by USDA to draw and prepare pistachio samples.

(10) Lot means any quantity of pistachios that is submitted for testing purposes under this part.

(11) *Person* means an individual, partnership, limited-liability corporation, corporation, trust, association, or any other business unit.

(12) *Pistachio* means the nut of the pistachio tree, *Pistachia vera*, whether inshell or shelled.

(13) Secretary means the Secretary of Agriculture of the United States or any officer or employee of the United States Department of Agriculture who is, or who may hereafter be, authorized to act in his/her stead.

(14) *Shelled pistachios* means pistachio kernels, or portions of kernels, after the pistachio shells have been removed.

(15) Substandard pistachios means pistachios, inshell or shelled, that do not comply with the aflatoxin regulations of this section.

(16) USDA means the United States Department of Agriculture, including any officer, employee, service, program, or branch of the Department of Agriculture, or any other person acting as the Secretary's agent or representative in connection with any provisions of this section.

(17) USDA laboratory means laboratories of the Science and Technology Programs, Agricultural Marketing Service, USDA, that perform chemical analyses of pistachios for aflatoxin content.

(18) USDA-accredited laboratory means a laboratory that has been approved or accredited by the U.S. Department of Agriculture to perform chemical analyses of pistachios for aflatoxin content.

(b) *Importation Requirements*. The importation of any lot of pistachios for human consumption is prohibited unless it meets the requirements contained in this section, which are determined to be the same as or comparable

to those imposed upon domestic pistachios handled pursuant to Order No. 983, as amended (part 983 of this chapter).

(c) Maximum aflatoxin tolerance. No importer shall ship for domestic human consumption lots of pistachios that exceed an aflatoxin level of 15 ppb. Compliance with the aflatoxin requirements of this section shall be determined upon the basis of sampling by a USDA-authorized inspector and testing by a USDA or USDA-accredited laboratory. All shipments must be covered by an aflatoxin inspection certificate issued by the laboratory. Testing and certification must be completed prior to the importation of pistachios.

(d) Sampling.

(1) Prior to, or upon, arrival of a pistachio lot at a port of entry, the importer shall provide a copy of the Customs entry documentation for the pistachio lot or lots to the Inspection Service office that will draw and prepare samples of the pistachio shipment. More than one lot may be listed on one entry document. The documentation shall include: The Customs entry number; the container number(s) or other identification of the lot(s); the weight of the pistachios in each lot being imported, the location where the lot will be made available for sampling; and a contact name or telephone number at the testing location. The Inspection Service shall sign, stamp, and return the entry document to the importer. The importer shall provide a copy of the relevant entry documentation and such other identifying information as may be requested for each pistachio lot to the inspector at the time samples are drawn and prepared.

(2) All sampling for aflatoxin testing shall be performed by USDA-authorized inspectors in accordance with USDA rules and regulations governing the inspection and certification of fresh fruits, vegetables, and other products (7 CFR part 51). The cost of each such sampling and related certification

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shall be borne by the applicant. Whenever pistachios are offered for sampling and testing, the applicant shall furnish any labor and pay any costs incurred for storing, moving, and opening containers as may be necessary for proper sampling and testing. The applicant should make advance arrangements with the Inspection Service to avoid delay in scheduling sampling. Importers may make arrangements for required sampling by contacting the Inspection Service office closest to where the pistachios will be made available for sampling. For questions regarding inspection services, a list of Federal or Federal-State Inspection Program offices, or for further assistance, importers may contact: Fresh Products Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW., Room 1536-S, Washington, DC, 20250; Telephone: (202) 720-5870; Fax: (202) 720-0393.

(3) Lot samples shall be drawn from each lot of pistachios designated for aflatoxin testing, and individual test samples shall be prepared by, or under the supervision of, an inspector. Each sample shall be drawn and prepared in accordance with the sample size requirements outlined in Tables 1 and 2 below. The gross weight of the inshell lot and test samples for aflatoxin testing and the minimum number of incremental samples required are shown in Table 1. The gross weight of the kernel lot and test samples for aflatoxin testing and the minimum number of incremental samples required is shown in Table 2. If more than one test sample is necessary, the test samples shall be designated by the inspector as Test Sample #1 and Test Sample #2. Each sample shall be placed in a suitable container, with the lot number clearly identified, and the importer shall submit it, along with a copy of the customs entry documentation, to a USDA or USDA-accredited laboratory. The importer shall assume all costs for shipping samples to the laboratory.

TABLE 1—INSHELL PISTACHIO LOT SAMPLING INCREMENTS FOR AFLATOXIN CERTIFICATION

Lot weight (lbs.)	Minimum number of incremental samples for the lot sample	Total weight of lot sample (kilograms)	Weight of test sample (kilograms)
220 or less	10	2.0	2.0

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TABLE 1—INSHELL PISTACHIO LOT SAMPLING INCREMENTS FOR AFLATOXIN CERTIFICATION—

Continued

Lot weight (lbs.)	Minimum number of incremental samples for the lot sample	Total weight of lot sample (kilograms)	Weight of test sample (kilograms)
221–440	15	3.0	3.0
441–1,100	20	4.0	4.0
1,101–2,200	30	6.0	6.0
2,201–4,400	40	8.0	8.0
4,401–11,000	60	12.0	6.0
11,001–22,000	80	16.0	8.0
22,001–150,000	100	20.0	10.0

TABLE 2—SHELLED PISTACHIO KERNEL LOT SAMPLING INCREMENTS FOR AFLATOXIN CERTIFICATION

Lot weight (lbs.)	Minimum number of incremental samples for the lot sample	Total weight of lot sample (kilograms)	Weight of test sample (kilograms)
220 or less	10	1.0	1.0
221–440	15	1.5	1.5
441–1,100	20	2.0	2.0
1,101–2,200	30	3.0	3.0
2,201–4,400	40	4.0	4.0
4,401–11,000	60	6.0	3.0
11,001–22,000	80	8.0	4.0
22,001–150,000	100	10.0	5.0

(e) Aflatoxin testing. Importers may make arrangements for required chemical analysis for aflatoxin content at the nearest USDA or USDA-accredited laboratory. For further information concerning chemical analysis and a list of laboratories authorized to conduct such analysis contact: Science and Technology Programs, AMS, USDA, 1400 Independence Avenue SW., STOP 0270, Washington, DC 20250-0270; Telephone: (202) 720-5231; Fax: (202) 720-6496.

(1) Aflatoxin test samples shall be received and logged by a USDA or USDAaccredited laboratory, and each test sample shall be prepared and analyzed using High Pressure Liquid Chromatography (HPLC) or the AOAC-approved immunoaffinity column with direct fluorometry method. The aflatoxin level shall be calculated on a kernel weight basis.

(2) Lots that require a single test sample will be certified as "negative" on the aflatoxin inspection certificate if the sample has an aflatoxin level at or below 15 ppb. If the aflatoxin level is above 15 ppb, the lot fails and the laboratory shall fill out an *Imported Pistachios—Failed Lot Notification* report (Form FV-249) as described in paragraph (h)(1) of this section.

(3) Lots that require two test samples will be certified as "negative" on the aflatoxin inspection certificate if Test Sample #1 has an aflatoxin level at or below 10 ppb. If the aflatoxin level of Test Sample #1 is above 20 ppb, the lot fails and the laboratory shall fill out an Imported Pistachios—Failed Lot Notification report (Form FV-249). If the aflatoxin level of Test Sample #1 is above 10 ppb and at or below 20 ppb, the laboratory may, at the importer's discretion, analyze Test Sample #2 and average the test results of Test Samples #1 and #2. Alternately, the importer may elect to withdraw the lot from testing, rework the lot, and resubmit it for testing after reworking. If the importer directs the laboratory to proceed with the analysis of Test Sample #2, a lot will be certified as negative to aflatoxin and the laboratory shall issue an aflatoxin inspection certificate if the averaged result of Test Samples #1 and #2 is at or below 15 ppb. If the average aflatoxin level of Test Samples #1 and #2 is above 15 ppb, the lot fails and the laboratory shall fill out an Imported Pistachios-Failed Lot *Notification* report (Form FV-249).

(4) If an importer does not elect to use Test Sample #2 for certification purposes, the importer may request that the laboratory return the sample to the importer.

(f) Certification. Each lot of pistachios sampled and tested in accordance with paragraphs (d) and (e) of this section shall be covered by an aflatoxin inspection certificate completed by the laboratory. The certification expires for the lot or remainder of the lot after 12 months. Each such certificate shall set forth the following:

(1) The date and place of sampling and testing.

(2) The name of the applicant.

(3) The Customs entry number pertaining to the lot or shipment covered by the certificate.

(4) The quantity and identifying marks of the lot tested.

(5) The aflatoxin level of the lot, stated on a kernel weight basis.

(6) The statement, if applicable: "Meets U.S. import requirements under section 8e of the AMA Act of 1937."

(7) If the lot fails to meet the import requirements, a statement to that effect and the reasons therefore.

(g) Failed lots/rework procedure. Any lot or portion thereof that fails to meet the import requirements prior to or after reconditioning may be exported, sold for non-human consumption, or disposed of under the supervision of Customs and, if necessary for verification purposes, the Federal or Federal-State Inspection Programs, with the costs of certifying the disposal of such lot paid by the importer.

(1) Inshell rework procedure for aflatoxin. If inshell rework is selected as a remedy to meet the aflatoxin requirements of this part, then 100 percent of the product within that lot shall be removed from the bulk and/or retail packaging containers and reworked to remove the portion of the lot that caused the failure. Reworking shall consist of mechanical, electronic, or manual procedures normally used in the handling of pistachios. After the rework procedure has been completed, the total weight of the accepted product and the total weight of the rejected product shall be reported by the importer to Customs and USDA on an Imported Pistachios-Rework and Failed Lot Disposition report (Form FV-251) as de-

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scribed in paragraph (h)(2) of this section. The reworked lot shall be sampled and tested for aflatoxin as specified in paragraphs (d) and (e) of this section, except that the lot sample size and the test sample size shall be doubled. If, after the lot has been reworked and tested, it fails the aflatoxin test for a second time, the lot may be shelled and the kernels reworked, sampled, and tested in the manner specified for an original lot of kernels, or the failed lot may be exported, used for non-human consumption, or otherwise disposed of.

(2) Kernel rework procedure for aflatoxin. If pistachio kernel rework is selected as a remedy to meet the aflatoxin requirements of this part, then 100 percent of the product within that lot shall be removed from the bulk and/or retail packaging containers and reworked to remove the portion of the lot that caused the failure. Reworking shall consist of mechanical, electronic, or manual procedures normally used in the handling of pistachios. After the rework procedure has been completed the total weight of the accepted product and the total weight of the rejected product shall be reported to Customs and USDA on an Imported Pistachios-Rework and Failed Lot Disposition report (Form FV-251). The reworked lot shall be sampled and tested for aflatoxin as specified in paragraphs (d) and (e) of this section.

(3) Failed lot reporting. If a lot fails to meet the aflatoxin requirements of this part, the testing laboratory shall complete an *Imported Pistachios—Failed Lot Notification* report (Form FV-249) as described in paragraph (h)(1) of this section, and shall submit it to Customs, the importer, and USDA within 10 working days of the test failure. This form must be completed and submitted each time a lot fails aflatoxin testing.

(h) Reports and Recordkeeping.

(1) Form FV-249 Imported Pistachios— Failed Lot Notification. Each USDA or USDA-accredited laboratory shall notify the importer; Customs; and the Marketing Order and Agreement Division, Fruit and Vegetable Programs, AMS, USDA; of all lots that fail to meet the maximum aflatoxin requirements by completing this form and submitting it within 10 days of failed aflatoxin testing.

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(2) Form FV-251 Imported Pistachios— Rework and Failed Lot Disposition. Each importer who reworks a failing lot of pistachios shall complete this report and shall forward it to Customs and the Marketing Order and Agreement Division, Fruit and Vegetable Programs, AMS, USDA, no later than 10 days after the rework is completed. If rework is not selected as a remedy, the importer shall complete and submit this form within 10 days of alternate disposition of the lot.

(i) *Exemptions*. Any importer may import pistachios free of the requirements of this section if such importer imports a quantity not exceeding a total of 5,000 dried pounds between September 1 and August 31 of each year. Substandard pistachios imported for use in non-human consumption outlets shall be subject to the safeguard provisions contained in §999.500.

(j) Reconditioning prior to importation. Nothing contained in this section shall be deemed to preclude reconditioning pistachios prior to importation, in order that such pistachios may be made eligible to meet the applicable aflatoxin regulations prescribed in paragraphs (c) through (f) of this section.

(k) *Comingling*. Certified lots of pistachios may be comingled with other certified lots, but the comingling of certified lots and uncertified lots shall cause the loss of certification for the comingled lots.

(1) *Retesting*. Whenever USDA has reason to believe that imported pistachios may have been damaged or deteriorated while in storage, USDA may reject the then effective inspection certificate and may require the owner of the pistachios to have them retested to establish whether or not such pistachios may be shipped for human consumption.

(m) Compliance. Any person who violates any provision of this section shall be subject to a forfeiture in the amount prescribed in section 8a(5) of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), or, upon conviction, a penalty in the amount prescribed in section 8c(14) of the said Act, or to both such forfeiture and penalty. False representation to any agency of the United States on any matter within its jurisdiction, knowing it to be false, is a violation of 18 U.S.C. 1001, which provides for a fine or imprisonments or both.

(n) Other import requirements. The provisions of this section do not supersede any restrictions or prohibitions on pistachios under the Federal Plant Quarantine Act of 1912, or any other applicable laws or regulations of city, county, State, or Federal Agencies including the Federal Food, Drug and Cosmetic Act.

[77 FR 51691, Aug. 27, 2012]

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