



Western Pistachio Association

7030 N. Fruit Avenue, Suite 117 • Fresno, California 93711-0782

Telephone: (559) 475-0435 • Facsimile: (559) 475-0624

E-mail: info@westernpistachio.org • Website: westernpistachio.org

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March 3, 2010

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Dear Sir/Madam:

**Re: Product Tracing Systems for Food
[Docket No. FDA-2009-N-0523]**

In response to the November 3, 2009 *Federal Register* Notice announcing a public meeting and requesting comments on product tracing systems for food, the Western Pistachio Association is pleased to provide the following comments.

The Western Pistachio Association is a trade association representing pistachio growers throughout the western United States. The WPA is a grower led organization, with oversight provided by a board of 18 directors. The WPA is now serving as the sole pistachio grower member trade association whose directors are elected by pistachio growers.

The WPA programs are the following: nutrition and health research, marketing (domestic and international), and governmental affairs.

In addition to the WPA, there are two other democratically administered transparent organizations servicing grower and processor requirements.

The Administrative Committee for Pistachios has the mission of aflatoxin food safety testing for the domestic market. The California Pistachio Board has the mission of aflatoxin food safety testing for export markets.

There are approximately 800 U.S. pistachio growers. Growers vary in size from a few acres to several thousand acres. On the processor side, there are approximately 14 processors in the U.S. However, seven of the processors process 95 percent of the U.S. crop. Our pistachios are sold either raw or roasted as an in-shell product or as kernels (shells removed).

Harvest and Processing

Because of the nature of producing and processing pistachios, our industry has found it particularly challenging to trace every nut that is grown and processed as some food industries are able to do. Pistachio growers harvest their crop every September; pistachios are an alternate bearing crop and the size of the harvest varies from year to year. The pistachios are shaken from the tree by a mechanical shaker, and they fall directly into a canvas receiver. Attached to the receiver is a cart for holding pistachios during the harvest; the cart takes the pistachios from the receiver and dumps them into a harvest trailer.

From the orchard, the pistachios are taken by a harvest trailer to a processing plant. At the processing plant, each harvest trailer load of pistachios is weighed and recorded electronically. When the pistachios are received at the processing plant from the grower, they are fresh and must be hulled and dried. Each load of pistachios generally weighs 50,000-60,000 pounds, before the processing begins with the wet hull intact. The nuts are sent to the precleaning stage of the process where the leaves and sticks are removed. Mechanical “peelers”, as used in carrots and potatoes, are used to remove the hull, the fleshy outer layer. The hulls are washed away, and the pistachios go into a float tank, as a first quality step. The pistachios are sent to the float tank to separate mature pistachios from the immature. Very small pistachios are also taken out at this step.

From the float tank step, the pistachios are sent to the dryer. Moisture management is a key issue in pistachio processing. Once in the commercial dryers, the moisture content is taken down from 30% to 10% in a 6 hour period. The product at this point will be a mix of open inshell, closed shell, and shelling stock (kernels). The pistachios are then stored in silos at the processing plant until they need to be roasted and then packaged. While in the silos, ambient air is used to continue the drying process and the moisture content of the pistachios is taken down to 5% moisture level. Storage silos commonly contain one million pounds of pistachios per silo. Each silo can contain pistachios from one grower to as many as 50-70 different growers’ crop. The processors keep internal records for each silo that indicates the origin information for the product in each silo. Crops from previous years can be blended with the most recent crop harvested. However, the pistachio processors are reconsidering this practice.

Pistachios are moved from the silo into the processing/sorting plant. The goal is to segregate the pistachios into different grades and sizes. Foreign material is first removed with a gravity table as this will take out most remaining twigs, sticks, small rocks and pebbles, etc. Nuts then go through a pin picker to separate the open inshell from the closed shell and then to a sizing table made of round hole screens. By passing the pistachios over the screens, different size pistachios fall through the screen holes. Nuts then go through an electronic eye sorting process to remove stained nuts and then finally to a hand sorting process.

Roasting is the final step before human consumption. Roasting is necessary for the flavor of the pistachio; if pistachios are allowed to absorb moisture, the flavor will not be acceptable. Along with flavor, roasting is considered a “kill step”. The high temperatures kill any food borne pathogen that would sicken the consumer.

During the processing, pistachios in the various stages of hulling and drying, roasting and packaging are kept on separate conveyor lines. By keeping the stages separate, this allows an assurance that the batch is not contaminated by food borne contaminants. Processors keep internal records of lot numbers for each batch of pistachios run and the processing lines on which the lot was run. These records include sanitation records as well. Packaging consists of hermetically sealed plastic packaging or containers. Each consumer package or container is marked with a specific lot code as an identifier.

When processors export pistachios to other countries, the product is sent in either 22,000 pound or 44,000 pound bulk containers. These pistachios are sorted, graded and ready to be roasted. Once the pistachios are in the final country of destination, individual processors within the country further process the pistachios to their standards and taste. Each shipping container is also marked with lot codes and all the required information for customs and the importing country standards.

Food Safety Concerns in the Industry

Pistachios, like many other nuts, are subject to instances of contamination of food borne pathogens and aflatoxin producing fungi. Aflatoxin is a proven carcinogen and is therefore unacceptable in pistachios consumed by humans. The U.S. industry has mandated testing for all pistachios sold in the domestic market; therefore, the U.S. pistachio industry has placed more stringent standards, 15 ppb, on pistachios sold in the domestic market, than required by federal law (20 ppb). *Codex Alimentarius* has recently established the standards of 15 ppb for further processing and 10 ppb for human consumption in pistachios that are traded in the international marketplace. Countries are moving towards accepting those standards including the EU.

Salmonella has also become an increasing concern of the U.S. pistachio industry. The U.S. pistachio industry has a partnership with the U.S. Department of Agriculture, AMS to establish higher standards for food safety that would apply to the industry in the pistachio federal marketing order. These standards include:

- Must have a HACCP plan that identifies critical control points
- HACCP plan must be according to either accepted ISO or US standards
- Food Safety Plan must address prerequisite programs
 - Sanitation – both operational and monitoring
 - Education
 - Salmonella Primary Control Area
 - Zoning by hazard/risk
 - Air and traffic flow
- Not limited to foodborne pathogens – also allergens and foreign material
- “Kill” step to achieve a validated reduction in potential contamination (log kill yet to be determined. FDA says 5 log, we think that 3 log will be adequate)
- No domestic shipping without the kill step, except to verified users

Comments – Questions from FDA

In light of our industry's standards for growing, harvesting and processing and our concerns about certain food borne pathogens, we appreciate the opportunity to comment on tracing systems for food and the impact this will have on the U.S. pistachio industry.

- (1) **Should a lot code be assigned to food?**
Yes.
- (1a) **If so, at what stage should it be assigned or modified?**
After the sorting stage in the pistachio processing. Each processor keeps a processing history of each lot that is processed at their facility.
- (2) **Should a lot code be assigned for all finished food products, whether sold in packaged or unpackaged form?**
Yes.
- (3) **Should a lot code be assigned whenever food is manipulated (such as when pistachios are commingled, packed or repacked)?**
Yes.
- (4) **What data or information would be useful to include in a lot code?**
A clear identifier of the processor and additional elements that correspond to the processors internal records which would include the silo of storage, the processing line, and the date of processing.
- (5) **What (if any) procedures should be used to establish a lot code?**
Industry standards that are already in place in the pistachio industry.
- (6) **Should any such procedures address the size of a lot or the time frame from production of a lot?**
The production time frame of a particular lot needs to be noted in internal records that are kept by the processor.
- (7) **Should the location of a lot code depend on the type of food, other factors, or both?**
The location of the lot code should depend on other factors which include the package size and whether it is ready for direct consumption.
- (8) **Should a lot code be located:**
 - (8a) **On the label (or container or package) of a packaged food?**
Yes.
 - (8b) **On the shipping container of packaged food, unpackaged food or both?**
Yes

- (8c) **In internal records (such as receiving records, batch production records, inventory records, and distribution lists)?**
Yes
- (8d) **In external records accompanying commercial transactions (such as a bill of lading, airway bill, invoice, manifest, shipping record, or packing list)?**
Yes
- (9) **What ways might the lot code be linked to internal and external records associated with the food?**
Pistachio processors are able to link the internal and external records through an electronic method. The lot code follows the product through sorting, roasting and packing. From the packing step, pistachios are shipped, and the processor keeps records of where the shipment goes. The records are inextricably linked at the processor level.
- (10) **Should a shipment identifier be considered an information element of an enhanced product tracing system?**
The pistachio industry feels that the shipment identifiers should be a part of the internal records that the processor must keep.
- (10a) **If so, are there any business practices (e.g. the way shipments are currently identified) that would be impacted?**
Not applicable.
- (11) **Should any other information not already required by 21 CFR Part 1, Subpart J, Sec. 1.337 and 1.345 be considered an information element of an enhanced product tracing system?**
The information that is required by the Code of Federal Regulations is sufficient.
- (12) **Should product tracing information not currently required to be on the package of a packaged food or on a shipping case be present on the package or shipping case?**
No.
- (12a) **If so, what additional product tracing information should be present on the package or shipping case?**
The lot code is sufficient.
- (12b) **If so, at what stage or stages in the supply chain should such information be included?**
Not applicable.
- (12c) **If so, should such information be present for all food or only some food?**
Not applicable.

- (13) **Should some information about pistachios be sent forward farther in the supply chain than "one down"? If so, how far in the supply chain should such information go? For example, should such information be transmitted as far as the retail establishment that sells the pistachios to consumers, or as far as the last person in the supply chain before the retail establishment?**
Lot code should be maintained all the way to retail.
- (14) **Should some information about packaged food (such as information identifying the manufacturer of a processed food) be sent forward farther in the supply chain than "one down"?**
Yes.
- (14a) **If so, how far in the supply chain should such information go? For example, should such information be transmitted as far as the retail establishment that sells the food to consumers, or as far as the last person in the supply chain before the retail establishment?**
As far as the retail packaging.
- (15) **What if any information elements in an enhanced product tracing system should be standardized?**
All the information should be standardized.
- (16) **Are there specific information elements (such as shipment identifier and a lot code) that are particularly amenable to standardization?**
For the pistachio industry, yes. They should be identifiable to the processor.
- (17) **Would such standardization be specific to a specific industry sector or type of food or could it apply across industry sectors or types of food?**
Standardization should be specific to the specific industry sector.
- (18) **What standards already exist and how useful are they for product tracing?**
There are no formal standards for the pistachio industry but all processors keep individual lot numbers and can trace all of their product.
- (19) **If standards can and should be used for certain information elements in an enhanced product tracing system, should FDA develop the standards?**
Industry should develop the standards.

- (20) **Would current or newly developed standards for the content and format of electronic systems have practical utility for persons who continue to use paper-based records? For example, could human readable data that supports standardized electronic data be useful to persons who continue to use paper-based records?**
Systems should be electronically based and not written depending upon the size of the operation. All data should be human readable all the way down to the consumer.
- (21) **Would it be useful for persons, in addition to those who manufacture, process or pack food, to establish and maintain a record of a lot code? If so, for which persons (e.g., distributors, retailers) would it be useful?**
Everyone needs to keep a record of a lot code.
- (21a) **If it would be useful for some persons, in addition to those who manufacture, process, or pack food, to establish and maintain a record of a lot or code number, would it be equally useful irrespective of the type of food (e.g., packaged food or fresh produce)?**
Yes.
- (22) **Would it be useful for nontransporters who manufacture, process, or pack food to establish and retain any additional records to facilitate linkage?**
Yes.
- (23) **In particular, would it be useful for persons who manufacture, process, or pack food to establish and maintain a “linking record” that would link a specific lot of an incoming ingredient to all released food containing that specific lot of ingredient?**
Yes.
- (23a) **If so, should some or all of these records be created at the time of receipt or release of food or be existing records, or should some or all of these records be new records created upon the request of FDA (e.g., during an outbreak investigation or traceforward operation)?**
The records should be created upon the release of food.
- (23b) **If so, would it be useful for FDA to specify the format of the record? For example, should FDA provide a model form that could be used to provide the information in such a record? Or would it be more useful for FDA only to specify the information elements of such a record?**
The forms need to be harmonized by FDA.
- (23c) **If so, should all such records be in electronic form?**
Yes.

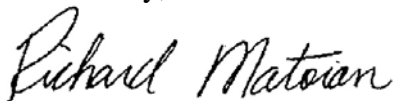
- (24) **Should some or all product tracing records be established and maintained in electronic form? If so, should information established and maintained in electronic form also be human readable?**
Yes. Should be in electronic form and human readable.
- (25) **If information would be sent to FDA, how should it be transmitted? For example, could the information be transmitted by e-mail, fax, or courier service? Or should there be an electronic portal (such as the Reportable Food Registry)?**
No Comment.
- (26) **Should any or all enhancements to current product tracing systems apply regardless of risk, or should such enhancements be based on risk? If based on risk, what criteria should be used to determine risk? If not based on risk, should such enhancements be developed or phased in based on risk?**
No Comment.
- (27) **What are the costs, benefits and feasibility of implementing an enhanced product tracing system for each of the persons in the supply chain for various segments of the food industry?**
For the pistachio industry, there should be no additional costs because we already have a tracing system in place that we believe works.
- (28) **To what extent would an enhanced product tracing system affect current business practices? What would be the cost of any such changes in current business practices for each link in the supply chain?**
Not applicable.
- (29) **What determines the costs for food distributors and retailers to maintain records of lot code information for manufactured products, and farm related information for fresh produce?**
Not applicable to the pistachio industry.
- (30) **What determines the costs for food service establishments to maintain records consistent with the BT regulations, as well as lot code information for manufactured or processed food products and farm-related information for fresh produce?**
Not applicable to the pistachio industry.
- (31) **What determines the costs for small food retailers to maintain records consistent with the BT regulations, as well as lot code information for manufactured or processed food products and farm-related information for fresh produce?**
Not applicable to the pistachio industry.

- (32) **What determines the lot size of a lot manufactured or processed food products and how do lot sizes vary by food category and size of the manufacturer?**
The size of a lot depends upon the type of product being sold, i.e. kernel product or in-shell product. The size of the manufacturer also determines the lot size given the range of processor sizes. One lot of a large processor may exceed the output of a small processor.
- (33) **What determines the costs for maintaining "linking" records to manufacturers?**
Not applicable.
- (34) **What, if any, additional outreach from FDA would better enable manufacturers, processors and packers to comply with the requirements to maintain records of the lot or code number to the extent this information exists?**
Pistachio processors already maintain these records.
- (35) **What if any additional outreach from FDA would better enable all persons subject to 21 CFR Part 1, subpart J to better comply with its requirements?**
The U.S. pistachio industry complies with the regulations set forth by FDA. The only outreach that we believe would be helpful would be to inform people that they are subject to the regulations. Some may not realize that they need to be regulated based on their size.

Conclusion

The U.S. pistachio industry appreciates the opportunity to provide comments regarding a national enhanced tracing system. We have taken part in the discussion and debate concerning a working tracing system and understand the obstacles involved. Pistachio processors, though, already maintain records that enable them to trace their product; therefore, we are concerned that a national tracing system will place undue strains on the processors in our industry especially the smaller ones. We welcome more discussion on this very important topic that will enable informed decisions on launching a national tracing system. If you need further information on the U.S. pistachio industry, please contact Richard Matoian, Executive Director, Western Pistachio Association, at 559-475-0435.

Sincerely,



Richard Matoian
Executive Director