



This document is scheduled to be published in the Federal Register on 08/27/2012 and available online at <http://federalregister.gov/a/2012-20974>, and on FDsys.gov

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 999

[Doc. No. AMS-FV-09-0064; FV09-999-1 FR]

Specialty Crops; Import Regulations; New Pistachio Import Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule establishes a minimum quality regulation for lots of pistachios imported into the United States. The regulation specifies maximum aflatoxin tolerance levels as well as mandatory aflatoxin testing and certification requirements. These import quality requirements are the same as or comparable to those in effect for the domestically produced commodity. Under this regulation, aflatoxin levels in imported pistachios may not exceed 15 parts per billion (ppb), as certified by aflatoxin inspection certificates issued by an accredited laboratory. This action is intended to assure consumers that all pistachios offered for sale in the United States meet the same aflatoxin standards, thus promoting high quality product in the market place and fostering consumer satisfaction.

EFFECTIVE DATE: [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Laurel May or Kathleen Finn, Marketing Order and Agreement Division, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or E-mail: Laurel.May@ams.usda.gov or Kathy.Finn@ams.usda.gov.

Small businesses may request information on complying with this regulation by contacting Laurel May at the above mentioned address.

SUPPLEMENTARY INFORMATION: This final rule is issued under section 8e of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act," which provides that whenever the grade, size, quality, or maturity of certain specified commodities, including pistachios, are regulated under a Federal marketing order, imports of these commodities into the United States are prohibited unless they meet the same or comparable grade, size, quality, and maturity requirements as those in effect for the domestically produced commodities. To ensure that these requirements are met, the Act also authorizes the Department of Agriculture (USDA) to perform inspections and related functions such as commodity sampling, and to issue inspection certificates for such imported commodities.

USDA is issuing this rule in conformance with Executive Order 12866.

There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of import regulations issued under section 8e of the Act.

This final rule adds a new § 999.600 under 7 CFR part 999 - Specialty Crops; Import Regulations, and establishes quality requirements for maximum aflatoxin tolerance levels and mandatory testing and certification requirements for pistachios offered for importation into the United States. These quality requirements for imported pistachios are the same as or comparable to those established for pistachios grown in California, Arizona, and New Mexico under Marketing Agreement and Order No. 983 (7 CFR part 983) (order), both as amended.

This final rule also revises § 999.500, which specifies safeguard procedures for the importation of walnuts and dates that are exempt from § 8e regulations. This section is revised to include safeguard procedures for the importation of pistachios intended for exempted purposes.

The order prohibits the shipping of pistachios for domestic human consumption that do not meet the quality requirements for aflatoxin levels in the nuts. Such quality requirements specify that aflatoxin levels may not exceed

the maximum tolerance of 15 ppb. Pistachios that fail to meet these requirements must be reworked and retested, or disposed of as specified in the order. This regulation was designed to ensure that only high quality pistachios containing low levels of aflatoxin are shipped, thus promoting high quality product in the market place and fostering consumer satisfaction.

The order, which was established for California pistachios in 2004, was recently amended to include the states of Arizona and New Mexico. Pistachios grown in California, Arizona, and New Mexico represent over 99 percent of the U.S. domestic production, and 98 percent of the domestic consumption. Thus, almost all domestically produced pistachios are regulated under Marketing Order No. 983. There is no other Federal marketing order in effect for pistachios produced in the United States.

According to USDA's Foreign Agricultural Service (FAS), Iran is typically the world's largest pistachio producer, followed by the U.S. and Turkey, although Syria's production has increased in recent years. During the three most recent crop years (September through August) for which complete data is available, 2007-08 through 2009-10, the production averages in millions of pounds (inshell basis) for Iran, the

U.S., Turkey, and Syria were approximately 386, 350, 120, and 141, respectively.

Historically, the bulk of U.S. pistachio imports have come from Turkey and Iran, although Iranian imports have been prohibited since July 2010. The remainder comes from other countries, including Italy, China, Switzerland, France, Australia, Hong Kong, and Israel. Imported pistachios may be inshell or shelled. According to FAS, the U.S. imported an average of approximately 1.7 million pounds of pistachios (inshell basis) annually during the three crop years from 2007-08 through 2009-10. Average U.S. consumption of pistachios during that same period was approximately 100 million pounds (inshell basis) annually. Imports, therefore, represent approximately two percent of U.S. pistachio consumption.

Requirements

Definitions

The new regulation includes definitions of terms used in the import regulation. Such terms are the same as or comparable to those defined in the marketing order for domestic pistachios as established at 69 FR 17844 (April 5, 2004) and amended at 74 FR 56532 (November 2, 2009).

Under the new regulation, "pistachio" means the nut of the pistachio tree, Pistachia vera, whether inshell or

shelled. "Importer" is defined as a person who imports pistachios into the United States. "Aflatoxin" is defined as a mycotoxin that can be found in nuts, dried fruits, and grains. "Aflatoxin inspection certificate" means a certificate issued by a USDA or USDA-accredited laboratory. "USDA laboratory" and "USDA-accredited laboratory" are defined as laboratories authorized to test imported pistachios for aflatoxin content. "Inspector" means any inspector authorized by USDA to draw and prepare pistachio samples for testing. "Lot" means any quantity of pistachios submitted for testing. Other terms useful in the administration of the import regulation are also defined.

Maximum aflatoxin tolerance.

The presence or absence of aflatoxin is considered a quality characteristic in pistachios¹ because concerns about aflatoxin contamination can impact consumers' perception of the quality of pistachios, and therefore negatively impact demand. According to research provided by the industry, poor quality pistachios impact demand and the potential growth of demand for pistachios². Moreover, any market disturbances related to aflatoxin in pistachios, regardless

1 Gibbons, Jeff; 2002. Testimony in Pistachios Grown in California; Hearing on Proposed Marketing Agreement and Order No. 983. Pages 326-359.

2 Sumner, Daniel A; 2002. Testimony in Pistachios Grown in California; Hearing on Proposed Marketing Agreement and Order No. 983. 2002. Pages 698-735 and 747-820.

of the origin of those pistachios, could have a detrimental effect on the pistachio industry³.

The new regulation establishes a maximum aflatoxin tolerance level of 15 ppb for lots of pistachios imported into the U.S. for human consumption. As required under section 8e of the Act, this is the same level currently prescribed for domestic pistachios regulated under the order. Establishing a 15 ppb limit for aflatoxin in all pistachios marketed for human consumption in the United States is expected to bolster overall consumer confidence in pistachio quality and strengthen the demand for pistachios. Comparatively, the international Codex Alimentarius Commission's (Codex) maximum aflatoxin tolerance for pistachios is 10 ppb. The domestic pistachio industry believes that 15 ppb is appropriate to ensure the quality of pistachios sold in U.S. markets⁴. Research also supports the 15 ppb tolerance⁵. Additionally, a 15 ppb tolerance for aflatoxin in domestic and imported pistachios is consistent with existing regulations for all domestic and imported

3 Reinecke, Karen; 2002. Testimony in Pistachios Grown in California; Hearing on Proposed Marketing Agreement and Order No. 983. Pages 152-183.

4 Gibbons, Jeff; 2002. Testimony in Pistachios Grown in California; Hearing on Proposed Marketing Agreement and Order No. 983. 2002. Pages 326-359.

5 Eaton, David L.; Jennifer E. Hobden; and Bruce J. Kelman. 2002. Aflatoxin in Pistachios: Establishing a Regulatory Action Level in Support of a Proposed Federal Marketing Order. 11 pages.

peanuts marketed in the United States, for which USDA has established a 15 ppb aflatoxin tolerance⁶.

Aflatoxin sampling and testing procedures.

The new regulation provides for aflatoxin sampling procedures based on lot size. Such sampling procedures are the same as or comparable to those established for domestic shipments, and mirror the sampling procedures prescribed for pistachio shipments to the European Union. At the discretion of the importer, pistachio lots arriving at a U.S. port of entry will be warehoused near the port or shipped inland to a pistachio handling facility to await aflatoxin sampling and testing. Importers will be responsible for any transportation or storage fees incurred. Depending on the size of the lot, a specified number of incremental samples will be pulled and combined to form a lot sample. The lot sample will then be divided into smaller test samples, depending upon the size of the lot to be tested. The required weight of lot samples and test samples differs between inshell pistachios and shelled kernels because of the additional weight of the shells for inshell pistachios. The drawing and dividing of all samples must be conducted by or under the supervision of a Federal or Federal-State inspector.

⁶ 7 CFR part 996 - Minimum Quality and Handling Standards for Domestic

Following the drawing and dividing of samples, each sample must be properly identified and submitted to a USDA or USDA-accredited laboratory for analysis. Test samples will be prepared and analyzed using High Pressure Liquid Chromatography (HPLC) or the immunoaffinity column with direct flourometry method as approved by the Association of Official Analytical Chemists (AOAC). The aflatoxin level will be calculated on a kernel weight basis.

For lots of up to 4,400 lbs, one test sample will be analyzed. If the sample has an aflatoxin level at or below 15 ppb, the lot may be certified as negative for aflatoxin on the aflatoxin inspection certificate, which will be completed by the laboratory. If the aflatoxin level is greater than 15 ppb, the lot fails, and the laboratory will fill out a failed lot notification report for submission to the importer, the U.S. Customs and Border Protection (Customs), and USDA.

For lots of more than 4,400 lbs, two test samples will be prepared. If the first sample has an aflatoxin level at or below 10 ppb, the lot may be certified as negative for aflatoxin on the aflatoxin inspection certificate. Analysis of the other test sample would be unnecessary. If the aflatoxin level of the first test sample is above 20 ppb,

and Imported Peanuts Marketed in the United States.

the lot fails, and the laboratory will fill out a failed lot notification report for submission to the importer, Customs, and USDA. If the aflatoxin level of the first test sample is higher than 10 ppb and at or below 20 ppb, the importer may elect to test the second sample or rework the lot and resubmit it for testing. If the importer chooses to proceed with testing the second sample, the results from testing both samples will be averaged. If the average results are at or below 15 ppb, the lot may be certified negative for aflatoxin. If the average results are higher than 15 ppb, the lot fails and the accredited lab will submit a failed lot notification report to the importer, Customs, and USDA. If the importer chooses to rework the lot after the first sample is analyzed, the lot will again be subject to sampling and testing as if it were a new lot. If an aflatoxin inspection certificate is issued certifying that a lot is negative for aflatoxin at any stage of the sequential testing (meaning that the lot's aflatoxin content is below the maximum threshold), the certification will state that the lot meets the § 8e import aflatoxin requirements. The certification will expire after 12 months.

Upon notification of any failed lot, the importer will work with Customs to determine the appropriate disposition of the pistachios. Pistachios that fail to meet the

aflatoxin requirements will be required to be sold for non-human consumption, exported to another destination with a higher aflatoxin tolerance, or disposed of under the supervision of Customs, and the Federal or Federal-State Inspection Programs could be called upon to verify disposals. Any costs associated with certifying a disposal will be paid by the importer.

Rework procedures.

Although reworking and retesting of a failed lot is not required, importers may opt to take those steps, which would provide them with an opportunity to secure a return for their imported product while maintaining the integrity of the aflatoxin requirements. The alternative would be to dispose of the lot through proper channels as described above. The rework procedures described below are the same as or comparable to those required for domestic pistachios under the order.

Inshell pistachios. Rework procedures for inshell pistachios failing to meet aflatoxin requirements require importers to remove 100 percent of the failing lot from its bulk or retail packaging. These pistachios are required to pass through the sorting stages of the handling process in order to remove those nuts having the characteristics most susceptible to harboring aflatoxin. After reworking the

lot, the importer will report the weight of the total accepted and rejected product to Customs and USDA on a rework and failed lot disposition report, and the acceptable portion of the reworked lot will be resampled and tested for aflatoxin. In the case of a reworked lot, the lot sample size and the test sample size will be doubled from that specified in the initial testing. If, after having been reworked, the lot fails aflatoxin testing for a second time, the lot may be shelled and the kernels reworked, sampled, and tested in the manner required for an original lot of pistachio kernels. If the importer decides not to pursue further reworking of the failed lot, those pistachios are prohibited from entering the stream of commerce for domestic human consumption. The lot must be exported, sold for domestic non-human consumption purposes, or disposed of as described above. The importer must report the lot's final disposition to Customs and USDA on a rework and failed lot disposition report.

Shelled pistachios. Rework procedures for pistachio kernels failing to test negative for aflatoxin will also require a reprocessing of 100 percent of the volume of the failing lot. As with inshell pistachios, after reworking, the total weight of the accepted product and the total weight of the rejected product will be reported by the

importer to Customs and USDA on the rework and failed lot disposition report. The reworked lot of kernels must be resampled and retested for aflatoxin content as previously described.

Comingling.

Importers may comingle certified lots with other certified lots of pistachios. However, to maintain the integrity of certified lots, the comingling of certified and uncertified lots of pistachios will cause the loss of certification for the comingled lots.

Exemptions.

Section 983.70 of the marketing order provides that domestic handlers may handle pistachios free of the regulatory and assessment provisions of the order if such pistachios are handled in quantities not exceeding 5,000 dried pounds during any production year. The purpose of this provision is to provide an exemption from the requirements of the order for small quantities of pistachios such as those that are grown for home or personal use. Further, this exemption is applied on a production year basis. Accordingly, under the import regulation, a comparable 5,000-pound annual exemption applies to importers of pistachios for human consumption. Also, substandard pistachios imported for use in non-human consumption outlets

are not subject to the proposed aflatoxin regulations.

Compliance.

Any importer who violates any provision of the import regulation may be subject to a forfeiture in the amount prescribed in section 608a(5) of the Act (7 U.S.C. 601-674), or, upon conviction, penalties in the amounts prescribed in section 608c(14) of the Act, or to both 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 imprisonment or both.

Safeguards.

Safeguard procedures in the form of importer and receiver reporting requirements will be used to ensure that substandard pistachios imported for purposes other than human consumption are used only in authorized outlets exempt from the aflatoxin regulations. The safeguard procedures are comparable to those currently specified for the importation of other exempted commodities. Under the new regulation, importers and receivers of pistachios for other than human consumption purposes are required to complete and submit to USDA an Importer's Exempt Commodity Form (Form FV-6), the generic form used by importers and receivers of other exempted commodities. The information provided on

Form FV-6 will be used by USDA to track pistachios marketed for exempted uses.

This rule establishes maximum aflatoxin tolerance levels and mandatory testing and certification requirements for lots of pistachios offered for importation into the United States. The import quality requirements will be implemented in accordance with section 8e of the Act. These provisions are intended to ensure that pistachios imported into the United States for the purposes of domestic human consumption are of a quality comparable to those pistachios regulated under Marketing Order No. 983 and contain no more than 15 ppb of aflatoxin.

Final Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612), the Agricultural Marketing Service (AMS) has considered the economic impact of this final rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought

about through group action of essentially small entities acting on their own behalf. Import regulations issued under the Act are based on those established under Federal marketing orders.

Small agricultural service firms, which include importers and receivers, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000.

AMS estimates that there are approximately 64 importers and receivers who handled shipments of pistachios into the United States between 2007 and 2009. About 10 of the 64 firms are also substantially engaged in the marketing of U.S. grown pistachios, and are large firms according to the SBA definition. Most of the remaining 54 firms import a number of different food products, and most are also likely to be large firms under the SBA definition, even though they generally import only small quantities of pistachios. There are also seven USDA-accredited laboratories in California that perform aflatoxin testing for pistachios. AMS estimates that four of the seven laboratories would be considered small firms according to the SBA definition.

Turkey and Iran have historically been the source of most pistachios imported into the U.S. Turkish pistachios are imported predominantly in the shell, while Iranian

pistachios are typically imported shelled. Imported pistachios also come from Italy, China, Switzerland, France, Australia, Hong Kong, and Italy. Most pistachios imported from other nations are also shelled. This import regulation establishes protocols for aflatoxin analysis for both inshell and shelled pistachios.

Section 8e of the Act provides that when certain domestically produced commodities, including pistachios, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, quality, size, and maturity requirements.

This rule establishes minimum quality requirements for lots of imported pistachios by specifying a maximum aflatoxin tolerance level as well as aflatoxin testing and certification requirements. Importers are responsible for arranging for the required transportation, storage, sampling, testing, and certification of such pistachios prior to importation. Sampling is conducted by the Federal or Federal-State inspection services, and aflatoxin testing and certification is performed by USDA or USDA-accredited laboratories.

These import aflatoxin testing and certification requirements are the same as or comparable to those implemented under the order regulating the handling of

pistachios grown in California, Arizona, and New Mexico. Pistachios failing to meet the aflatoxin requirements on initial analysis may be reworked and retested, exported to another destination with a higher aflatoxin tolerance, or disposed of in authorized outlets under the supervision of Customs, with assistance from the inspection service if necessary, to verify proper disposal of substandard nuts. Procedures for these activities are also described. Lots of imported pistachios that fail aflatoxin testing may be diverted to certain non-human consumption outlets and are subject to the safeguard provisions of § 999.500. Some reporting and recordkeeping requirements also are included in the pistachio import regulation. These requirements also are the same as or comparable to those implemented under the order.

The cost of testing pistachios for aflatoxin varies, depending on such factors as the location of the port of entry and the size of the lot to be tested. For purposes of estimating an average per-pound testing expense for imported pistachios, this analysis assumes an average lot equal to one container load weighing 16,000 pounds of inshell pistachios arriving at the Port of San Francisco and being tested for aflatoxin by an accredited laboratory in Fresno, California.

In the following example computation of testing costs, there are four elements: (1) a fee (at an hourly rate) charged by the inspection service to draw and prepare the sample, (2) overnight shipping, (3) a fee charged by the laboratory to determine the level of aflatoxin, and (4) the "unit value" of the quantity of pistachios drawn for the sample. The unit value used in this example computation is the average for the last 3 complete marketing years for which import data are available, 2007/08 - 2009/10. The unit value for the 3-year period (\$1.68 per pound) is computed by dividing the average 3-year import value (\$2,900,000) by the average import quantity (1,725,000 pounds). Data are from FAS.

The inspection service fee of \$74 per hour is multiplied by the estimated time of 2 hours to draw a sample, for a cost of \$148. The overnight shipping cost and laboratory fee are estimated at \$200 and \$100, respectively.

The next step in the example computation is value of pistachios drawn for the sample. Under the new section 996.600, in section d) Sampling, the weight of a lot sample is 16 kilograms (equivalent to 35.3 pounds) for a lot weighing between 11,001 and 22,000 pounds. Multiplying 35.3 pounds times the unit value of imported pistachios (\$1.68) yields a value of the tested sample of approximately \$59.

Assuming that aflatoxin certification of the 16,000-pound lot requires the testing of only one sample, the sum of the four cost elements would be \$507, or approximately 3.2 cents per pound (approximately two percent of the unit value of imported pistachios).

It is likely that a pistachio lot arriving at the Port of San Francisco would be transported to an inland handling facility to await sampling and testing and would incur no additional storage costs. However, if the lot is stored at a Customs warehouse near the port, storage fees ranging between \$100 and \$500 per day could be incurred while the samples are analyzed. Analysis and certification is estimated to require between two to five days. Assuming a three day turnaround for a lot incurring \$200 per day storage fees, approximately \$600, or 3.75 cents per pound of pistachios could be added to the testing expense described above.

Regarding the impact of this rule on affected entities, this final rule establishes an import regulation for pistachios as provided in section 8e of the Act. The import regulation requires importers to arrange for the testing and certification of all imports of pistachios for human consumption prior to importation. There are some increased costs to importers associated with the testing and

certification of imported product. However, it is expected that consumer satisfaction, and therefore demand, will be increased by regulating imports and domestic product uniformly. The additional costs are expected to be offset by the benefits of supplying the U.S. marketplace with only high quality pistachios. As mentioned above, these import requirements are the same as or comparable to those established for U.S. domestic pistachio shipments. The domestic industry recently adopted aflatoxin sampling and testing procedures that align with the Codex Alimentarius Commission's (Codex) sampling plan (75 FR 43045; July 23, 2010). The Codex sampling plan is used by the European Commission as its regulation for the importation of tree nuts into the European Union. Thus, these import requirements are comparable to those widely recognized by international pistachio markets.

Industry information suggests that when aflatoxin levels in imported lots of pistachios exceed the FDA maximum tolerance of 20 ppb, the levels are generally significantly higher than 20 ppb. Very few lots test between 15 ppb and 20 ppb. It is anticipated that most imported lots will test below the proposed 15 ppb tolerance. Thus, establishing a maximum aflatoxin tolerance of 15 ppb for imported

pistachios is not expected to have a significant impact on trade.

This import regulation requires importers to report any pistachio lots that fail aflatoxin testing and any lots that are reworked or disposed on two new forms. It is estimated that the total reporting burden associated with these two forms is 11.6 hours for the industry as a whole. The new reporting forms require the minimum amount of information necessary to effectively carry out the requirements and intent of the Act and to administer section 8e compliance activities. These reports are the same as or comparable to the reports and procedures currently required by other domestic marketing orders and import regulations.

The alternative to this action is to continue to allow pistachios to be imported without having to meet aflatoxin requirements that are the same as or comparable to those established for domestic pistachios. However, the import regulation is necessary to ensure that imported and domestic pistachios for human consumption in the United States are of uniformly high quality. Further, the Act requires that import regulations be issued whenever marketing order regulations are established for pistachios. Therefore, this alternative is not appropriate.

In compliance with OMB regulations (5 CFR part 1320) which implement the Paperwork Reduction Act of 1995 (44

U.S.C. Chapter 35), forms FV-249 Imported Pistachios - Failed Lot Notification Report and FV-251 Imported Pistachios - Rework and Failed Lot Disposition Report, were approved by OMB and assigned OMB Number 0581-0278 on November 23, 2011. Following the publication of this final rule, AMS will submit a request to OMB to merge these two forms with the forms currently approved under OMB No. 0581-0215, Pistachios Grown in California, Arizona, and New Mexico.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Additionally, except for the applicable domestic regulations, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule. Reports and forms required under the pistachio import regulation will be reviewed periodically to reduce information requirements and duplication by industry and public sector agencies.

A proposed rule regarding this action was published in the Federal Register on October 21, 2011 (76 FR 65411). Copies of the rule were mailed or sent via facsimile to all known pistachio importers and to the embassies of countries

from whom pistachios are currently imported in significant volumes. The rule was made available through the Internet by USDA and the Office of the Federal Register. A 60-day comment period ending December 20, 2011, was provided to allow interested persons to respond to the proposal.

Four comments were received during the comment period in response to the proposal. All four commenters were supportive of the proposed regulation. One commenter, representing the domestic pistachio industry, noted that the proposed provisions for reworking and retesting imported lots that test positive for aflatoxin provided a safeguard against testing anomalies so that shipments are not unfairly rejected while ensuring a flow of high quality pistachios into the stream of commerce. Two private citizen commenters urged USDA to facilitate the timely and uniform sampling and testing of imported lots upon entry to optimize product freshness and marketability. Import regulations are applied uniformly at all U.S. ports of entry, and Federal and Federal-state inspection protocols are consistent throughout the U.S. Similarly, all laboratories authorized to participate in aflatoxin testing for imported pistachios have been approved by USDA and conform to uniform analytical standards and practices. The sampling and testing of

imported lots will be handled with the same timeliness and integrity applied to domestic lots.

The proposed regulation named a commercially available testing kit as one option for aflatoxin analysis in imported pistachios. One commenter suggested that any AOAC-approved method, rather than a particular product, be specified in the regulation to encourage the ongoing development of improved technology and ensure its availability to the industry. USDA does not intend to endorse the use of specific commercial products. However, as mentioned above, to ensure analytical testing uniformity and integrity, USDA has currently approved only two methods for aflatoxin testing in domestic and imported pistachios. Both are included in the import regulation. Accordingly, § 999.600(e)(1) of the import regulation has been modified by replacing the name of the specific testing kit with a generic description of the approved method. USDA would consider further modifications to the regulation as new analytical methods are tested and approved.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at:
www.ams.usda.gov/MarketingOrdersSmallBusinessGuide. Any questions about the compliance guide should be sent to

Laurel May at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

In accordance with section 8e of the Act, the United States Trade Representative has concurred with the issuance of this final rule.

After consideration of all relevant matter presented, including the information provided by the industry and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 999

Dates, Filberts, Food grades and standards, Imports, Nuts, Prunes, Raisins, Reporting and recordkeeping requirements, Walnuts.

For the reasons set forth above, 7 CFR Part 999 is amended as follows:

PART 999—SPECIALTY CROPS; IMPORT REGULATIONS

1. The authority citation for 7 CFR Part 999 continues to read as follows:

Authority: 7 U.S.C. 601-674.

2. Amend § 999.500 by revising the section heading and paragraphs (a) and (d) to read as follows:

§ 999.500 Safeguard procedures for walnuts, certain dates, and pistachios exempt from grade, size, quality, and maturity requirements.

(a) Each person who imports or receives any of the commodities listed in paragraphs (a)(1) through (a)(3) of this section shall file an "Importer's Exempt Commodity Form" (FV-6) with the Marketing Order and Agreement Division, Fruit and Vegetable Programs, AMS, USDA, and shall provide a printed copy of the completed Form FV-6 to the U.S. Customs and Border Protection Regional Director or District Director, as applicable, at the port at which the customs entry is filed. A printed copy shall accompany the lot to the exempt outlet specified on the form. Any lot of any commodity offered for inspection or aflatoxin testing and, all or a portion thereof, subsequently imported as exempt under this provision shall also be reported on an "Importer's Exempt Commodity Form." Such form, accompanied by a copy of the applicable inspection certificate, shall be provided to the Marketing Order and Agreement Division. The applicable commodities are:

(1) Dates which are donated to needy persons, prisoners or Native Americans on reservations;

(2) Walnuts which are: green walnuts (so immature that they cannot be used for drying and sale as dried walnuts);

walnuts used in non-competitive outlets such as use by charitable institutions, relief agencies, governmental agencies for school lunch programs, and diversion to animal feed or oil manufacture; or

(3) Substandard pistachios which are for non-human consumption purposes.

* * * * *

(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.

3. Add a new § 999.600 to read as follows:

§ 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 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
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	Total weight of lot sample (kilograms)	Weight of test sample (kilograms)
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	the lot sample		
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 USDA-accredited 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 described 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.

(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.

(l) 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.

Dated: August 21, 2012

David R. Shipman
Administrator
Agricultural Marketing Service

Billing Code: 3410-02P

[FR Doc. 2012-20974 Filed 08/24/2012 at 8:45 am; Publication Date: 08/27/2012]