## Good Manufacturing Practices (GMP's) For Almond Handlers

#### Introduction: Why we need GMP's

Food safety and product quality have always been top priorities for the California almond industry. The Almond Board's Quality Control Committee constantly examines safety and quality issues and makes recommendations to maintain and improve California almond quality.

All food products are coming under increasing scrutiny by government agencies and consumer groups. With the fast growth of the California almond industry comes the increasing possibility of contamination, whether by unintentional mixing of almonds with other nuts being processed on the same production line, or by the accidental exposure of almonds to microorganisms, foreign matter or pesticides. Remember, as an almond processor, you are also a food processor. The almonds you process are going to be used as an ingredient in other foods, or consumed as is.

By maintaining and documenting Good Manufacturing Practices, California almond processors can assure government regulators and customers worldwide that our industry is diligent in its commitment to offer safe, highquality nuts.

This guide is designed to help you examine and improve your own manufacturing practices and ensure that they meet the generally accepted standards of Good Manufacturing Practices. GMP's are the minimum sanitary and processing requirements necessary to ensure the production of wholesome food. GMP's are broadly written and are not intended to be plant specific, but instead, explain tasks that are part of many jobs within a facility. Finally, GMP's, along with GAP's and Sanitation Standard Operating Procedures (SSOP's), are pre-requisite activities to the development and writing of a Hazard Analysis and Critical Control Point (HACCP) plan unique and specific for each facility.

In several locations throughout these GMP's, forms are recommended for use. These forms are provided as samples only, and haven't been approved for use by state or federal regulatory agencies. You may use them as is, modify them to suit your needs, or create new ones as necessary. In all cases, forms and documents should be reviewed by technical and/or legal experts prior to use to ensure their adequacy in meeting requirements under state and/or federal regulations. In several of the following sections, "food" will be used and refers to almonds or almond products.

## **Risk reduction**

The GMP portion of the FQSP represents generally accepted, broad-based guidance, developed from current knowledge of food safety practices. The guide focuses on risk reduction, not risk elimination. Current technologies cannot eliminate all potential food safety hazards with product eaten in a raw form.

These GMP's provide broad, scientifically based principles. You should use the guide to help assess microbiological hazards within the context of the specific conditions (climatic, geographical, cultural, economic) that apply to your own operation, and implement appropriate and cost effective risk reduction strategies.

## **Company Organization Chart**

#### Who's responsible?

Regulatory officials and your customers want to know. An organizational chart spells out who is responsible for the various phases of your operation. Identify who is responsible to answer customer, consumer, or state and federal government regulator inquiries. Describe each individual's specific responsibilities relevant to each aspect of GMP's, e.g., pest control is the responsibility of the QA Manager, in a manner that is clear and easy to understand to avoid confusion when describing who is responsible for making decisions and for their consequences. The chart should include office, cell, and home phone numbers, pager numbers, and after hours emergency contact information.

Include a copy of your organization chart in this document.

In your company organization chart, delineate every position, from floor managers and plant employees to the company president and staff.

## **Minimizing Microbiological Hazards**

Microbiological contamination from s*almonella* or *E. coli*, for example, is a significant concern. Why?

- Testing is not always able to identify contamination.
- New strains of contamination can evolve.
- Almonds are often consumed raw, and therefore not subject to a microbiologically lethal process.
- Contaminants/pathogens on the ground may be transferred to almonds during harvest operations, and then to the processing facility.

In no case do the recommendations in this guide supercede applicable federal, state, or local laws or regulations for U.S. operators.

## Take a proactive approach

Growers and handlers are urged to take a proactive role in minimizing food safety hazards potentially associated with almonds. Being aware of and addressing common risk factors will result in a more effective, cohesive response to emerging concerns about the microbial safety of almonds.

The adoption of safe practices should be encouraged throughout the "farmto-table" food chain – including growers, huller/shellers, distributors, custom processors, exporters, importers, retailers, food service operators and consumers – to ensure that your individual efforts will be enhanced.

## **Basic Principles of Minimizing Microbiological Hazards**

**<u>Principle 1.</u>** Prevention of microbial contamination is favored over reliance on corrective actions once contamination has occurred.

**Principle 2.** To minimize microbial food safety hazards, growers, handlers, or shippers should use good agricultural and management practices.

**Principle 3.** Almonds can become microbiologically contaminated at any point along the farm-to-table food chain. The most common source of microbial contamination is associated with human or animal feces.

**<u>Principle 4.</u>** Water, which comes in contact with food products, may be a potential source of microbiological contamination.

**Principle 5.** Practices using animal and avian manure should be managed closely to minimize the potential for microbial contamination. Do not use either product unless it has been certified by its supplier to be free from contamination through composting or similar treatment, and chemical and microbiological test results accompany the shipment.

**Principle 6.** The use of municipal waste products or "biosolids" is not a recommended practice for almond growers.

**Principle 7.** Worker hygiene and sanitation practices during production, harvesting, sorting, packing, and transportation play a critical role in minimizing the potential for microbial contamination. Building structure, equipment design, and pest control are also critical elements.

**Principle 8.** Follow all applicable local, state, and Federal laws and regulations.

**Principle 9.** Accountability at all levels of agricultural processes is important to facilitate the ability to track almonds back through the distribution channels to the producer by use of a unique lot identification scheme.

Reference (A copy of this document will be found under "Regulations and Guidelines")

## FDA

• Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

## **Plant Schematic**

#### Show the scheme of things

You probably already have a plant schematic in your files. It is a vital reference document for customers, government regulators and anyone in your company involved in planning production changes or implementing GMP's. If any parts of the processing are subcontracted to another facility, those subcontracted operations should have GMP's of their own and should be included in any third party audit or certification activity. Schematics should be reviewed and updated each year prior to the beginning of the processing season.

A schematic can be a simple line drawing or an elaborate, mechanically drawn blueprint.

In addition to a simple schematic of your plant, make sure to create a drawing that shows product or "process" flow. The process flow schematic should briefly describe the most relevant features of each processing step: time, temperature, etc.

For handy reference, put copies of your plant schematics after this page.

## **Buildings and Facilities**

#### Plant construction and design

California state and federal regulations require that food processing plants and facilities shall:

- Have adequate space to store equipment and materials in a way that will maintain sanitary operations and the production of safe food.
- Be designed in a way that reduces the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. This is accomplished by using good food safety controls and by separating raw almond areas from processed areas from possible contamination sources by one or more of the following means: location, time, partition, air flow (from processed area towards raw area), enclosed systems, or other effective measures.
- Encourage proper precautions to protect almonds stored outdoors by any effective means, including:
  - Using protective coverings.
  - Controlling areas over and around the vessels to eliminate harborages for pests.
  - Checking on a regular basis for pests and pest infestation.
- Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and in good repair; that drip or condensation from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
- Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

- Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other airblowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces. Air coming into processed areas should be filtered to reduce the risk of finished product contamination.
- Provide, where necessary, adequate screening or other protection against pests. Building construction and maintenance must be designed to prevent pest entry.
- Maintain the plant exterior and grounds in a condition that will provide any visitor or inspector a good first impression of the facilities.

#### Restrooms

Employers are required by law to provide employees with adequate, readily accessible toilet facilities. To comply with regulatory requirements:

- Keep washbasins, toilets, urinals, walls, ceilings and floors clean and in good repair.
- Sanitize basins, toilets and urinals at least twice per shift using an effective bactericide. Empty wastebaskets and sanitary napkin holders frequently.
- Provide self-closing doors.
- Provide doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination, such as double doors or positive airflow systems.
- Provide adequate and convenient hand-washing facilities furnished with running water at a suitable temperature, soap, sanitary towels or hand dryers. Multiple use towels should not be used.
- Washroom fixtures, such as water control valves, should be of a type designed to protect against recontamination of clean, sanitized hands.
- Post easily understood signs directing employees to wash and, if appropriate, sanitize their hands before they begin work, before returning to work from a break and any time their hands may have become soiled or contaminated. Post these signs in restrooms, in the

processing rooms and anywhere employees may handle food or materials and surfaces involved in the production process.

- Hand sanitizing does not replace hand washing.
- Construct and maintain waste receptacles in ways that protect against food contamination.
- Store, convey and dispose of rubbish and processing waste so as to minimize odor and the potential for attracting flies and other pests.
- Protect against contamination of food, surfaces that come in contact with food, water supplies and ground surfaces.

## **References** (copies of these documents will be found under "Regulations and Guidelines")

## FDA

• 21 CFR 110.20(a)(1)-(4) (Grounds) and (b)(1)-(7) (Plant construction and design)

## California

- CDHS Code, Sections 111950-111960 and Sections 111970-112010 (Maintenance of facilities, construction, and design)
- CDHS code, Sections 112040-112050 (Inspection of buildings)

## **Pest Control**

All animals, including mammals, birds, reptiles, and insects, are potential sources of contamination in processing environments because they harbor, or could be a vector for, a variety of pathogenic agents, such as *Salmonella* or *E. coli*. A good pest control program is essential to good plant sanitation. In general, pest problems can be minimized by taking precautions such as:

## Establish a pest control system

• For all facilities, establish a pest control program to reduce the risk of contamination by rodents and other animals. The program should include regular and frequent monitoring of affected and treated areas to accurately assess the program's effectiveness.

## **Establish pest control procedures**

- All procedures should be written and all agrichemicals must be registered for use in food handling establishments.
- Pest control procedures should describe the location of any indoor or outdoor bait stations, glue boards, and insectocutors. Indoor bait traps should be placed every 10 to 15 feet and immediately on each side of doorways both inside and out. Outside bait traps should be placed every 20 to 20 feet. Document trap or bait station locations with a schematic map. Include information on when placed, when bait was replenished, and/or when the trap was last checked. Make sure all stations are numbered and types of trap(s) are described. Records of bait disappearance and catches must be kept for each bait station and trap. The insect control procedures must be described. If applicable, bird control and control of animals that wander into the facility should be described.
- Maintain a pest control log that includes dates of inspection, inspection report, and steps taken to eliminate any problems. Establish frequent monitoring of affected and treated areas to determine the effectiveness of the treatment applied.
- Maintain the grounds in good condition.
- Grounds in the immediate vicinity of all packing areas should be kept clear of waste, litter, and improperly stored garbage. Keep all grasses

cut to discourage the breeding, harboring, and feeding of pests, such as rodents and reptiles.

- Remove any unnecessary articles, including old and inoperative equipment that is no longer used, to eliminate areas that harbor rodents and insects.
- Clean and sanitize daily to remove product or product remnants that attract pests in and around the packing facility and any other packing location where product is handled or stored.
- Maintain adequate surface drainage to reduce breeding places for pests and food contamination by seepage.
- Operate water treatment and disposal systems so that they do not become a source of contamination. If grounds not under your control border the plant, protect your facility by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

## Monitor and maintain facilities regularly

- Regularly inspect all facilities to check for evidence of pest populations or animal contamination. Minimize the availability of food and water to pests.
- Remove dead or trapped birds, insects, rodents, and other pests promptly to ensure clean and sanitary facilities and to avoid attracting additional pests.
- Ensure that potential nesting or hiding places for pests have been eliminated.
- Clean surfaces soiled by birds or other wildlife.
- If the plant was fogged with insecticide, clean, sanitize and inspect all equipment afterwards to insure removal of all dead insects.
- Follow all applicable label directions, including proper disposal of empty containers.

- Block access of pests into enclosed facilities
- Exclude pests by blocking areas, such as holes in walls, doors, flooring, and vents that allow entrance into the facility. Use screens, wind curtains, and traps.

## **References** (a copy of this document will be found under "Regulations and Guidelines")

## FDA

• 21 CFR 110.35(c) (Pest control)

## **Chemical Control**

#### Key to safety: lock it up

Most plants use a number of chemicals that require proper handling and storage.

- Store pesticides and pesticide equipment separately from oils and products used in food processing.
- Label all pesticides, rodenticides, and cleaning chemicals accurately.
- Store cleaning chemicals where only employees who regularly use them can gain access.
- Lock up rodent eradication chemicals.
- Establish procedures and documentation for chemical use to avoid over usage or misapplication.
- Develop a training program and identify those employees with authorization to apply chemicals.

#### Know who can use it

Managers need to know which employees are hazardous materials and be sure that they are properly trained in how to use them. Have each employee sign a certificate after he or she has been properly trained. Maintain records of employee training and authorization as appropriate in their employee file. Sample forms to document employee training follow this section.

## **Worker Training Documentation**

#### **Date:**

Topics Discussed:	
Trainer(s):	Affiliation:

#### Attended by:

Attendees	Signature of Attendee

This form is only a sample and should be modified to meet the needs of your particular operation.

## **Employee Training Documentation**

Employee: \_\_\_\_\_ Position: \_\_\_\_\_

Hire Date: \_\_\_\_\_

Date of Training	Topic of Discussion

This form is only a sample and should be modified to meet the needs of your particular operation.

## Acknowledgement of Pesticide Safety Training

**Employee's Last Name** 

First Name

Middle Initial

It is the responsibility of the employee to make sure he/she understands the items discussed herein regarding pesticide safety. Your signature indicates that you have read, understand, and agree to it. Applicators will be held personally responsible for violations of pesticide labeling. If there is something you do not understand, ask your trainer.

List the training methods and materials used to train employees in the safe handling of pesticides. One copy must be kept in the employer's files (study guides, slides, videotapes, etc.).

The Pesticide Safety Series is always available to employees and is posted at:

## (List specific location[s] – to be filled out by employer)

Product Label	Date	Employee Signature

Trainer's Signature

Employer's Signature

This form is only a sample and should be modified by the appropriate technical experts and legal advisors to meet the needs of your particular operation.

## **Employee Training**

Employee training in good handling practices, which covers the key areas of sanitation and worker hygiene, is critical to achieving the goals of the Almond Board of California FQSP. Establishing a written training program for employees that addresses general sanitation and good hygiene practices will help reduce the risk of microbiological contamination. All training programs should be evaluated routinely and updated as necessary. Documentation of employee training is also necessary to verify that federal, state and local requirements for worker safety training are met.

An integral part of employee training is education on all aspects of these GMP's. All training should be documented with refresher training provided periodically. It may be necessary to have bilingual training classes depending on the composition of your workforce. Use the form -1 at the end of this section to document the subject material covered during training classes and attendees.

Past outbreaks of food borne illness associated with raw and minimally processed product have usually been the result of product becoming contaminated with fecal material. Place a high priority on ensuring the use of good agricultural and management practices that minimize the potential for direct or indirect contact between fecal material and raw almonds.

It is important to ensure that all personnel, including those indirectly involved in almond operations such as equipment operators, potential buyers and pest control operators, comply with established hygienic practices. Personnel responsible for ensuring the sanitation of the plant should be experienced with sanitation practices or have educational background to support their work.

## Establish a training program

- All employees, including supervisors, full-time, part-time and seasonal personnel should have a good working knowledge of basic sanitation and hygiene principles. The level of understanding needed will vary as determined by the type of operation, the task, and the assigned responsibilities.
- Handlers should develop a sanitation training program for their employees. Depending on the situation, formal presentations, one-on-

one instruction, or demonstrations may be appropriate. Depending on the workers' job requirements, periodic refresher or follow-up training sessions may be needed.

• If a formalized training program is not practical, such as for part-time and/or seasonal personnel, the handler or the supervisor should verbally instruct and demonstrate to newly hired workers proper health and hygiene practices.

## Become familiar with typical signs and symptoms of infectious diseases

- The pathogens *Salmonella*, *Shigella* species, *E. coli* O157:H7, listeria, *Endamoeba histolytica*, and hepatitis A virus have a high infectivity (the ability to invade and multiply in the body) and virulence (the ability to produce severe disease). Any worker showing symptoms of an active case of illness that may be caused by any of these pathogens must be excluded from work assignments that involve direct or indirect contact with almonds. Workers with diarrheal disease, colds, flu and/or symptoms of other infectious diseases should not work with almonds or the sorting and packing equipment in the packing facility.
- Supervisors should be familiar with the symptoms of infectious diseases so that if symptoms are evident, the supervisor can take appropriate steps.

## Provide protection from a lesion

• A lesion, such as a boil or infected wound that is open or draining and that is located on exposed parts of the body, presents an increased risk of contamination. If a worker has a lesion that cannot be effectively covered in such a way to prevent contact with raw almonds or related equipment, the employee should not be working in any aspect with raw almonds, utensils, or other food contact surfaces of equipment.

## Consider alternative good hygienic practices

• Single-service disposable gloves are an important and effective hygienic practice on sorting tables in combination with hand washing. If gloves are used, be sure they are used properly and do not become another vehicle for spreading pathogens. The use of gloves in no way lessens the need or importance of hand washing and proper hygienic practices.

## Ensure visitors to the facility follow good hygienic practices whenever they come into contact with <u>any</u> almonds

• Require almond inspectors, buyers, and other visitors to comply with established hygienic practices when inspecting facilities or product.

## Training principles: the importance of good hygiene

• All personnel should understand the impact of poor personal cleanliness and unsanitary practices on food safety. Good hygiene not only protects the worker from illness, but it reduces the potential for contaminating raw almonds, which, if consumed by the public, could cause a large number of illnesses.

#### The importance of proper hand washing techniques

Thorough hand washing before commencing work with almonds and after using the toilet is very important. Employees must wash their hands before working with raw almonds. Any employees having contact with food should also wash their hands before returning to their workstation. Many of the diseases that are transmissible through food may be harbored in the employee's intestinal tract and shed in the feces. Contaminated hands can also transmit infectious diseases. Don't assume that workers know how to wash their hands properly. Proper hand washing before and after the workday, using the bathroom, and eating, drinking, or smoking is a simple six-step process:

- 1. Wet hands with clean water
- 2. Apply soap (preferably anti-bacterial)
- 3. Scrub hands and fingernails (for 20 seconds)
- 4. Rinse off soap thoroughly with clean water
- **5.** Dry hands with single-use towels
- 6. Discard used towels in trash

#### General recommendations

- All food must remain in a break room. Coats, purses, etc., must not be in the production area. Personnel should not wear tank tops.
- Smoking is only permitted in designated areas that are not in the production area of the plant.
- All personnel must have adequate head and hair cover. Beards must be covered. Mustaches, unless well trimmed, should also be covered.

• Personnel working in the hulling/shelling area of the plant should not enter other areas of the plant. The movement of these workers into processed product areas could possibly contaminate equipment and product with extraneous matter or pathogens. Forklifts and other equipment used in the hulling/shelling area should also not move into processed product areas due to the risk of contaminating finished product.

## **Identify at-risk employees**

A wide range of communicable disease and infections may be transmitted by infected employees to consumers through food or food utensils. An important part of an on-going program to ensure the safety of raw almonds is to institute a system where workers can report any GI illnesses and be reassigned to non-food contact responsibilities until the condition is remedied without fear of reprisal or loss of work hours.

# **References (copies of these documents will be found under "Regulations and Guidelines")**

## FDA

• 21 CFR 110.10(a)-(d) (Personnel)

## OSHA

• 29 CFR 1910.141(g) (Food and beverage consumption on premises)

## **Workers Training Documentation**

Date: \_\_\_\_\_ Topics Discussed:\_\_\_\_\_\_ Trainer(s): \_\_\_\_\_\_ Affiliation: \_\_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_

\_\_\_\_\_

Attendees	Signature of Attendee

This form is only a sample and should be modified to meet the needs of your particular operation.

## **Plant Employees**

#### **GENERAL RULES:**

- 1. Employees must wear clean outer garments that are washable. Shoes must be in good repair and of leather construction. No open toes.
- 2. All employees must wash hands with soap and warm water and sanitize their hands prior to handling almonds, after using restrooms, returning to their work station from break or lunch, or at any other time when their hands may have become soiled.
- **3.** All employees are to wear effective hair restraints including hairnets, beard and mustache covers where applicable.
- 4. All jewelry, including watches, must be removed when entering the plant.
- 5. Shirt pockets are to be emptied and cleared of pencils, etc., when in the plant.
- 6. No glass or food items of any kind are permitted in the plant processing areas. Food may only be consumed in the lunchroom or outside the building.
- 7. No employee infected with any infectious or communicable disease, including boils, sores, infected wounds or any other affliction that may spread disease, may be in contact with almonds.
- 8. Candy, chewing gum, lozenges, etc. are not allowed in the plant.
- 9. Tobacco is not permitted in the plant. Smoking areas are designated.
- 10. Extra clothing must be stored in lockers or some other acceptable facility.

All employees are expected to comply with the Good Manufacturing Practices required by the US FDA and USDA.

Employee:	
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Date: \_\_\_\_\_

## **Rules for Plant Visitors**

<u>Identification:</u> I.D. is required of any person who wishes to conduct an inspection of the plant.

<u>Inspections:</u> Customer inspections are a regular practice for food processing plants and will occur at any time. OSHA inspections may result from employee complaint, complaint against an outside contractor or a random computer scheduling.

<u>Notification of Inspection</u>: The appropriate company staff must be notified before an inspection can begin. Staff will notify all other company officials and staff members involved with the operation.

<u>Admission of Inspectors:</u> An inspector may not be admitted into the plant without the permission of the company president or his appointed alternate. All inspectors must comply with all company rules and regulations.

<u>Conference</u>: All inspections are preceded by an opening conference chaired by the company president or his appointed alternate to determine the focus and purpose of the inspection.

<u>OSHA Log and Injury Records</u>: The inspector will request a review of the OSHA logs for the past several years and will review the employee injuries and illnesses listed on the logs.

<u>Programs and Procedures:</u> The inspector may inquire about the existence of certain programs or procedures, i.e., quality control or quality assurance, preventative maintenance, housekeeping, hazardous materials, etc. If copies of programs are given to the inspector, it is important that a note be made of the program taken by the inspector.

<u>Inspections:</u> Except for complaint inspections, inspectors may observe any area they choose during the walk-around portion of the inspection. During an OSHA or government inspection, do not walk through the processing area of the plant. Go directly to the requested area of concern.

<u>Photography:</u> Videotaping and photography must be approved by management and are not allowed unless permission is granted.

<u>Samples:</u> If the inspectors take samples during the inspection, duplicate samples must be requested by staff and sent immediately to a laboratory to be tested for the organism or chemical of concern.

<u>Equipment:</u> Never open any doors or covers to any operating equipment in an effort to explain a process to an inspector.

<u>Observations by the Inspector:</u> Staff and management will note any potential hazards that the inspectors point out. The hazard must be corrected before the inspector leaves the premises if at all possible. The sooner the correction, the more favorable the impression. Inspectors appreciate quick correction and immediate action. They will not ask for immediate correction, but they do expect it.

## **Plant Visitors Agreement**

GENERAL RULES: All visitors must agree to abide by all FDA, state and local regulations governing the operation of this facility.

- 1. Visitors must wear clean outer garments that are washable. Shoes must be in good repair and of leather construction. No open toes.
- 2. All visitors must wash hands with soap and warm water and sanitize their hands prior to handling almonds.
- **3.** All visitors are to wear effective hair restraints including hairnets, beard and mustache covers where applicable.
- 4. All jewelry, including watches, must be removed when entering the plant.
- 5. Shirt pockets are to be emptied and cleared of pencils, etc., when in the plant.
- 6. No glass or food items of any kind are permitted in the plant processing areas. Food may only be consumed in the lunchroom or outside the building.
- 7. No visitors infected with any infectious or communicable disease, including boils, sore, infected wounds or any other affliction, which may spread disease, may be in contact with almonds.
- 8. Candy, chewing gum, lozenges, etc. are not allowed in the plant.
- 9. Tobacco is not permitted in the plant. Smoking areas are designated.
- **10.** Extra clothing must be left in the office and not taken into the plant.

All visitors are expected to comply with the Good Manufacturing Practices required by the US FDA and USDA.

Visitor: \_\_\_\_\_ Date: \_\_\_\_\_

## **Employee Hygiene**

## **Restroom basics**

Employers are required by law to provide employees with adequate, readily accessible toilet facilities. To comply with regulatory requirements:

- Keep washbasins, toilets, urinals, walls, ceilings and floors clean and in good repair.
- Sanitize basins, toilets and urinals at least twice per shift using an effective bactericide. Empty wastebaskets and sanitary napkin holders frequently.
- Provide self-closing doors.
- Provide doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination, such as double doors or positive airflow systems.
- Provide adequate and convenient hand-washing facilities furnished with running water at a suitable temperature, soap, sanitary towels or hand dryers. Multiple use towels should not be used.
- Washroom fixtures, such as water control valves, should be of a type designed to protect against recontamination of clean, sanitized hands. All wash stations should have foot control valves to the faucet.
- Post easily understood signs directing employees to wash and, if appropriate, sanitize their hands before they begin work, before returning to work from a break and any time their hands may have become soiled or contaminated. Post these signs in restrooms, in the processing rooms and anywhere employees may handle food or materials and surfaces involved in the production process.
- Construct and maintain waste receptacles in ways that protect against food contamination.
- Store, convey and dispose of rubbish and processing waste so as to minimize odor and the potential for attracting flies and other pests.
- Protect against contamination of food, surfaces that come in contact with food, water supplies and ground surfaces.

The importance of food workers understanding and practicing proper hygiene cannot be overemphasized. Workers can unintentionally contaminate raw product, water supplies, and other workers, and transmit food borne illness if they do not understand and follow basic hygienic principles. Employees with infectious diseases, accompanied by diarrhea or open lesions that include boils, sores, or infected wounds, are a source of disease-causing microorganisms.

Be aware of and follow applicable standards for protecting worker health established under the Occupational Safety and Health Act (OSHA). In addition, the U.S. Code of Federal Regulations prescribes worker health and hygienic practices within the context of GMP's in the manufacturing, packing, or handling of human food. Appropriate standards should be considered when establishing hygienic practices appropriate for the agricultural environment.

# **References** (copies of these documents will be found under "Regulations and Guidelines")

FDA

- 21 CFR 110.37(d)(1)-(4) (Toilet facilities)
- 21 CFR 110.37(e)(1)-(6) (Hand-washing facilities)

## OSHA

• 29 CFR 1910.141(c)-(f) (Toilet, washing and clothes drying facilities, changing rooms)

## California

- CDHS Code, Section 112015 (Hand washing)
- CDHS Code, Sections 112020-112035 (Overall "non-permitted" employee behavior with respect to sanitation).

## Water Quality

## Water control counts with employees and customers

Water used in food processing is required to be safe and sanitary. This means that it must meet potable water standards for microbiological activity. If using an on-site well, a water sampling schedule must be in place with sampling results documented showing that the water is suitable for its intended purpose. Well and municipal water samples should be collected at the point of use to ensure that there has not been contamination within the facility's water delivery system. Only potable water should be used in production areas. Health officials also require proof in the form of a certificate of potability.

Plant water supplies should be tested at least once a year for pesticides, heavy metals and microbiology. If you use well water, the Central Valley is home to several good water laboratories that can help with the testing and certification process.

If municipal water is used, the microbiological quality should be checked to ensure it has not been re-contaminated by leaking pipes, dead-ends or cross connections with waste lines. City water supplies are tested frequently and you should obtain certification papers from City Hall to show regulators.

#### Water can clean – or contaminate

Water of inadequate quality has the potential to be a direct source of contamination and a vehicle for spreading localized contamination in the field, facility, or transportation environments. If water comes in contact with raw almonds, its quality dictates the potential for pathogen contamination. If pathogens survive on the almonds, they may cause food borne illness.

Water can be a carrier of many microorganisms including pathogenic strains of *Escherichia coli*, *Salmonella* spp., *Vibrio cholerae*, *Shigella* spp., *Cryptosporidium parvum*, *Giardia lamblia*, *Cyclospora cayetanensis*, *Toxiplasma gondii*, and the Norwalk and hepatitis A viruses. Even small amounts of contamination with some of these organisms can result in food borne illness.

You should consider the following issues and practices when assessing water quality and in applying controls to minimize microbial food safety hazards. Not all of the following recommendations will be applicable or necessary for all operations. Rather, you should select practices or combinations of practices appropriate to your operation and the quality of your water supply to achieve food safety goals.

- Perform periodic water sampling and microbial testing.
- Document your source of water and the results of random sampling.
- Change water as necessary to maintain sanitary conditions. Develop water change schedules for all processes that use water.
- Clean and sanitize water contact surfaces, such as blanchers, as often as necessary to ensure the safety of the almonds.
- Routinely inspect and maintain equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, to ensure efficient operation.
- Make sure there are no cross-connections between potable and nonpotable water supplies. All hoses, taps, or similar sources of possible contamination should be designed to prevent back-flow or siphonage of standing water.

## **Processing Water**

Processing water should be of such quality that it does not contaminate your product. Follow good manufacturing practices to minimize microbial contamination from processing water.

Water quality consistent with U.S. EPA requirements for drinking water or similar standards is recommended. If the plant has its own water source, it must comply with EPA regulations and the chlorination levels must be monitored and recorded. (See Resources for information on obtaining copies of EPA rules and regulations).

## **References** (copies of these documents will be found under 'Regulations and Guidelines'')

## FDA

- 21 CFR 110.37(a)-(b) (Sanitary facilities and controls)
- 21 CFR 110.80(a)(1) (Processes and controls)
- 21 CFR 110.35(d) (Sanitary operations)

## OSHA

• 29 CFR 1910.141(b) (Water supply)

## **Transportation of Raw Materials**

#### Repair or discard damaged bins

Inspect bins for damage on a regular basis. Because damaged container surfaces may harbor pathogenic microorganisms and cause damage to almonds, they should not be used.

#### Clean bins before using to transport raw almonds

Set aside an area in the receiving yard to clean bins. Containers used for ready-to-eat almonds should be cleaned and sanitized before use.

## Protect unused, cleaned and new packing containers from contamination when in storage

Packing containers and other packing materials that are not used right away should be stored in a way that protects them from contamination by pests (such as rodents), dirt, and water condensing from overhead equipment and structures. If packing containers are stored outside the packing facility, they should be cleaned and sanitized before use.

## Remove as much dirt and mud as practical from almonds outside of packing facilities or packing areas.

Take additional care to protect raw almonds from possible contamination because of possible exposure to manure and animal fecal material in the soil. Operators of open packing facilities should also be aware of potential contamination from airborne contaminants from any nearby livestock or poultry areas or manure storage or treatment facilities.

## **Carrier Inspection**

#### Do you know what that truck's been hauling?

Products previously shipped by your carrier can contaminate almonds. To reduce the possibility of contamination, inspect all carrier vehicles before you load your almonds.

Visually inspect trailers before loading, checking for:

- Signs of insect infestation
- Moisture
- Chemical residues
- Foreign material such as glass, metal, debris
- Unusual odors
- Evidence of other nutmeats

Document inspection procedures and practices for harvest trailers. Maintain written procedures for inspecting the sanitation conditions of trailer/cargo containers.

Scrutinize product transportation at each level in the system, including transportation from the field to the plant and on through the channels of distribution. The proper transportation of almonds helps reduce the potential for microbial contamination. An active and ongoing discussion with personnel responsible for transportation is essential for ensuring the success of any management program designed to deliver safe foods to the consumer.

Microbial cross-contamination from other foods and non-food sources and contaminated surfaces may occur during loading, unloading, storage, and transportation operations. Wherever produce is transported and handled, the sanitation conditions should be evaluated. Trailers used to transport chemicals or waste products should not be used for shipment of food products. Use the Carrier Inspection Form adapted to your own situation. If you're not already doing this procedure, your carrier may object at first. Better to reject a carrier vehicle until it's been sanitized than to have your product rejected because of contamination.

# **Reference** (A copy of this document can be found under "Regulations and Guidelines")

## FDA

• Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section VIII, "Transportation"

## **Carrier Inspection Form**

#### **CARRIER CONDITION:**

Floor:	Tight	Cracks	With holes		
Sides:	Smooth	Cracks	Broken		
Roof:	Smooth	Cracks	Holes		
Doors:	Excellent	Fair	Poor		
Door seals:	Excellent	Fair	Poor		
CARRIER CLEANLINESS					
Floor:	Clean	Needs Sweeping	Filthy		
Walls:	Clean	Dusty	Filthy		
Roof:	Clean	Dusty	Filthy		
Odors:	None	Off-odors	Putrid		
Insects:	None	Evidence	Live		
Rodents:	None	Evidence	Live		
Chemicals:	None	Evidence	Powders		
Other:	None	Evidence	Glass, etc		
COMMENTS:					

ACCEPT: \_\_\_\_\_ REJECT: \_\_\_\_\_REASON: \_\_\_\_\_

INSPECTOR: \_\_\_\_\_ DATE: \_\_\_\_\_

## **Positive Lot Identification**

A key element of a traceback program is positive lot identification. In the event of a foodborne illness associated with your product, the ability to quickly trace the product through your plant to the huller/sheller and back to the delivering grower will minimize the impact to your operation in terms of downtime, product recall/retrieval costs, and negative public opinion.

Adequate coding and distribution records are critical. Lack of a coding system and accurate records could lead to a total product recall with notification to all customers.

#### Lot numbering counts

For this reason, every load of almonds that comes into your plant should be assigned a unique lot number for control purposes. Your number should tie back to the lot number assigned by your grower for that lot. Your lot number identifies the product to everyone who will be associated with it, and is a major component should a recall be necessary. It should remain with the lot through all processing steps, grading, chemical and microbiological testing, storage and shipping.

## Julian code dating

Lot codes use Julian dating. For instance, the lot code "1030" indicates the  $30^{\text{th}}$  day of the year 2001. The year is the first number (1). The "030" is the number of days since Jan. 1. The Julian date may also be written "0301," with "030" as the number of days since the beginning of the calendar year and "1" as the year. This varies from handler to handler.

Be consistent in your lot numbering so there is no confusion. If you begin with a lot code using the year first and then the number of days since January 1, don't switch in mid-year to placing the number of days first and then the year.

Lot codes should at minimum be traceable to grower, production line, and production date and time. This code should be listed on the shipping invoice and plant records. Computer records of lots sent with shipments will make recall easier and product tracing significantly faster.

## **Grower Certification**

## Work with growers who implement their own on-farm food quality and safety program and Good Agricultural Practices (GAP's)

It's much easier and safer to carry out a FQSP when growers implement GAP's. Growers who utilize safe agricultural and handling practices will minimize the potential for microbiological contamination.

You can verify your grower's quality and GAP program through written documentation and on-site inspection.

- Check with the grower to see if he or she has GAP's in place.
- Maintain a copy of the grower's GAP's.
- Conduct on-site inspections to verify that growers are utilizing GAP's. You can have your own GMP manager do the inspection or hire a third party.
- Have each grower sign a Grower Agreement. You will find a sample agreement at the end of this section. This agreement should spell out any requirements or exclusions for the almonds the grower will deliver to you. An example would be that the grower agrees or certifies that no raw manure was used in the production of the contracted almonds. The agreement should also include keeping poultry and farm animals out of the orchard.

# **References** (A copy of this document will be found under "Regulations and Guidelines")

FDA

• 21 CFR 110.80(a)(2)-(4) (Raw materials)

## **Grower Agreement**

## **Purpose:**

The purpose of this agreement is to ensure that the almonds being produced and handled meet the guidelines of the voluntary Almond Board of California Food Quality and Safety Program (FQSP). The FQSP is a comprehensive program of voluntary guidelines for almond production and handling which enhances the safety and quality of the almonds shipped to markets. The program developed by the Almond Board of California uses "Good Agricultural Practices" for growers and "Good Manufacturing Practices" for handlers as its basis for minimizing the risks of microbiological contamination.

## **Agreement:**

I, \_\_\_\_\_, have received a copy of

the Almond Board of California's Good Agricultural Practices manual, and agree to use all reasonable efforts to comply with the guidelines provided in the ABC Food Quality and Safety Program when growing almonds for delivery to

(Name of Handler)

(Grower Signature)

(Date)

This form is only a sample and should be modified by the appropriate technical experts and legal advisors to meet the needs of your particular operation.

## Fumigation

#### Maintain accurate records

- Abide by all federal, state and local regulations to keep your workplace safe and your product in compliance.
- Fumigate all almonds coming into your plant to kill field pests and prepare the product for shelling.
- Document each treatment.
- Ensure workers have been properly trained and certified.
- Record the dates of fumigation on tags attached to the product container.
- Follow all applicable label directions.
- Keep the Material Safety Data Sheet (MSDS) for each pesticide on file.

The USDA requires food processors to document each fumigation treatment in a logbook for examination by USDA officials.

## **Fumigation Control Form**

Date	Lot	Number of Cases	Fumigant Identification Number	Chamber Size and Number	Time Held/Aeration	Remarks & Supervisor Sign-off

## **Foreign Material**

#### Make your plant a glass-free zone

GMP's recommend that except for eyewear, glass should not be allowed in almond processing plants.

- Coat lights with plastic or enclose them in plastic shields to prevent the possibility of glass shards falling into almonds being processed.
- Coat windows, clock facings, forklift lights and all other glass inside the plant with plastic to prevent the possibility of glass shards falling into almonds being processed.
- Limit employee beverages and bottles to break rooms or areas away from almond handling areas.

#### Metal Detectors hunt for buried trouble

Metal fragments in almond products can come from any number of sources, such as the trailer that brought the load to your plant, or worn-out pieces of processing equipment on your production line. Growers have been known to use pellet guns or shotguns to get rid of birds and other pests, and the pellets can also become embedded in the almonds.

Employees should remove any pens from pockets, exposed key rings, rings (except plain wedding bands), hair clips, earrings, necklaces, any items in pockets or pinned on the clothes above the waist, watches, etc. prior to entering the processing floor.

Use a quality metal detector that can locate both ferrous and non-ferrous material. Test the equipment regularly and keep accurate records showing when those tests were completed.

Incorporate magnetic devices that will pull ferrous metals out of the product prior to final packing, perhaps at several points along the line.

## References (copies of these documents will be found under "Regulations and Guidelines")

FDA

- 21 CFR 110.20(b)(5) (Lighting)
- 21 CFR 110.80(b)(8) (Extraneous material in food)

## **Magnet Check Form**

Date	Time	Findings Yes/No	Foreign Material	Inspector Initials	Remarks

## **Metal Documentation Form**

Date	Lot	Metal Review	Product Disposition	Supervisor Notification if Found	Remarks & Supervisor Sign-off
<u> </u>					

## **Glass Documentation Form**

Date	Lot	Glass Review	Product Disposition	Supervisor Notification if Found	Remarks & Supervisor Sign-off

## **Lethal Processes**

#### What are lethal processes?

In the context of this document, lethal processes refer to a step or process of steps that "kill" bacteria that may be present on almonds. A lethal step is recommended for all raw, natural almonds that will be consumed directly as such. In the absence of a lethal process, receive from your customers a letter certifying that all bulk, whole natural almonds will be further processed and not sold to consumers in a raw form.

The Almond Board is currently conducting validation research on the feasibility of a number of lethal processes to demonstrate their ability to deliver at minimum the lethality needed to control identified pathogens. Alternatives identified to date are propylene oxide (PPO), ultraviolet light or infrared heat, steam, ozone, or "plasticizers". Before using any of these processes, check with your customer and applicable laws in the intended destination market.

One process that is currently in use in the industry is treatment with PPO. PPO appears to be an effective sterilant for reducing microorganisms on tree nuts. Consult with an expert to determine if PPO treatment is appropriate for you. If treated, be sure to receive a letter of certification that records time, temperature, vacuum inches of mercury, dosage rate, lot number and total cases of product processed.

# **References (A copy of this document will be found under "Regulations and Guidelines")**

- FDA
  - 21 CFR 110.80(a)(2) and (b)(4)(Control of microorganisms)

Keep records of lethal processes with all your other records for each lot number. Include copies of all your blank lethal process documents following this page.

## **Allergen Control**

#### Why an allergen program?

Tree nuts are among the 8 most allergenic foods responsible for 90% of food allergies. While afflicting a small percentage of the overall population, food allergies, particularly to peanuts and tree nuts, can be severe.

Even if a person is not allergic to almonds, he or she may be allergic to other types of nuts. Therefore, it's very important for handlers to ensure that no other nuts – even in tiny amounts – are processed with or come in contact with almonds. The Almond Board recommends that other nuts NOT be processed in the almond plant, particularly if using almond processing equipment.

#### **Cleaning reduces the possibility of cross-contamination**

However, if your business requires processing nuts other than almonds, you need an allergen prevention program. This is especially true if more than one type of nut is processed on the same line, because the potential for cross-contamination increases substantially.

A documented cleaning program is a must in order to eliminate even the tiniest residue of other nut products. Every time a product other than almonds is processed at your plant, be sure ALL line equipment is completely cleaned before the next production run. Products are frequently recalled because of mislabeling, and this may become even more common as researchers develop new methods for detecting cross-contamination.

## **Reference** (Copies of these documents will be found under "Regulations and Guidelines")

- Food Allergy Issues Alliance: Food Allergen Labeling Guidelines
- NFPA: Code of Practice on Managing Food Allergens

FDA

- Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens
- Guide to Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients

## **Allergen Inspection Form**

			Clean/Not			
Date	Time	Equipment	Clean	Inspector	Supervisor	Remarks

## **Product Hold and Release**

#### Know when to hold them

A product hold and release program should be established to ensure that no product is released until all the necessary chemical, physical, grade and microbiological analyses have been completed and customer specifications have been met.

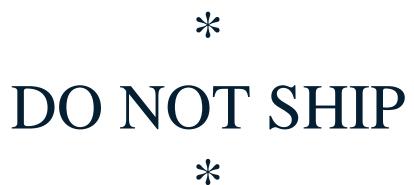
All "HOLDS" should be coordinated through the Quality Control Department. Each department should to notify Quality Control personnel of any "HOLD" and secure the hold tags for the product. Holds should be clearly labeled, e.g., with a red "HOLD" tag, such as the one following this section, on the containers or pallets.

All products coming into the plant should be automatically placed on hold until tests have been completed and the central QC authority has determined the products are within specification. Products that don't meet standards should remain on hold until it is proven that they are in compliance with specifications.

Any product in process and any finished product determined to be out of specification should be held for further evaluation. Finished product should be logged in and controlled by the lot number or by a control number stamped on each case or pallet of almonds.

- Hold notices are completed with all necessary information. The Hold notice is issued to all departments involved.
- The hold product will be placarded with a completely filled-out hold tag and the lot number will be recorded.
- Product pallets will be removed to the hold area for further disposition.
- Disposition of the product will be determined by the Director of Technical Services or the Quality Control Manager.
- HOLD tags may only be removed by Quality Control personnel.
- All HOLD tags must be accounted for by Quality Control.

HOLD NUMBER \_\_\_\_\_



ISSUED BY: \_\_\_\_\_ DATE: \_\_\_\_\_

LOT NUMBER: \_\_\_\_\_

IMPORTANT: HOLD TAG SHOULD BE PRINTED ON RED CARD STOCK

## **Grading and Inspection**

#### Graded and certified

Almonds are graded and certified by either the USDA or the Dried Fruit Association (DFA). Inspection and grading of incoming almonds is mandatory. Grading of almonds leaving your plant is an individual issue between you and your customer.

In order to receive a USDA certification, final product ready for shipment must comply with established USDA standards. The final product must also comply with the standards if there are claims on invoices, product labels or advertising as to the grade of the final product.

## **References** (copies of these documents will be found under 'Regulations and Guidelines")

#### FDA

• 21 CFR 110.80(a)(1) (Raw materials inspection)

#### USDA

- US Standards for Grades of Shelled Almonds, reprinted 3/24/97
- US Standards for Grades of Almonds in the Shell, reprinted 3/24/97

Insert your plant's grading and inspection forms after this page for review by customers and government agencies.

## **Net Weight Control**

#### Avoid net weight loss – and net weight gain

Labels must accurately reveal the quantity of food in the container exclusive of wrappers or packaging. Reasonable variation in quantity is recognized but cannot be unreasonably large. Customers as well as government regulators frown on short weights. And long weights mean you're losing money. A good GMP program includes a well-managed net weight control plan. A sample form to record weight control is included after this section.

Institute a program of random sampling to ensure <u>labeled</u> net weight reflects <u>actual</u> net weight.

## **References** (A copy of this document will be found under "Regulations and Guidelines")

FDA

• 21 CFR 101.105(g) (accurate quantity), and 21 CFR 101.105 (q) (quantity variation)

## **Control Chart for Weights**

Date	
<b>Product</b>	
Location	

Shift	
Inspector	
Time of Sample	

				Corrective	
	Indicated	Actual		Action	Supervisor
Lot ID #	Weight	Weight	Variance	Taken	Acknowledgement
		<u> </u>			

## **Product Recall**

#### **Recalls** – mock and real

No handler wants to face a product recall. However, having a product recall program in place is invaluable when a given lot is found to be in violation of regulatory requirements. It also demonstrates to regulatory officials that if necessary, you can recall any given lot number from its destination. In fact, mock recalls are part of sound GMP's.

To begin, appoint a Recall Coordinator and team. Use a recall team contact list to identify the recall team. The recall team should include at minimum a coordinator, a designated spokesperson, and representatives from marketing, distribution, technical, and production departments. Give the coordinator the authority to notify each customer who has received almonds that must be called back. Sample recall documents follow this section.

Conduct a mock recall to determine if you are able to produce accurate information on a timely basis verifying that all effected product can be rapidly identified and removed from the marketplace. Mock recalls are important as they:

- Test the overall effectiveness of your recall plan
- Assess supplier/customer recall programs
- Evaluate the reliability and accuracy of traceback systems
- Evaluate response time
- Assess the accuracy of record keeping systems
- Identify opportunities for program improvement

#### Implementing the recall

- 1. The recall coordinator first determines the lot, day codes and total number of cases involved. All products are tracked by lot number, and that number should be shown on all documents from production to shipping.
- 2. Find out where every case has been shipped. The lot number will reveal every customer who received the almonds in question.
- 3. Notify each of those customers that they must return the product to your plant.

- 4. As the product arrives back at your plant, account for every case and store it safely, clearly marked "HOLD", in a holding location away from other almonds.
- 5. Talk with the appropriate regulatory agency to decide how or whether to dispose of the affected almonds.
- 6. Almonds can then be reworked, sterilized or destroyed, depending on the agreement reached with the regulatory agency.
- 7. If the product is still usable, it must be retested and re-evaluated before shipping. It is highly recommended that a third party be used to confirm the effectiveness of treatment. A regulatory agency may have to give its approval before the product can be shipped.
- 8. Make all your recall records available to everyone involved who has a legal right to see them.
- 9. Alert the Almond Board of the recall.

#### **Types of FDA Action**

According to the FDA, a **recall** is the removal of a marketed product considered to be in violation of FDA regulations. **Market withdrawal** is the removal of a distributed product, which involves a minor violation not subject to legal action by FDA. **Stock recovery** is the removal of product that has not been marketed or has not left direct control of the company.

#### Recalls

*Class I*: Reasonably likely that the use of, or exposure to, a contaminated product will cause serious health consequences or death.

*Class II*: Reasonably likely that the use of, or exposure to a contaminated product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

*Class III*: Reasonably likely that the use of, or exposure to a contaminated product is not likely to cause adverse health consequences.

The FDA does not have the authority to order a recall under the Food, Drug, and Cosmetic Act but it can get a court order to seize product if a recall is requested and the company does not comply. In FDA guidelines, companies are expected to undertake recalls when asked by FDA, to notify FDA when recalls are started and to make progress reports to FDA on the recall.

#### **Recall Communication**

It is critical that recall communications be handled correctly and as expeditiously as possible. Only designated people should speak to the media. In the event it becomes necessary to issue a press release, the following information should be included:

- Company name, contact names and phone numbers
- Address, including city and state
- Quantity and/or type of product
- Reasons for recall and a statement of possible hazard
- Area of distribution
- Specific information as to how the product can be identified
- Status and number of illnesses or injury
- A brief explanation of what is known about the problem
- Information on what consumers should do with the product and where they can get additional information

## The company President/CEO should approve any changes in the recall procedure.

## **Crisis/Recall Team Contact List**

President/CEO	Phone #:
	Fax #:
	Cell phone #:
	Home phone #:
	E-mail:
Recall Coordinator	Phone #:
	Fax #:
	Cell phone #:
	Home phone #:
	E-mail:
Distribution	Phone #:
	Fax #:
	Cell phone #:
	Home phone #:
	E-mail:
Production	Phone #:
Toduction	Fax #:
	Cell phone #:
	Home phone #:
	E-mail:
Quality Assurance	Phone #:
	Fax #:
	Cell phone #:
	Home phone #:
	E-mail:
Consumer Affairs	Phone #:
	Fax #:
	Cell phone #:
	Home phone #:
	E-mail:
Accounting	Phone #:
Recounting	Fax #:
	Cell phone #:
	Home phone #:
	E-mail:
Legal Counsel	Phone #:
	Fax #:
	Cell phone #:
	Home phone #:
	E-mail:
Public Relations	Phone #:
	Fax #:
	Cell phone #:
	Home phone #:
	E-mail:
Technical	Phone #:
	Fax #:
	Cell phone #:
	Home phone #:
	E maile
	E-mail:
Marketing	E-mail: Phone #:
Marketing	E-mail: Phone #: Fax #:
Marketing	E-mail: Phone #: Fax #: Cell phone #:
Marketing	E-mail: Phone #: Fax #:

## **Recall Team Responsibilities**

#### **Recall Coordinator**

- 1. Manage activities related to recall.
- 2. Convene recall team meetings and coordinate activities.
- 3. Keep recall master file.
- 4. Maintain recall plan.

#### Distribution

- 1. Stop all in-transit shipments of questionable material, and arrange for return of product to collection points.
- 2. Prepare inventory and distribution status of product showing where, when, and to whom quantity shipped.

#### **Production and Quality Assurance**

- 1. Prepare lot identification.
- 2. Halt production of product if related problem.
- 3. Investigate cause of problem. Check all records.
- 4. Clear product only as recommended by the Recall Coordinator.
- 5. Do not destroy any product without observation by FDA if a health hazard is involved.
- 6. Keep records of any destruction.

#### **Consumer Affairs**

- 1. Prepare responses for consumers.
- 2. Answer all consumer inquiries.

#### Accounting

1. Set up collection system to determine cost of recall.

#### Legal Counsel

- 1. Handle legal implications.
- 2. Review all press and company correspondence.

#### **Public Relations**

- 1. Prepare press releases.
- 2. Prepare message points for people authorized to speak to the press.
- 3. Handle all media inquiries.
- 4. Coordinate all activities through Recall Coordinator.

#### Technical

- 1. Obtain lot identification and samples.
- 2. Obtain product analysis.
- 3. Coordinate all action through the Recall coordinator until problem is solved.
- 4. Consult with lab.
- 5. Consult with regulatory agencies if there is a recall.

#### Marketing

- 1. Notify sales managers and brokers.
- 2. Arrange for pick-up at retail if necessary.
- 3. Arrange for proper credit to be given.

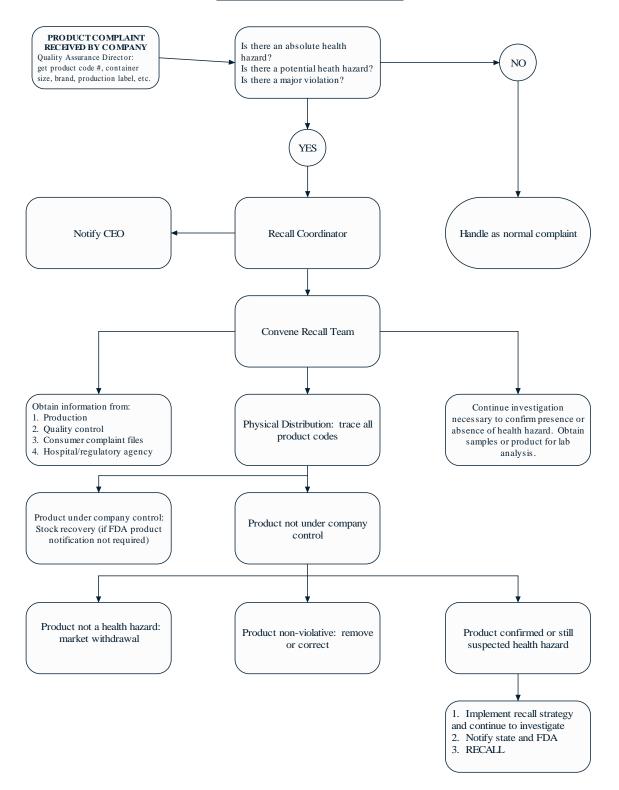
#### **Regional Sales Managers**

- 1. Aid in contacting customers.
- 2. Assist in product pick-up and issuance of credit.

#### **Brokers**

- 1. Aid in contacting customers.
- 2. Utilize sales force in actual product pick-up.

## **Recall Decision Tree**



### Traceback

Traceback is the ability to track food items, including almonds, back to their source (growers, packers, etc.). A system to identify the source of almonds alone cannot prevent the occurrence of a microbiological hazard that may lead to an initial outbreak of food borne disease. However, the ability to identify the source of a product through traceback serves as an important component of good agricultural and management practices intended to prevent the occurrence of food safety problems. Information gained from traceback investigation may also be useful in identifying and eliminating a hazardous pathway.

#### **Overview of the traceback process**

Once an outbreak is suspected, public health officials begin scientific studies to determine common food items consumed during the period of infection for the pathogen. If these studies implicate a particular food product and hazard analysis shows that other contributing causes were not to blame (for example, cross-contamination, ill food workers, other sources of infectious agent, etc.), health officials attempt to obtain the following information:

- At the Point-of-Service establishment (where the product was sold or prepared), pertinent product identifying information, including product types, packaging, labeling, and lot numbers if applicable, is obtained. Health officials also determine when the product was purchased or prepared, and determine receiving, stock rotation, inventory, handling and shipping procedures. Records are collected about suppliers and shipments of the implicated product to the Point-of-Service over the shelf life of the implicated product.
- Data relating to distribution of the implicated product is charted and analyzed. This analysis is accomplished either by tracing lot numbers, if they are available, or using a shipment delivery time line to identify suspect shipments based on knowledge about the time period when the implicated product was produced and shipped.
- Distributor interview, data collection, and analysis are repeated for each level of distribution until health officials identify the source of the product.

Depending on the contamination involved and the suspected food source, there can be wide variations in the reliability of the data obtained from such studies. Public health investigators must rely on record review and interviews. This method increases the time and resources necessary to trace an implicated product back to its source. Further, review of records that may not be complete and interviews with people whose memories may be imperfect make it more difficult to narrow down the cause(s) of an outbreak.

#### Advantages of an effective traceback system

Despite the best of efforts by food processors, food may never be completely free of microbial hazards. However, an effective traceback system, even if only some items carry identification, can give investigators clues that may lead to a specific region, packing facility, or even orchard, rather than your entire inventory or an entire commodity group. It also builds confidence among regulators and consumers that the industry is truly in control of all phases of production.

From a public health perspective, improving the speed and accuracy of tracing implicated food items back to their source may help limit the population at risk in an outbreak and the accompanying publicity. Rapid and effective traceback can also minimize the unnecessary expenditure of valuable public health resources and reduce consumer anxiety. Tracing implicated food items may also help public health officials to determine potential causes of contamination, thereby providing data for growers, shippers, and others for identifying and minimizing future microbial hazards.

#### Instituting effective traceback systems

Because of the diversity of handling practices throughout the almond distribution and marketing chain, a traceback system may be more easily implemented for some companies than others. For example, traceback systems may be more easily implemented for larger operations that have more direct control over a greater number of steps in the growing/packing/distribution chain. However, industry associations, growers, and handlers are encouraged to consider ways to provide this capability where feasible.

Handlers should examine current company procedures and develop additional procedures if necessary to track individual containers from the farm to the handler, and then to and through the distributor to the customer in as much detail as possible. An effective traceback system should document the source of a product and a mechanism for marking or identifying the product that can follow the product from the farm to the consumer. Documentation at minimum should include:

- Orchard identification and date of harvest
- Huller/sheller
- Who product sold to and date of sale and shipment
- Anyone else who handled the almonds, from grower to handler

# Reference (A copy of this document can be found under "Regulations and Guidelines")

FDA

• Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section IX, "Traceback"