Pasteurization Protocol for Pecan Shellers

- **Ensure Good Manufacturing Practices and Food Safety Prerequisites are in place and consistently monitored by experienced personnel**
- **Recommended 4-5 log reduction in Salmonella**
- **Determine salmonella reduction step in process**
- **Validate process through a recognized authority**
- **Conduct audit of process annually**
- **Implement procedures to reduce possibility of post shelling/processing contamination**

Purpose: In the past several years, the nut industry has experienced several major food safety incidents due to the presence of salmonella. Although contamination in pecans is not common, there is always a risk. Proper Good Manufacturing Practices must be followed and a validated salmonella reduction process step must be in place to ensure reduction of salmonella.

Salmonella: *Salmonella* can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting, and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the blood stream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis, and arthritis.

Good Manufacturing Practices/Food Safety Prerequisites: FDA mandated Good Manufacturing Practices should be followed by all employees and visitors (Attached). In addition, Food Safety Prerequisites should be in place (Attached).

Recommended Log Reduction: The Almond Industry requires a minimum 4-log reduction with no significant degradation of the sensory and quality characteristics of almonds such as flavor, color, texture, or skin integrity. The FDA performance standard for the meat industry is a 5 log reduction. For peanut processing, the FDA is recommending a 5 log reduction in all peanut-derived products used as ingredients and sold as food according to the FDA guidance document Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Peanut-derived Product as an Ingredient (Attached). In addition, the FDA recommends that pistachio suppliers have validated processes in place to adequately reduce the presence of Salmonella spp. by 5 logs. (Draft Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Pistachio-Derived Product As An Ingredient)

The National Pecan Shellers Association Technical Committee recommends a 4-5 log reduction based on standards set in related industries. Further research is needed to determine the log reduction that is feasible in pecans due to their unique surface characteristics.

Types of Salmonella Reduction Steps: Identified technologies for a 5 log reduction in almonds are: steam pasteurization, fumigation with PPO, blanching and oil roasting (Attached pasteurization techniques). In a recent Thermal Inactivation Study conducted by the American Peanut Council, dry roast and oil roast conditions were tested. Common processes in a pecan shelling operation that might reduce the level of salmonella contamination include hot water systems (tempering / pasteurizing), oil/dry roasting, PPO treatment and chlorine dip. Per the Almond Board, a 4 log reduction in salmonella can be achieved with:

- Hot water treatment – 2 minutes @ 190 F
- Oil roasting – 2 minutes @ 260 F
- Propylene Oxide (PPO) treatment - .5 ounces/ft3

These conditions might also be suitable for salmonella reduction in pecans. More research is needed to determine the effectiveness of a chlorine dip. Effectiveness of any process can only be confirmed through validation by an experienced authority.

Validation Process: Equipment and process(es) to be validated should be designed and/or selected so that validation requirements are consistently achieved. This should be done with the participation of all appropriate groups that are concerned with assuring a safe quality product, e.g., engineering design, production operations, and quality assurance personnel.

Validation of any process must be performed by an authority who has the educational requirements and experience to evaluate the effectiveness of a process to reduce the level of salmonella. The authority must be able to understand the process, apply the standardized inoculation and testing procedures, develop the temperature profiles and write a validation report (Attached "Role of Process Authority"). The Pecan Shellers Association Technical Committee recommends that Process Authorities approved by The Almond Board be chosen for all validation work (Attached list)

Annual Auditing of Process: In keeping with best practices established by The Almond Board, the technical committee also recommends that all validated processes be audited on an annual basis by a different process authority.

Post Shelling /Processing Contamination: The best pasteurization system is located immediately prior to finished product packaging in order to reduce the possibility of post pasteurization contamination. However this may not always be possible depending on the system used at each facility. Therefore, Food safety procedures and practices must be in place to prevent post shelling/processing cross contamination. This includes, but is not limited to:

- Complete segregation between raw and pasteurized products. (include employees, traffic patterns, etc)
- Do not share containers, totes, material handling equipment, etc. between raw and pasteurized products.
- Proper air ventilation (positive air flow) between raw and pasteurized areas.
- Environmental swabbing program using the "zone" method.

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[Revised as of April 1, 2008]
[CITE: 21CFR110]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION

PART 110 CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

Subpart A--General Provisions

Sec. 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) *Acid foods or acidified foods* means foods that have an equilibrium pH of 4.6 or below.

(b) *Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) *Batter* means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) *Blanching,* except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) *Critical control point* means a point in a food process where there is a high probability that improper control may cause,

allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) *Food* means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) *Food-contact surfaces* are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

(h) *Lot* means the food produced during a period of time indicated by a specific code.

(i) *Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective "microbial" instead of using an adjectival phrase containing the word microorganism.

(j) *Pest* refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) *Plant* means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) *Quality control operation* means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) *Rework* means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) *Safe-moisture level* is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (aw). An awwill be considered safe for a food if adequate data are available that demonstrate that the food at or below the given awwill not support the growth of undesirable microorganisms.

(o) *Sanitize* means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in

substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) *Shall* is used to state mandatory requirements.

(q) *Should* is used to state recommended or advisory procedures or identify recommended equipment.

(r) *Water activity* (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Sec. 110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

Sec. 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control.* Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) *Cleanliness.* All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) *Education and training.* Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) *Supervision.* Responsibility for assuring compliance by all

personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

Sec. 110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Authority: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.
Source: 51 FR 24475, June 19, 1986, unless otherwise noted.

Food Safety Prerequisite Programs

Prerequisite programs are just as important as Critical Control Points when it comes to food safety. The following is a list of common food safety and HACCP pre-requisite programs:

Standard Sanitation Operating Procedures
Good Manufacturing Practices
Allergen Control Program
Preventive Maintenance Programs
Traceability and Recall program
Employee Training
Plant and Equipment Sanitary Design
Traffic Patterns
Material and Ingredient Receiving Inspection
Product Specifications
Environmental Monitoring Program
Air Sampling Program
Glove Use Policy
Glass, Ceramic and Hard Brittle Plastic Control Program
Foreign Material Control
Customer Complaint Investigation and Corrective Action
Sanitation and Food Safety Self Audits
Good Laboratory Practices
Process Control
Vendor Certification
Rework Policy
Crisis Management
Food Defense

General requirements for Pre-requisite programs:

- Written Procedures
- Actual measurement of observations
- Corrective Actions
- Documentation
- Training
- Verification

Food

Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Peanut-Derived Product as an Ingredient

March 2009

Guidance for Industry
Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Peanut-Derived Product as an Ingredient

Additional copies are available from:
Office of Food Safety
Division of Plant and Dairy Food Safety, HFS-315
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) **301-436-2367**
http://www.cfsan.fda.gov/guidance.html

You may submit written or electronic comments regarding this guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov/. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
March 2009

Table of Contents

Guidance for Industry[1]

Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Peanut-Derived Product as an Ingredient

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

This guidance is intended for manufacturers who use a peanut-derived product as an ingredient in a food product. Peanut-derived products include peanuts, peanut butter, peanut paste, peanut meal, and peanut granules. We are issuing this guidance because recent outbreaks indicate the potential for foodborne illness resulting from the consumption of foods containing peanut-derived products if a peanut-derived product used as an ingredient is contaminated with *Salmonella* species (*Salmonella* spp.) (Ref. 1). FDA may take enforcement action, including pursuing product seizure, where food has tested positive for *Salmonella* spp[2]

This guidance does not provide recommendations for producers of peanut-derived products. Importantly, this guidance does not diminish the responsibility of producers of peanut-derived products to ensure that foods that they produce are not "adulterated" under the Federal Food, Drug, and Cosmetic Act (the act) or otherwise in violation of the law.[3] Remedies for violations of the act include seizure, injunction, and criminal prosecution.[4]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. Discussion

A. Considerations for Evaluating the Effectiveness of Certain Salmonella Control Measures

Salmonella spp. are bacteria that ordinarily are sensitive to heat and high acidity. This sensitivity is often the basis for food processing used to control the presence of the organism. For example, it takes only 3 seconds to achieve a 5-log reduction in *Salmonella* at 71 °C (equivalent to 160 °F) in fruit juices (Ref. 4).

While considered heat sensitive, *Salmonella* spp. can become heat resistant in dry food products such as powdered milk or in low water activity products like chocolate syrup and peanut butter (Refs. 5 and 6). The relationship of *Salmonella* heat resistance to water activity has been well-studied at water activities between 0.99 and 0.85. Generally, *Salmonella* becomes more heat resistant as the water activity of a food becomes lower (Refs. 7 and 8). For example, it takes less than 5 minutes to achieve a 5-log reduction of *Salmonella* at 140 °F in a food with a water activity of 0.99 (Ref. 9). However, it takes 50 minutes to achieve the same reduction of *Salmonella* at 140 °F in a food with a water activity of 0.85 (Ref. 10).

The influence of the food on the heat resistance of *Salmonella* is not limited to the effects of water activity. The composition of the food (such as fat content, protein content, and acidity) may also affect heat resistance. For example, it can take more than 6 hours to obtain a 5-log reduction of *Salmonella* in milk chocolate at a temperature of 194 °F and more than 30 hours to achieve the same log reduction at 160 °F (Ref. 5).

The water activity of peanut-derived products is generally low; for example, the water activity of peanut butter and peanut paste is typically 0.35 or less (Ref.11). There are few data available on the heat resistance of *Salmonella* at such extremely low water activities. Moreover, many peanut-derived products, such as peanut butter and peanut paste, have a high fat content. In general, based on the available information about the heat resistance of *Salmonella* spp., *Salmonella* is expected to be even more resistant to heat in foods like peanut butter and peanut paste than it would be in a food with a water activity such as 0.85.

The effectiveness of processing conditions used to reduce *Salmonella* spp. in a

particular food product may depend on whether, and to what extent, an ingredient with a very low water activity is rehydrated. There are some processes that are likely to adequately reduce[5] *Salmonella* spp. introduced into a food through an ingredient containing a peanut-derived product such as peanut butter or peanut paste. If *Salmonella*-containing peanut butter or peanut paste is completely mixed into a high water activity food, given sufficient time to fully rehydrate, and then either heat processed for an adequate length of time at temperatures greater than 160 °F or acidified to a pH of 3.5 or less, then we would expect the *Salmonella* to be adequately reduced.

However, if a peanut-derived product such as peanut butter or peanut paste added to a food product such as ice cream remains identifiable as a lump, particle, or "swirl," any *Salmonella* spp. in the peanut-derived product likely would remain in the low water activity environment of the peanut-derived product and, thus, remain highly resistant to heat. As another example, if a peanut-derived product such as peanut butter or peanut paste added to a food product is thoroughly mixed into a food such as a bakery product mix, *Salmonella* spp. originally present in the peanut-derived product has the potential to diffuse uniformly in the mix, rehydrate, and become less resistant to heat. However, even if *Salmonella* present in the peanut-derived product has the potential to diffuse and rehydrate in a bakery product mix, factors such as the amount of time between preparing the bakery product mix and cooking it could affect the susceptibility to heat of the *Salmonella* spp. when exposed to the heat of the baking process. In addition, knowing that a baked good is heated at an oven temperature such as 375 °F for a fixed time (such as 10 minutes) does not provide information about the temperature actually achieved at the coldest point in the bakery product, the uniformity of the temperature achieved in the bakery product, and the actual duration of time that the bakery product experienced its final temperature.

B. Recommendations

Because procedures used to manufacture finished products containing a peanut-derived product as an ingredient may or may not adequately reduce the presence of *Salmonella* spp., FDA recommends that:

- Manufacturers of foods containing a peanut-derived product as an ingredient obtain peanut-derived product only from suppliers with validated processes in place to adequately reduce the presence of *Salmonella* spp. (e.g., by 5 logs).
- Manufacturers purchasing a peanut-derived product as an ingredient in a form for which no such validated process is available (e.g., raw shelled or blanched peanuts), and manufacturers that have purchased a peanut-derived product about which questions have been raised concerning the potential presence of *Salmonella* spp. in a particular lot or lots, ensure that their own manufacturing process would adequately reduce the presence of

Salmonella spp. (e.g., by 5 logs) (based upon a combination of time and temperature, or other means). In evaluating the ability of their manufacturing processes to reduce the presence of Salmonella spp. in the finished product, such manufacturers should take the following considerations into account:

- Based on the available data and information, the processing conditions appropriate to adequately reduce *Salmonella* spp. in a particular food product vary depending on the specific characteristics of the food product.
- Determining the processing conditions appropriate to adequately reduce *Salmonella* spp. in a particular food product involves considerable expertise in both food microbiology and the physics of heat transfer.
- The most reliable way to determine whether a manufacturing process would reduce the presence of *Salmonella* spp. in a food product containing a peanut-derived product as an ingredient is to conduct a scientific study to determine the death rate of *Salmonella* spp. in the product using microbiological challenge studies, taking into account properties of the food (such as water activity, fat content and pH).
- A history of negative microbiological tests for *Salmonella* spp. in the finished product, while useful in a verification program for a process, is not sufficient, by itself, to determine the adequacy of a process in reducing the presence of *Salmonella*.

FDA is aware that the Grocery Manufacturers Association (GMA), collaborating with other food industry organizations in a *Salmonella* Control Task Force, has very recently published an industry guidance document reviewing and synthesizing information about industry programs in place to control *Salmonella* spp. and help ensure the safety of low-moisture food products (Refs. 12 and 13). Manufacturers that use a peanut-derived product as an ingredient in a food product may find GMA's document useful. Please be aware that FDA is not responsible for the content of GMA's document, which FDA did not create and has not verified.

III. FDA Web Site References

The following references were available on FDA's Web site as of February 4, 2009. We also have placed these references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA. 2009. Recall of Products Containing Peanut Butter; Salmonella Typhimurium, Accessed and printed February 4, 2009. As of the date of this guidance, this Web site is an active site that adds information over time to

provide the most current information about the outbreak. Persons who access this Web site after February 4, 2009, may find more information than the information we placed in the Division of Dockets Management.

2. FDA. 2005. Compliance Policy Guide Sec. 527.300 Pathogens in Dairy Products (7106.08). Accessed and printed February 8, 2009.
3. FDA. 1995. Compliance Policy Guide Sec. 555.300 Foods, Except Dairy Products - Adulteration with Salmonella (7120.20). Accessed and printed February 8, 2009.

IV. References Without Web Site Addresses

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

4. Mazzotta, AS. 2001. Thermal Inactivation of Stationary-Phase and Acid-Adapted *Escherichia coli* O157:H7, *Salmonella*, and *Listeria monocytogenes* in Fruit Juices. *Journal of Food Protection* 64 (3): 315-320.
5. Goepfert JM, Biggie, and RA. 1968. Heat Resistance of *Salmonella Typhimurium* and *Salmonella seftenberg* 775W in Milk Chocolate. *Applied Microbiology* 16: 1939-1940.
6. Shachar D, and Yaron S. 2006. Heat Tolerance of *Salmonella enterica* Serovars Agona, Enteritidis, and Typhimurium in Peanut Butter. *Journal of Food Protection* 11: 2687-2691.
7. Corry J. 1976. The Safety of Intermediate Moisture Foods with Respect to Salmonella. In *Intermediate Moisture Foods*, eds R Davies, G Birch and K Parker, 215-238. London: Applied Science Publishers Ltd.
8. D'Aoust J-Y. 1989. Salmonella. In *Foodborne Bacterial Pathogens*, ed M Doyle, 327-445. New York: Marcel Dekker.
9. Baird-Parker AC, Boothroyd M, and Jones E. 1970. The Effect of Water Activity on the Heat Resistance of Heat Sensitive and Heat Resistant Strains of *Salmonellae*. *Journal of Applied Bacteriology* 33: 515-522.
10. Gibson B. 1973. The Effect of High Sugar Concentrations on the Heat Resistance of Vegetative Microorganisms. *Journal of Applied Bacteriology* 36: 365-376.
11. Burnett S, Gehm E, Weissinger, WR, and Beuchat LR. 2000. Survival of Salmonella in peanut butter and peanut butter spread. Journal of Applied Microbiology 89 (3): 472-477.

V. Non-FDA Web Site References

The following references were available on the Internet on the date identified in

the reference list. As of February 5, 2009, FDA had verified the Web site addresses it makes available as a hyperlink from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to the Web sites after posting this guidance on its Web site. We have placed these references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

12. Grocery Manufacturers Association. 2009. Control Of Salmonella In Low-Moisture Foods. (available in PDF) Accessed and printed on February 5, 2009.
13. Grocery Manufacturers Association. 2009. Annex to Control Of *Salmonella* In Low-Moisture Foods. (available in PDF) Accessed and printed on February 5, 2009.

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(1) This guidance has been prepared by the Division of Plant and Dairy Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

(2) See e.g., Compliance Policy Guide (CPG) Sec. 527.300 Pathogens in Dairy Products (7106.08) and CPG Sec. 555.300 Foods, Except Dairy Products - Adulteration with Salmonella (7120.20) (Refs. 2 and 3).

(3) The circumstances under which food is deemed adulterated are set forth in section 402 of the Act, and related prohibitions applicable to adulterated food are contained in section 301 (21 U.S.C. 342 & 331).

(4) See, e.g., sections 301(a) through (c) and section 303(a).

(5) In this document, we use the phrase "adequately reduce" to mean capable of reducing the presence of *Salmonella* to an extent sufficient to prevent illness. The extent of reduction sufficient to prevent illness usually is determined by the estimated extent to which *Salmonella* spp. may be present in the food combined with a safety factor to account for uncertainty in that estimate. For example, if it is estimated that there would be no more than 1000 (i.e., 3 logs) *Salmonella* organisms in the food, and a safety factor of 100 (i.e., 2 logs) is employed, a process adequate to reduce *Salmonella* spp. would be a process capable of reducing *Salmonella* spp. by 5 logs.

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December 2008

ALMOND ACTION PLAN

Pasteurization Treatments

As a result of two *Salmonella* incidents in 2001 and 2004, the California almond industry approved a mandatory pasteurization plan for almonds. A voluntary industry initiative, the **"Action Plan"** calls for a change in the outgoing quality standards under the federal Marketing Order for almonds. On February 3, 2006, the Almond Board of California's (ABC) Board of Directors unanimously approved submitting the regulatory change to USDA. On August 22, 2006 the Board of Directors amended several provisions of the regulatory language previously submitted to the USDA. The amended regulatory language was submitted to the USDA in September 2006 and the final rule was published in the Federal Register March 30, 2007 with an implementation date of September 1, 2007.

Pasteurization Process – Raw Almonds	*Process Description and Availability*
Who evaluates the pasteurization technologies for their ability to provide a minimum 4-log reduction?	All pasteurization technologies are evaluated by the ABC's Technical Expert Review Panel (TERP) for their ability to provide a minimum 4-log reduction in Salmonella contamination and to demonstrate no significant degradation to the sensory, quality and nutritional characteristics of almonds. Based on a risk assessment conducted for the ABC and reviewed by FDA, it has now been determined that a 4-log reduction is an appropriate level of control.
Propylene Oxide (PPO) Fumigation (for raw almonds)	PPO was confirmed by both TERP and the Food and Drug Administration (FDA) to achieve greater than 5-log reduction with a minimum of 0.5 oz/ft^3 PPO concentration. PPO product is to be pre-warmed to at least 86˚F (30˚C); treatment chamber temperature are not to exceed 125˚F (52˚C) for 4 hours. These parameters are specified in the PPO Standard Operating Procedure available from the Almond ABC of California. The FDA has determined that when operating under specified parameters for 5-log reduction, treated almonds may be labeled as "pasteurized". PPO has proven to achieve a 5-log reduction on inshell almonds as well. Expert evaluation has concluded that PPO treatment results in no significant or meaningful impact on quality/sensory characteristics. Available PPO treatment capacity for almonds at nine facilities in California is estimated to be over 250,000,000 pounds per year – sufficient to treat 68% of domestic shelled almond shipments. Cost: Handler sources advise cost to construct a PPO facility ranges from $500,000-$1,250,000; custom processing is being offered at $0.04 to $0.05 per pound A list of PPO treatment facilities is available from ABC.
FMC JSP-I Almond Surface Pasteurization Technology (for raw almonds)	A proprietary HTST (High Temperature Short Time) process using moist heat in a non-pressurized environment. Product is exposed to heat for pasteurization and drying for less than one minute. TERP has accepted operating parameters for both 4- and 5-log reduction. In addition, the FDA has determined that when operating under specified parameters for 5-log reduction, treated almonds may be labeled as "pasteurized". The accepted parameters are for the pasteurization system; individual equipment must be validated on its ability to deliver the operating parameters, providing that there is no change in equipment design. Accelerated shelf-life and initial expert sensory evaluations have indicated that the treated almonds demonstrate no meaningful or significant difference from untreated almonds. Cost: Operating costs are estimated to be less than $0.01 per pound. Contact vendor for specific equipment and installation costs. Contact: FMC Technologies Inc; 2300 Industrial Avenue, Madera, CA 93639. Tel: (559) 661-3200, paul.favia@fmcti.com

Pasteurization Process – Raw Almonds	*Process Description and Availability*
MRL Industries Humid Air Pasteurizer (for raw almonds)	MRL technology is a continuous proprietary process which utilizes hot humid air flow through an almond bed to pasteurize almonds. Water is vaporized to create the hot humid air which the almonds travel through. TERP has approved both 4 and 5-log processes for MRL technology. Cost: Vendor estimated cost for complete system (equipment and installation) vary based on capacity requirements and individual upstream and downstream requirements. Operating costs are estimated to be less than $0.01 per pound. Contact vendor for specific equipment costs. Contact: MRL Industries, 19500 Nugget Blvd., Sonora, CA 95370. Tel: (209) 533-1990, Kris Bergstrom, Direct: 209-536-6120, kris.bergstrom@mrlind.com
H_2O Express	H2O Express is a patented, low temperature steam pasteurization process developed by Sterilization and Fumigation Services, Inc. This is a batch process which treats the product in its packaging and can meet organic standards. The system involves air evacuation, steam conditioning and product cooling. TERP has approved 4-log operating parameters for 50-lb containers and 2,200 lb. tri-wall fiber totes. Further validation trials for alternative packaging configurations such as plywood bins, super sacks and in-shell almonds are underway. Cost: Contract processing services are available at approximately $0.05/lb for the 2006-07 crop. Contact: Sterilization and Fumigation Services, Inc., 3500 Shiells Road, Newman, CA 95360, Tel: (209) 862-4074, Bill Lanning, Direct: (208) 896-5331, cell: (208) 880-0746, blanning@bioreduction.com. Peter Baker, Direct: (209) 862-4074, Cell (972) 877-6182, peter_baker@bioreduction.com.
Upcoming Technologies	Research is being conducted on a number of other technologies; it is anticipated these alternatives will be available shortly: • **Vacuum Steam.** A small scale vacuum steam process has demonstrated proof of principle and valuation trials are in process. • **Small Scale Steam.** Capacity for small handlers with a throughput of 1,000-1,500 pounds per hour. Proof of principle; industrial validation trials now underway. • **Radio Frequency.** Parameters to achieve 5-log reduction have been established. Commercial validation trials now underway. • **Two Moist Heat Processes.** Two moist heat applications are in the final stages of the TERP approval process.
Other Research	A number of new technologies are continuing to be evaluated. • **Infra Red.** Preliminary results show promise; further research is underway.

A number of industry processes have also been evaluated by TERP for their ability to provide a 4 or 5-log reduction in *Salmonella.* Following is a summary of these processes.

Pasteurization Process – Processed Almonds	*Process Description and Availabilility*
Hot Water (blanching)	Confirmed a greater than 5-log reduction. TERP concluded that pasteurization was achieved after a minimum of 2 minutes with a minimum water temperature of 190°F at the coldest point in the blancher. The FDA has determined that, when operating under specified parameters for 5-log reduction, blanched almonds may be labeled as "pasteurized".
Oil Heat (oil roasting)	Confirmed a greater than 5-log reduction. TERP concluded that pasteurization was achieved after a minimum of 2 minutes at a minimum oil temperature of 260°F at the coldest point in the oil roaster. The FDA has determined that, when operating under specified parameters for 5-log reduction, oil roasted almonds may be labeled as "pasteurized"
Other Thermal Processes (dry roast, wet or dry plasticizing)	Other thermal processes have shown limited effectiveness in achieving a 4-log reduction in *Salmonella* contamination. Dry roasting processes may achieve a 4-log reduction under certain parameters; however, this is equipment/process specific. A variety of thermal and non-thermal treatments are available to the industry which meet the pathogen-reduction criteria for almonds. Studies to date indicate that processes appropriate for raw almonds have not resulted in any significant or meaningful impact on raw almond characteristics (i.e., freshness, surface integrity, color, texture); a more comprehensive sensory and quality evaluation of pasteurized almonds is currently underway. Thermal treatments meet organic standards.

Almond Board of California
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What is the Role of a Process Authority?

As part of the Almond Board of California's (ABC) program to ensure the safety of almonds, ABC developed a program whereby processes designed to treat almonds to reduce potential levels of *Salmonella* must be validated or established by an ABC-approved Process Authority. The following provides information intended to clarify the concept of using process authorities for establishing processes.

For handlers and manufacturers, this means having a Process Authority **validate** that their processing procedures (e.g. oil roasting, blanching, etc.) meet existing parameters for achieving a 4-log reduction of *Salmonella* in almonds. For processing procedures which are new or "different" from existing parameters, the Process Authority **establishes** that the processing procedures are sufficient to achieve the 4-log reduction.

The United States Food and Drug Administration's (FDA) regulations for thermal processing in the food industry states that processes for these products must be established by "*competent Process Authorities.*" The regulation does not, however, define how one becomes a process authority, what classes or education he or she should take or how the FDA evaluates competence.

The ABC has adopted the following definition for a Process Authority:

> *"A person who has expert knowledge of processing requirements for almonds and has adequate facilities for making such determinations. The person shall also have the ability and knowledge to evaluate process deviations to determine whether there is a public health risk and make recommendations to destroy, re-process, or divert affected product to ensure that the public health is protected."*

According to the Marketing Order, the ABC must evaluate and approve Process Authorities who will validate or establish treatments for almonds. The application to become a Process Authority can be found on the ABC website. The application requests information for the following areas in which potential Process Authorities must demonstrate competence.

1. Knowledge about product characteristics and equipment used for the treatment process
2. Experience in conducting studies to determine the ability of equipment to deliver the appropriate treatment
3. Ability to determine, by evaluation of the acquired information, that sufficient data has been gathered to identify the critical factors needed to ensure the safety of the final product
4. Ability and expertise to ensure that the processor understands and adheres to the requirements of the process, as well as understands the defined critical factors and how to measure and control them.
5. Ability to evaluate potential deviations to determine whether the product involved represents a potential hazard to health and to make appropriate recommendations to ensure proper disposition (destruction, re-processing or release) of the product.
6. Experience in establishing or validating a process, preferably a process in the food industry.

It is essential that the ABC conducts a complete and thorough evaluation of all applicants. If an approved Process Authority validates or establishes procedures that are inadequate or inappropriate, this could pose a public health risk, and the entire industry may suffer.

Persons wishing to become Process Authorities must demonstrate to the satisfaction of the ABC that they have the ability, equipment and facilities to validate and establish processes.

June 18, 2007

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Almond Action Plan
Process Authorities

The Almond Board of California (ABC) has approved the following Process Authorities (PAs) for use by handlers, custom processors and Direct Verifiable (DV) Users for the purpose of pasteurization process and equipment validation. This list will be continuously updated as the status of PAs change and/or new PAs are approved. Should you have any questions regarding PAs, please direct them to ABC staff member Judy Scott-McKay: (209) 343-3235; jscottmckay@almondboard.com.

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NPSA Annual Meeting
Industry Forum
September 11, 2009

Ideas for Next Steps

I. Quality Programs

- A. Review and update current NSPA GMP's
- B. Create HACCP guidelines
- C. Regulatory compliance procedures – on members only site – FDA Rights and Obligations

II. Crisis Communication

- A. Encourage individual companies to create crisis plans
- B. Memo from NPSA to members in the event of a crisis
- C. Review (Patrick Archer) and redistribute crisis communications plan to members

III. Regulatory

- A. Pending regulations will change the rules of the road – for now, no mandatory HACCP regulations for pecans
- B. Develop coalition between NPSA and other tree nut associations
- C. Present a united front through the association coalition
- D. Traceability – back to the orchard – assess industry ability

IV. Pathogenic Research

- A. Risk assessment – inshell prevalence study?
- B. Communicate to Mexican shellers expectations
- C. Research on new technologies