

Why we need Good Manufacturing Practices

Food safety and product quality have always been top priorities for the California Almond industry. The Almond Board's Food Quality and Safety Committee constantly examine quality and safety issues. The committee also makes recommendations on how to maintain and improve almond quality and to protect consumers and industry from food safety problems.

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 risk of contamination from various sources, including unintentional mixing of almonds with other nuts or accidental exposure of almonds to microorganisms, foreign matter or pesticides. Remember, as an almond processor, you are a food processor. The almonds you process are going to be used as an ingredient in other foods, or consumed directly.

By executing and documenting Good Manufacturing Practices (GMPs), California almond processors can assure government regulators and customers worldwide that our industry is diligent in its commitment to processing safe, high-quality 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. GMPs are the minimum sanitary and processing requirements necessary to ensure the production of wholesome food. They have been written and organized with reference to the U.S. FDA GMP Regulations, Code of Federal Regulations (21 CFR 110). In no case do the recommendations in this guide supersede applicable federal, state or local laws or regulations for U.S. operators. GMPs are broadly written and are not intended to be plant specific, but instead, they explain re-

quirements for the food industry. Finally, GMPs, along with Good Agricultural Practices (GAPs) and Sanitation Standard Operating Procedures (SSOPs), are prerequisite activities to the development and writing of a Hazard Analysis and Critical Control Point (HACCP) plan unique and specific for each facility.

Forms are recommended for use in several locations throughout these GMPs. These forms are provided as samples only, and have not 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 first be reviewed by technical and/or legal experts before using to ensure their adequacy in meeting requirements under state and/or federal regulations.

Risk reduction

The GMP portion of the Food Quality and Safety Program (FQSP) represents generally accepted, broad-based guidelines, developed from scientifically based principles and current knowledge of food safety practices. The guide focuses on risk reduction--not risk elimination. Current technologies cannot eliminate all potential food safety hazards from product eaten in a raw form. This guide should be used to help assess food safety hazards within the context of the specific conditions (climatic, geographical, cultural, and economic) that apply to your own operation, and to implement appropriate and cost-effective risk-reduction strategies.

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

Good Manufacturing Practices



and addressing common risk factors will result in a more effective, cohesive response to emerging concerns about the safety of almonds.

The adoption of safe practices should be encouraged throughout the “farm-to-fork” food chain—including growers, huller/shellers, distributors, custom processors, exporters, importers, retailers, food service operators and consumers.

1. Personnel

Employee training in good handling practices, covering the key areas of sanitation and worker hygiene, is critical to achieving the goals of the almond industry's Food Quality and Safety Program (FQSP). Establishing a written training program for employees that addresses general sanitation and good hygiene practices will help reduce the risk of all forms of 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 Good Manufacturing Practices. All training should be documented with subsequent training provided periodically. It may be necessary to have bilingual training classes, depending on the composition of your workforce. You can use the Employee Training Documentation in the Appendix to document the subject material covered during training classes and attendees, or create one of your own.

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 Manufacturing 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, buyers, pest control operators and visitors 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.

Company organization chart

An organization chart helps clarify and document the roles of staff. This chart should identify 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. A job description should contain each individual's specific responsibilities relevant to each aspect of GMPs, (e.g., pest control is the responsibility of the QA Manager). These responsibilities should be written in a manner that is clear and easy to understand to avoid confusion when describing who is responsible for making which decisions and for their consequences. The chart should include office, cell, and home phone numbers, pager numbers, and after hours emergency contact information for key staff members.

Basic personnel safety and hygiene requirements

The following steps should be taken to minimize potential contamination associated with employees and visitors to your plant.

1. Employees must wear clean outer garments that protect against contamination of almonds, almond-contact surfaces or almond packaging materials. Garments shall have no shedding fibers. No tank tops are allowed. Shoes must be in good repair and of leather construction. No open-toed shoes are allowed.
2. All employees must wash hands with soap and warm water before work, after using restrooms, upon returning to their work station from break or lunch, or at any other time when their hands may have become soiled. Sanitizers are also recommended after wash-

- ing to afford additional protection, but they are not a substitute for hand washing.
3. All employees are to wear effective hair restraints, including hairnets and beard and mustache covers where applicable.
 4. No objects--pens, pencils, cell phones, etc.-- shall be carried above the waist or placed in pockets above the belt.
 5. No food, candy, chewing gum, lozenges, or other comestibles are allowed in the plant.
 6. Personal items must be stored in lockers or other designated locations outside processing areas.
 7. All jewelry must be removed when entering the plant (plain wedding bands are frequently exempted from this requirement). No hairpins or other objects that could fall into food may be worn in the process areas. Fingernail polish and false fingernails should not be allowed.
 8. No employee infected with or showing symptoms of any infectious or communicable disease, or that demonstrate open sores, boils, infected wounds or any other affliction that may spread disease, shall be in contact with almonds, almond surfaces or almond packaging materials. Supervisor shall monitor for these conditions.
 9. Monitor employees, conduct internal audits and record corrective action taken when appropriate.
 10. Visitors and contractors shall follow the same rules as employees. Use the Plant Visitor's Agreement sample form in Appendix, page 6.
 11. No glass items of any kind are permitted in the plant processing areas.
 12. If employees wear gloves they shall be of an impermeable material. Gloves shall be cleaned and/or sanitized at the beginning of work, after returning to work station, or at any other time when the gloves become soiled.
 13. Tobacco is not permitted in the plant. Smoking is permitted only in designated areas outside the plant.
 14. Personnel working in the hulling/shelling or other "dirty" areas 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 also should not move into processed product areas due to the risk of contaminating finished product.

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. They should understand the impact of poor personal cleanliness and unsanitary practices on food safety. Good hygiene not only protects the worker from illness, it also reduces the potential for contaminating almonds., Contaminated almonds consumed by the public could cause a large number of illnesses. The level of understanding needed will vary as determined by the type of operation, the task, and the assigned responsibilities.

To ensure that every employee understands sanitation and hygiene principles, handlers should develop a sanitation training program. All new employees should be trained on basic sanitation and hygiene principles. Depending on the situation, formal presentations, one-on-one instruction, or demonstrations may be appropriate. Depending on the workers' job requirements, periodic updates or follow-up training sessions may be needed.

Resources (Located under "Regulations and Guidelines")

- [Occupational Safety Health Administration - 29 CFR 1910.141\(g\) \(Food and beverage consumption on premises\)](#)

2. The Environment

Contamination can be significantly reduced through effective housekeeping, maintenance and organization. The same steps used for maintaining cleanliness inside your facility should be used for the exterior and perimeter of your operation.

Plant schematic

Most operations have a plant schematic (a blueprint or layout of the facility) on file. This is a vital reference document for customers, government regulators and anyone in your company involved in planning production changes or implementing GMPs. If any processing steps are subcontracted to another facility, those subcontracted operations should have GMPs of their own and should be included in any third-party audit or certification activity. Schematics should be reviewed and updated each year, or whenever any process changes occur. A schematic can be a simple line drawing by hand or an elaborate, mechanically drawn blueprint.

In addition to a simple plant schematic, processors are advised to create a drawing that demonstrates the product or “process” flow. The process flow schematic should briefly describe the most relevant features of each processing step: time, temperature, etc.

Plant environment

The following recommendations should be implemented to minimize the potential for contamination associated with the plant.

1. Ensure that all glass lights in processing and warehouse areas are shielded or otherwise protected.
2. Provide adequate lighting in all almond pro-

cessing and support areas, including hand-washing areas, dressing and locker rooms, restrooms, and all areas where almonds are examined, processed or stored.

3. Whenever possible, glass and hard plastics are prohibited in food factories. However, a glass-control policy should be implemented defining procedures on how glass is monitored and controlled when in the factory. This includes a glass registry identifying all glass in the factory. All glass will be inspected at the start of each day for any sign of damage or breakage. The policy will also detail the actions to be taken when glass breakage occurs.
4. Provide adequate space and layout to facilitate production and prevent accidental contamination of almonds.
5. Ensure that floors, walls, and ceilings are constructed of appropriate materials that facilitate cleaning and maintenance.
6. Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate almonds. Locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating almonds, almond-packaging materials, and almond-contact surfaces.
7. Develop procedures for reviewing any potential changes in the facility for their impact on GMPs and modify accordingly. This would include changes in layout, infrastructure, equipment or addition of new equipment. Changes should be reviewed in light of their effect on executing current GMPs or the possible introduction of contaminants.

Grounds environment

The following recommendations should be implemented to minimize the potential for contamina-

tion associated with plant grounds.

1. Maintain plant grounds so as to reduce the potential for contamination. Grounds must be free of trash and debris. Grounds must have adequate grading and/or drainage to avoid standing water. Vegetation should be controlled to prevent pest harborages.
2. If there are other activities on site of the facility or nearby, preventive measures shall be taken to prevent the cross contamination of almonds stored or processed on the facility by biological, chemical or physical hazard.
3. Building and grounds must be maintained to prevent entry of pests. Provide, where necessary, adequate screening or other protection against pests. Building roof, walls, doors, floor and windows shall be constructed and maintained to prevent pest entry.
4. Waste facilities must be well maintained and designed to prevent contamination of product or packaging material. Waste containers must be clearly identified and emptied in a timely manner.
5. Roads, yards and parking lots must be maintained so they do not pose a threat of contamination to any stored almonds on site.
6. Equipment stored on the grounds shall not provide sources of contamination or pest harborages.
7. Conduct internal audits of grounds by inspecting and recording observations concerning items 1-6 above. If deviations are found, record them and take appropriate corrective action.
8. Store, convey and dispose of rubbish and processing waste to minimize odor and the potential for attracting flies and other pests and to protect against contamination of almonds, almond contact surfaces, water supplies and ground surfaces.

Pest Control

The following recommendations should be implemented to minimize the potential for contamination associated with plant grounds

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*. Each facility should establish a pest control program to reduce the risk of contamination by rodents, insects, birds and any other pests.

1. An effective pest control program should include regular and frequent monitoring of affected and treated areas to accurately assess the program's effectiveness. A staff member should be trained to implement the program and work with outside pest control contractors as needed. Detailed pest control logs describing treatments and results should be maintained.
2. No pests or domestic animals shall be allowed in any area of an almond plant.
3. Maintain the grounds in good condition. Grounds in the immediate vicinity of all packing areas should be cleared of all 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 items, including unused and inoperative equipment to eliminate areas that harbor rodents and insects.
4. Clean and sanitize daily to remove product or product remnants that attract pests in and around the packing facility and any other location where almonds are handled or stored.
5. Maintain adequate surface drainage to reduce breeding places for pests and food contamination by seepage.

6. Operate water treatment and disposal systems so that they do not become a source of contamination or pest attractant. If grounds not under your control border the processing plant, protect your facility by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.
7. 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.
8. Pest control procedures and logs should describe the location of any outdoor bait stations, glue boards, and insectocutors (bait stations are not permitted inside the plant). Trap or bait station locations should be documented with a schematic map. Traps and stations should be checked frequently to detect activity and a record should be maintained. Traps should be cleaned and maintained. Dead pests should be removed immediately and disposed of to prevent any potential contamination or infestation.
 1. A list should be maintained of all pesticides used at the facility along with Manufacturer's Safety Data Sheets (MSDS) and recommendations. All pesticides shall be used in accordance with manufacturer's labeled recommendations and State and Federal regulations. Individuals using and applying pesticides shall receive appropriate training and shall have certificates or licenses from appropriate authorities. A record should be maintained of all pesticide applications, including name of chemical, concentration, where applied, and date. If the plant was fogged with insecticide, clean, sanitize and inspect all equipment afterwards to insure removal of all dead insects and ensure that no residues of insecticide remain. Use of pesticides in product storage areas could lead to the detection

of pesticide residues in finished product. Please refer to the manufacturer's recommendation for proper use in food storage areas.

2. Records should be kept detailing pesticide usage, including date of application, location, dosage rate, target pests, etc.

Resources (Located under "Regulations and Guidelines")

- [Food and Drug Administration - 21 CFR 110.35\(c\) \(Pest control\)](#)

3. Sanitary Operations

Cleaning and sanitation

An effective cleaning and sanitation program is critical for minimizing the potential for contamination with microorganisms and foreign debris. The following general practices should be implemented when appropriate.

1. Establish a plant sanitation program that includes employee training for cleaning plant equipment, the facility and utensils. Records of training should be maintained.
2. All almond contact surfaces, including utensils and almond contact surfaces of equipment, shall be cleaned and sanitized as frequently as necessary to protect against contamination.
3. General cleaning and sanitation procedures for equipment. Research conducted by the University of California, Davis, funded by the Almond Board of California, has indicated that wet cleaning can lead to increased levels of pathogens in the plant environment if the equipment is not thoroughly dried before reuse. Because of this finding, it is not recommended that wet cleaning be conducted unless the equipment can be completely dried before reuse.
 - a. Dry Cleaning Procedures
 - i. Lockout/Tagged procedure for power.
 - ii. Remove all almonds from the area being cleaned.
 - iii. Wear proper protective equipment.
 - iv. Check for oil leaks on all gear boxes and motors and report problems to maintenance supervisor. Document the incident.
 - v. Vacuum all equipment, conveyors, product contact surfaces, motors, support frames, and any other exposed surfaces to remove all debris. Begin at the highest point of equipment and work downward. Remove all almond residues from equipment and surfaces.
 - b. Wet Cleaning Procedures
 - i. Lockout/Tagged procedure for power.
 - ii. Remove all almonds from the area being cleaned.
 - iii. Wear proper protective equipment.
 - iv. Check for oil leaks on all gear boxes and motors, report problems to maintenance supervisor and document the incident.
 - v. Vacuum all equipment, conveyors, product contact surfaces, motors, support frames, and any other exposed surfaces to remove all debris. Begin at the highest point of equipment and work downward. Remove all almond residues from equipment and surfaces.
- vi. Where it is not possible to vacuum, carefully blow and/or sweep surfaces. Special care must be taken to avoid blowing foreign material throughout the plant.
- vii. Sanitize food contact surfaces with appropriate sanitizer (quaternary ammonia or other sanitizer). Do not apply sanitizers (quaternary ammonia or other sanitizer) directly on to edible product. All sanitizers used on food contact surfaces should be food grade.
- viii. Rinse off sanitizer and allow equipment to thoroughly dry before use. Alcohol-based sanitizers may be most appropriate where short drying times are required.
- ix. Refer to manufacturer's recommendations for specific instructions on use. Follow all label and Manufacturer Safety Data Sheet precautions for chemicals.

- vi. Where it is not possible to vacuum, carefully blow and/or sweep surfaces. Special care must be taken to avoid blowing foreign material throughout the plant.
 - vii. Check for oil leaks on all gear boxes and motors, report problems to maintenance supervisor and complete action slip.
 - viii. Vacuum all equipment and motors to remove loose debris. Start at the highest piece of equipment and work down. Remove all almond products from the area.
 - ix. Cover all motors and gear boxes with plastic coverings.
 - x. Rinse with water, apply detergent with hot water or steam clean.
 - xi. Scrub with brushes and other cleaning tools as needed. Agitate all equipment and food contact surfaces to remove dirt or residue buildup.
 - xii. Rinse with fresh water.
 - xiii. Sanitize food contact surfaces with appropriate sanitizer (quaternary ammonia or other sanitizer). Do not apply sanitizers (quaternary ammonia or other sanitizer) directly on to edible product. All sanitizers used on food contact surfaces should be food grade.
 - xiv. Rinse off sanitizer and allow equipment to dry thoroughly before use.
 - xv. Refer to manufacturer's recommendations for specific instructions on use. Follow all label and Manufacturer Safety Data Sheet precautions for chemicals.
4. Almond contact utensils and processing tools should be cleaned and sanitized daily using a food grade sanitizer. Utensils and processing tools should be washed to remove dust and debris, then sanitized using a commercial sanitizer of a concentration specified by the supplier that meets government regulations.
- 5. A master sanitation schedule and recordkeeping log should be developed for the facility that lists the frequency of cleaning for all equipment, surfaces, utensils and infrastructure. The schedule may need to be adjusted depending on the results of your environmental monitoring program (see Environmental Monitoring Program).
 - 6. Develop written procedures that detail all steps in cleaning, including chemicals used, contact time, temperatures, and who conducts cleanup.
 - 7. Effectiveness of cleaning should be verified by visual inspection or by other means, such as environmental testing with swabs and/or bioluminescence testing. Verification of cleaning should be done at an interval that ensures that cleaning is effective and consistent and a record should be kept (see Environmental Monitoring Program). If verification results in an unacceptable condition, items should be re-cleaned or changes made in the cleaning procedures.
- ### Chemicals
- Improper use of chemicals can pose a risk to food and employees. Implementation of the following recommendations regarding chemical handling and employee training are critical to minimizing issues associated with chemical use.
- 1. Those employees designated to handle hazardous materials must be trained in proper handling. Each employee should sign a certificate after he or she has been properly trained. Maintain records of employee training and authorizations as appropriate in employee files. Sample forms to document employee training are located in the Appendix.
 - 2. Chemicals must be stored away from almond processing areas so as not to contaminate

- almonds, almond contact surfaces or almond packaging materials. Store pesticides and pesticide equipment separately from oils and products used in food processing. When possible chemicals should be stored in a non-food-product warehouse.
3. All chemicals must be properly labeled and packaged.
 4. Procedures and controls should be established for the securing, checkout and return of chemicals to avoid unauthorized use.
 5. Workers authorized to apply chemicals shall receive appropriate training in the use, storage, documentation and disposal of these chemicals.
 6. The plant should maintain an inventory and Manufacturer Safety Data Sheets (MSDS) for all chemicals used in the facility.
 7. Chemical control procedures should be developed that outline procedures for listing all chemicals used in the facility; the handling, storage and labeling of chemicals; procedures for distribution and control of chemicals; procedures for ensuring MSDSs are maintained and are current; procedures for ensuring that cleaners, sanitizers and lubricants have documentation that guarantees approved regulatory status; and procedures for disposition of empty chemical containers or waste chemicals.
 8. Cleaning and sanitizing agents shall meet appropriate regulations and documentation shall be obtained from suppliers verifying this.
 9. Chemicals that may contact almonds or almond contact surfaces (such as lubricants) must be food grade.
 10. Disposal of empty containers or waste must conform to local and state regulations for the particular chemical. No empty containers must ever be stored in areas that would present the possibility of potential contamination to almonds, almond packages, or water sources.
 11. Manufacturers' recommendations for use of chemicals used in or around food contact areas should be adhered to.
 12. Records should be kept detailing chemical usage, including date of application, location, dosage rate, purpose, etc.

4. Sanitary Facilities and Controls

Water

Water used in food processing is required to be safe and sanitary. This water must meet drinking water standards for microbiological activity. If using an on-site well, a water sampling schedule must be in place with documented sampling results demonstrating 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, which can be supplied by your water provider.

Plant water from a ground or well source should be tested at least once a year for pesticides, heavy metals and microbiology. California has several water laboratories that can assist 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 certification papers should be obtained from the local Department of Public Works or water agency and filed for future reference.

Water of substandard quality may 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 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*, *Toxoplasma 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.

1. All water used for almond contact or almond contact surfaces or used in the facility for employee services must be potable and meet state and federal regulations for drinking water.
2. If chlorine is added to water as a disinfectant, the concentration of chlorine should be recorded daily.
3. There must be no cross-connections between potable and non-potable water supplies. A plumbing diagram should be on file to verify this.
4. All hoses, taps, and piping systems must be designed to prevent back-flow or siphonage of standing water and/or have backflow devices installed. Have a map of any backflow devices that are installed in the water lines. Piping shall not have any "dead ends."
5. If water is from a non-municipal source the almond processor must establish that the water meets microbiological and chemical criteria for potable water. This should be done via a testing program with a recognized third-party laboratory. Water should be tested at a minimum of once per year.
6. There should be a certificate of analysis on file for the water if it is from a municipal source.

7. Equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, should be routinely inspected to ensure efficient operation. Provide a map detailing the location of this equipment.
 8. Monitor practices by using internal audits, record observations and take corrective action when appropriate.
 9. Clean and sanitize water contact surfaces, such as blanchers, as often as necessary to ensure the safety of the almonds.
 10. Change water as necessary to maintain sanitary conditions. Develop water change schedules for all processes that use water.
 11. The water supply must be adequate for peak usage, and hot water supply must be adequate for clean-up requirements.
 12. Plumbing must be adequate to convey water to required locations and to convey sewage and liquid waste from the processing facility.
 13. Sewage disposal must be deposited into an adequate sewage treatment system or another method that eliminates potential for contamination.
5. Signs must be posted instructing employees to wash their hands.
 6. Toilet facilities must be adequately supplied with toilet paper, warm water, soap, and paper towels or air dryers for drying hands. Multiple-use towels should not be used. Toilet facilities must be checked daily and re-stocked as necessary to ensure adequate supplies.

Hand washing

Toilets

1. Each almond facility must provide employees with adequate, readily accessible toilet facilities.
 2. Toilet facilities must not have doors that open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against contamination, such as double doors or positive air-flow systems.
 3. Toilet facilities must have self-closing doors.
 4. Toilet facilities must be kept clean, neat and in good repair. Basins, toilets, urinals, walls, ceilings and floors should be cleaned and sanitized daily or as necessary. There must be adequate waste disposal.
1. Each almond facility must 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. Handwash stations must be checked daily and re-stocked as necessary to ensure adequate supplies.
 2. Restroom fixtures, such as water control valves, should be of a type designed to protect against recontamination of clean, sanitized hands. Foot control valves or sensing systems are preferred.
 3. Easily understood signs must be posted 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. These signs should be posted in restrooms, in the processing rooms, and anywhere employees may handle food or materials and surfaces involved in the production process. Signs should be bi-lingual, if appropriate to the facility.
 4. Provide and maintain waste receptacles in ways that protect against food contamination.
 5. Hand sanitizers are not a substitute for hand washing. However, hand sanitizers may be placed at various locations within the plant, to be used as a supplement to hand washing.

Resources (Located under “Regulations and Guidelines”)

- Food and Drug Administration - 21 CFR 110.37(d)(1)-(4) (Toilet facilities), 21 CFR 110.37(e)(1)-(6) (Hand washing facilities)
- Occupational Safety and Health Administration - 29 CFR 1910.141(c)-(f) (Toilet, washing and clothes drying facilities, changing rooms)
- California Department of Health Services - CDHS Code, Section 112015 (Hand washing, CDHS Code, Sections 112020-112035 (Overall “non-permitted” employee behavior with respect to sanitation)

5. Equipment and Utensils

Design, construction and maintenance of equipment and utensils

Your almonds are constantly in contact with the equipment surfaces and utensils in your facility. Specific attention should be given to equipment and utensils used in the processing of almonds to ensure that the design is sanitary in nature and that programs are in place for preventive maintenance, cleaning and sanitation.

1. All almond contact surfaces must be made of non-toxic materials, appropriate to their use, and resistant to deterioration by cleaning and sanitizing agents. These materials should be easy to clean and maintain.
2. Equipment and utensils must be designed so as to provide access for cleaning and sanitation.
3. Equipment must be well maintained, with no rust, excess lubrication, flaking paint, etc. Plastic (such as baskets, conveyors) should be well maintained without chips, cracks or breaks in the material.
4. All cold storage facilities in the plant must be equipped with a temperature measuring or recording device that can be accurately read to confirm temperature. This device should be calibrated at least annually to ensure accuracy. Cold storage facilities should have an alarm system or an automatic temperature control device.
5. If compressed gases are used in the facility, a certificate of purity must be obtained from the vendor and kept on file.
6. Develop a preventive maintenance program for equipment, utensils and plant infrastructure to ensure that all are properly maintained in order to avoid potential contamination of product and to maximize efficiency. A preventive maintenance program should include a list of all the equipment and sections of infrastructure that require maintenance, a list of scheduled maintenance and the interval required for maintenance. It should also include a record-keeping component to ensure that maintenance has been performed as scheduled.
7. Develop a calibration program for key process and laboratory equipment to ensure that they are recording accurately and consistently. This should include a list of all items, records that calibration has been performed, the results, and certification that calibration has been performed against a certified standard.
8. Seams and welds on equipment must be smooth so as to be cleanable and prevent contamination.
9. Design equipment to minimize exposed screws, bolts, bearings, etc. that could potentially contaminate almonds. Establish a frequent monitoring program for conducting physical inspection of equipment.
10. Utensils must be properly stored to prevent product contamination when not in use.
11. Brushes used for cleaning should be segregated by their use. Brushes used for cleaning drains and floors should be easily identified by color or other means and should not be used for almond contact surfaces. All employees should be trained on the proper use of utensils and brushes used for production or cleaning.

6. Processes and Controls

Raw materials, transportation, warehousing and distribution

Maintaining control over materials used in manufacturing and finished product as well as ensuring sanitary conditions during storage and distribution is critical to protecting the integrity of the processed almonds.

1. Remove as much dirt and mud as practical from almonds outside of packing facilities or packing areas. Take additional care to protect raw almonds against possible contamination from 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.
2. Almond bins should be cleaned before they are used to transport raw almonds.
3. Almond bins should be inspected for damage on a regular basis. Bins with damaged container surfaces should not be used.
4. Ensure that vehicles used to transport raw almonds to the facility are used only to convey dry food products. No chemicals, livestock, waste products or other potential contaminants may be transported without cleaning and sanitizing before almond transport. All non-almond residues are to be removed before transporting almonds. Request cleaning and sanitation records from your transportation company.
5. Almonds must be stored under conditions that protect against contamination and minimize deterioration.
6. Separate containers must be used for handling raw and processed almonds.
7. Reduce the potential for cross contamination of almonds, almond-contact surfaces, or almond-packaging materials with biological, chemical or physical hazards. Raw almond areas shall be physically separated from processed areas and controls shall be in place to prevent the contamination of raw almonds by workers, equipment or utensils.
8. Ensure that non treated almonds are labeled as “unpasteurized,” and are segregated from treated product in order to minimize the potential for post process contamination (see Treatment Program).
9. Measures shall be taken to prevent contamination of almonds with metal. Facilities should use inspection or metal detection devices (magnets or metal detectors) to prevent metal contamination. In-line magnets should be cleaned and tested daily to ensure they are performing correctly. A record should be kept of inspections. Metal detectors should be calibrated at an appropriate interval and the results recorded. An investigation should be made of metal rejected by magnets or metal detectors in order to determine the source and take corrective action. Sample magnet check form and metal documentation form included in Appendix (pages ?).
10. Obtain certificates of analysis and continuing letters of guarantees for ingredients other than almonds and for food contact packaging.
11. Develop a vendor control program to qualify and evaluate ingredient and packaging suppliers.
12. Containers used for ready-to-eat almonds should be cleaned and sanitized before each use.
13. Almond packaging material shall only be used to package almonds.
14. Warehouses used for finished products shall be maintained in a condition that protects almonds against biological, chemical and physical contaminants. Warehouses shall be neat,

orderly and designed to prevent contamination by pests. Warehouses should be audited at least monthly. Audits should focus on pest control, cleanliness, neatness, maintenance of space between rows and walls, and protection against potential contaminants.

15. Protect almonds stored outdoors by an effective means, including the use of protective coverings.
16. Control areas over and around almond storage to eliminate harborages for pests.
17. Monitor almond storage areas as necessary for evidence of pests and pest infestations.
18. Maintain accurate fumigation records, including treatment dates, product used, and the Material Safety Data Sheet for each pesticide used. Ensure employees have been trained properly and are certified to conduct fumigation treatments. Abide by the applicable label directions and all federal, state and local regulations to keep your workplace safe and your product in compliance. The USDA requires food processors to document each fumigation treatment in a logbook for examination by USDA officials. Sample Fumigation Control Form in Appendix (page 11).
19. Protect packaging containers from contamination when in storage. Packing containers and other materials that are not used immediately should be stored in a way that protects them from contamination by pests (such as rodents), dirt, and water condensation from overhead equipment and structures. If packing containers are stored outside the packing facility, they should be cleaned and sanitized before use.
20. Use of pest control fumigants in product storage areas should be carefully considered and manufacturers' recommendations should be adhered to in order to minimize the potential for drift on to almond surfaces.
21. Carrier vehicles used to transport finished product should be inspected before loading

for signs of insect infestation, moisture, chemical residues, foreign material, off odors, and evidence of other nut meats or contaminants. A record should be kept of the inspection. Microbial cross-contamination from other foods and non-food sources and contaminated surfaces may occur during loading, unloading, storage, and transportation operations. Whenever produce is transported and handled, the sanitation conditions should be evaluated. Trailers used to transport chemical or waste products should not be used for shipment of food products.

22. Implement a Carrier Inspection Program (form in Appendix Page ?). While you may encounter initial resistance from your carrier it is better to reject an unsanitized carrier vehicle than to have your product rejected because of contamination.

Resources (Located under "Regulations and Guidelines")

- [Food and Drug Administration - Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section VIII, "Transportation."](#)

7. Traceback/Product Recall

Traceback is the ability to track almonds back to their source (growers, huller/shellers, etc.). A system to identify the source of almonds alone cannot alone prevent food safety problems or the occurrence of a food safety recall. However, the ability to identify the source of a product through traceback serves as an important component of good agricultural and manufacturing practices and may prevent the occurrence of food safety problems. Information gained from traceback investigation may also be useful in identifying and eliminating a hazardous pathway. The minimum regulatory requirement is the ability to trace all food products forward one level in the supply chain and back one level in the supply chain. This action must be completed within twenty-four hours of notification. A product recall is a voluntary action initiated by a handler to remove product that regulatory authorities consider to be in violation of their food laws.

Traceback

Despite the best efforts of almond handlers, almonds may never be completely free of all hazards. However, an effective traceback system can give investigators clues that may lead to a specific region, packing plant, or orchard, rather than an entire inventory or commodity group. It also builds confidence among regulators, customers and consumers that our industry is in control of all phases of production and distribution.

From a public health perspective, improving the speed and accuracy of tracing implicated product back to their source may help limit the population at risk in an outbreak and the accompanying negative publicity. Rapid and effective traceback can also minimize the unnecessary expenditure of valuable resources and reduce consumer

anxiety. Tracing implicated product 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, growers, and handlers of all sizes are encouraged to establish protocols to provide traceback capability.

- Handlers should examine current procedures and develop additional procedures if necessary to track individual containers from the farm to the handler, and then to and through the processing and distribution chain to the customer in as much detail as possible. An effective traceback system should document the source of a product and include a mechanism for marking or identifying the product that can trace the product from the farm to the consumer. Documentation at minimum should include:
 - Orchard identification and date of harvest
 - Huller/sheller the almonds processed through
 - Production and quality records
 - Product inventory and warehouse records
 - Customer(s) purchasing product
 - Customer location and ship dates
 - Any other supply chain elements not noted above

Positive Lot Identification

A key element of a traceback program is positive lot identification. Adequate lot 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.

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 link 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.

There are many methods of lot numbering and code dating almonds. One of the most common methods is the use of Julian Code Dating. Julian Code Dating utilizes a Julian calendar to establish the date of production. For instance, the lot code “9030” indicates the 30th day of the year 2009. The year is the first number (9). The “030” is the number of days since January 1. The Julian date may also be written “0309,” with “030” as the number of days since the beginning of the calendar year and “9” as the year. This method varies from handler to handler.

Be consistent in your lot numbering to maintain accuracy and eliminate confusion. If you begin with a lot code using the year first and then the number of days since January 1, do not switch in mid-year to placing the number of days first and then the year.

In addition to identifying the production dates in the lot number (code), the code must also include lot numbers that can be traced to a grower

and production line. This code should be listed on the shipping invoice and maintained in plant records. Computer records of lots sent with shipments will make recall simpler and product tracing significantly faster.

Resources (Located under “Regulations and Guidelines”)

- [Food and Drug Administration - Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section IX, “Traceback”](#)

Product Recall

No handler wants to face a product recall. However, an established product recall program is invaluable should a food safety problem occur. Recalls are procedures used to identify and recover potentially adulterated, misbranded, and/or hazardous foods in order to prevent potential food safety problems.

Recall Definition

A recall is the procedures(s) conducted by responsible handlers to remove or correct a product that regulatory authorities consider – or may consider – to be in violation of their food laws. The ability to remove products from the marketplace quickly and effectively has been vital to the California Almond Industry and the food industry in general. Today it takes on added importance, since we have entered an era in which terrorists could use the food supply as a mechanism to disrupt commerce and cause public panic. So, the goal of a Product Recall Plan is to prepare handlers for the possibility of recalls and to enhance their ability to conduct rapid and effective removal of almonds, almond products and other food products containing almonds from the marketplace.

Prompting A Recall

There are many situations that can result in a food product recall. Some are emergency situations; others are not. Following is a list of potential causes of recalls involving almonds and almond products.

- Allergens – A product or component containing an unlabeled ingredient that may cause an allergic reaction in humans. (Almonds and other tree nuts are included on the FDA’s list of common allergens)
- Bacterial Contamination – Contamination by spoilage organisms or harmful bacteria (E Coli, *Salmonella*, Listeria, etc)
- Chemical Contamination – Presence of unapproved pesticides and/or residues of these items in amounts greater than the established residue tolerance levels. Naturally occurring chemical contaminants such as Aflatoxin.
- Communicable Diseases – Human illnesses that can be transmitted through foods.
- Handler generated information – Food Safety problems discovered through handlers internal record review and examination processes.
- Foreign Materials – Presence of glass, plastic or metal.
- Illnesses identified by food safety regulators.
- In-house Sabotage.
- Misbranding – Violations of labeling laws.
- Real or Fraudulent Customer or Consumer Claims.
- Tampering and Tampering Threats.
- Undeclared Ingredients.

The Decision To Recall

As you can see from the above list, there are many potential pitfalls in almond processing and distribution. Most often, a handler will first learn of a threat or problem from a State or Federal agency. So, it is important that handlers have

the right group of people trained and available to understand the nature of the threat and to assist in the most critical decision a handler will make – whether or not to embark on a product recall.

This group of people is the Handler’s Recall Team. In case of a potential recall, the team must be prepared to document all information that is available to support their decision – either to recall or not. It is important to understand that a recall, until otherwise determined by law, is a voluntary action.

If the initial notification comes from a customer or a regulatory agency, the decision NOT to recall must be discussed and agreed upon mutually. Otherwise, the customer likely will discontinue business; a regulatory agency could proceed with punitive actions; and the handler could incur greater liability in the event of a health or safety problem.

The size of the Recall Team will vary depending on the handler. The group is convened as necessary to assess a situation and make the recall decision. It is recommended that Recall Teams meet at least semi-annually to review the handlers recall plan. The Recall Team should also initiate mock recalls to test their plans.

Recall classifications

A *Class I* recall means there is “a reasonable probability” that the use of the contaminated product will cause serious adverse health consequences or death. Examples of Class I recalls are:

- *Salmonella* Contamination
- Undeclared Allergens (the presence of other tree nuts in almonds)

A *Class II* recall means the use of a contaminated product may cause temporary or medically reversible adverse health consequences. Examples of Class II recalls are:

- The presence of spoilage organisms
- The presence of unapproved additives or ingredients

Class III recalls are for products that violate federal regulations but are unlikely to cause adverse health consequences. Examples of Class II recalls are:

- Mislabeling such as incorrect weight declaration or non-organic almonds being labeled as organic.
- Almonds produced under unsanitary conditions

Regulators realize that some types of contamination (mold, insect, bird and rodent damage) are routine occurrences. The FDA have set what they call “defect action levels” for these items. The defect action level of almonds is 5%. If almonds exceed the defect action level they may become subject to regulatory action. However, these action levels are not binding and are considered on a case-by-case basis.

Handlers Responsibilities to Their Customers

When communicating recall information to customers, it must accurately reflect the level of danger that may be involved in using the product, as well as a strategy developed for the recall. By law, the recall communication must include the following details:

- The complete identity of the product, along with labels, brand name and code number information.
- That the product is being recalled

- The “further distribution or use of any remaining product should cease immediately.”
- That this customer should notify any of its own customers, down the line, if they received any of the product.
- Specific instructions for what to do with the product.

It should also include a “ready means” for the customer to report back to the company. The FDA’s suggestions are:

- A self-addressed postage paid postcard, or...
- A phone number for customers to call, collect or toll-free.

The law says this information can be imparted by “telegram, mailgrams, or first class letters conspicuously marked, preferably in BOLD RED TYPE, on the letter and envelope:”

- FOOD RECALL
- For Class I & II recalls it should also be marked URGENT.

Gathering the Facts about the Product or Problem for the Regulators

The lead regulatory agency contacts the handler to gather the following information. Depending on the circumstances, the lead agency may already have some of this information on file before contacting the handler:

1. Product Identity
 - a. Product name, including all brand names
 - b. Product code numbers
 - c. Product description
2. Manufacturer Identity
 - a. Handler name and address
 - b. Responsible individual at firm: name, title, phone, fax, and email address.
 - c. Recall contact

- d. Contact for the public
3. Reason for the Recall
 - a. Explanation of cause of problem and date/time it occurred.
 - b. Explanation of how and when the problem was discovered
 - c. Explain whether the problem affects all products in the lot being recalled or only a portion of the products being recalled.
 - d. If the handler received a positive microbiological sample laboratory result, get a copy of the confirmed result.
 - e. If the handler received complaints associated with the problem, they must provide dates of the complaints with descriptions that include details of injury or illness, lot numbers, code dates, etc.
 - f. If recall is due to presence of a foreign object, describe the size composition, hardness and/or sharpness of the object.
 - g. If recall is due to the presence of a chemical contaminant, explain level of contamination and provide labeling, list of ingredients and MSDS for the contaminant.
 - h. If recall is the result of a labeling issue, the company must provide and identify the correct and incorrect label, description and formulation.
4. Handlers Assessment of the Health Risk Associated with the Product Deficiency, Including any Supporting Data or Information.
5. Volume of Product Being Recalled
 - a. Total quantity produced
 - b. Date(s) produced
 - c. Quantity distributed
 - d. Quantity on hold by recalling firm and its distribution centers
 - e. Description of product quarantine procedures and conditions
 - f. Estimated amount of product remaining in the marketplace at: distributor level, retail level, and consumer level
6. Distribution Pattern

- a. List of consignees (Names, addresses, phone numbers)
- b. Indicate quantity of product shipped to each consignee, including dates

The lead agency will establish the timeframes for the exchange of communication with the businesses involved in order to facilitate efficient handling of the recall.

Handler Recall Team

The size and makeup of a recall team will vary by handler. Larger handlers may have different managers filling each of the responsibilities noted below. Smaller handlers may have only a few key personnel on the recall team with each individual responsible for one of more of the team functions. The important thing is to plan and document who is assigned responsibilities for each of the team functions noted below. Once you have established your recall team, establish a roster of all team members (and alternates). The roster should include Name, title, responsibilities and a 24-hour contact phone number.

Recall Coordinator

- Manage activities related to recall
- Convene recall team meetings and coordinate activities
- Maintain recall plan

Distribution

- Control and accountability for inventory of all product involved in recall
- Prepare inventory and distribution status report showing where, when and to who recalled product shipped or is currently warehoused.

Production & Quality Assurance

- Identify lot codes of product implicated
- Investigate cause of problem. Examine all pro-

Good Manufacturing Practices

duction, quality and lab records.

- Maintain implicated product quarantine until regulators approve product release.
- Do not process or destroy implicated product until directed to do so by regulators through the recall coordinator.

Sales/Marketing

- Notify customers of recall process
- Coordinate product return and replacement/credit

Public Relations

- Prepare press releases
- Prepare message points for people authorized to speak to press
- Handle all media inquiries

Technical/Laboratory

- Obtain lot identification and samples
- Perform laboratory analysis
- Advise recall team on technical matters

Legal Counsel

- Advise recall team on all legal implications of recall process

Testing the Recall Plan (Mock Recall)

A mock food recall is the best way to test your plan and your company's response time. How quickly can your team identify and segregate specific product, and disburse information to those who might be affected by selling or consuming the product?

For the test, select product from your actual production records. It should have real-life period codes, lot numbers and production dates. Pick at

least one lot that was fairly recently produced—some stock is still on-site or in storage, and some is already out in the marketplace. This allows you to check internal, as well as external, ability to account for the product. The test will only be effective if you also set timed goals.

The Recall Team should convene and “work the plan.” In all communication, however, be sure to stress the fact that this is a mock exercise designed strictly for emergency preparedness, and that nothing is wrong with the actual product! The mock recall should involve a complete review of company records and, to a certain extent, external sources of information. Brief the employees and communicate a time goal for meeting the research deadlines.

Perhaps the most important part of a mock recall is the debriefing session at the end. The entire point of the exercise is to prove that the company can effectively trace all raw materials through receiving, production, packaging and storage... and determine the locations to which all product has been shipped. Testing the plan will quickly point out any shortcomings, which can then be revised to work better in case of a real emergency.

The date and results of each mock recall should be documented in writing. If you modified your Recall Plan based on the results, this should also be noted.

Resources

- [University of Florida - Food Science & Human Nutrition, Food Recall Manual](#)

8. Allergen Control

Tree nuts are among the eight 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 and even fatal. The FDA list of eight most allergenic foods includes:

Peanuts	Tree Nuts
Eggs	Wheat
Dairy Products	Soy
Fish	Shellfish (Crustaceans)

Even if a person is not allergic to almonds, he or she may be allergic to other types of nuts. Therefore, it is very important for handlers to ensure that no other nuts--even in small amounts--are processed with or come in contact with almonds. Whenever possible other nuts should NOT be processed in almond plants, particularly if using almond processing equipment. This safety measure will minimize cross-contamination of your almonds.

Allergen control program elements

- 1 Identify and isolate any allergenic products in your processing facility.
 - Clearly label allergenic products (use bold lettering and color coded labels).
 - Designate specific areas that are clearly marked for allergen storage. Keep each allergen separate from other allergenic or non-allergenic food.
 - Utilize dedicated bulk storage containers or use poly bin liners that are discarded after use with allergenic materials.
- 2 Determine process and packaging lines where allergens may be present.
 - Minimize the number of process and packaging lines allergens come into contact with.
 - Whenever possible provide barriers and

other methods of isolating lines processing allergenic materials.

- 3 Establish a cleaning and verification program for process and packaging lines after allergen presence.
 - After allergenic materials have been in contact with any processing or packaging line, a detailed cleaning of all contact surfaces must take place.
 - All visible residue must be removed and disposed of during the cleaning process.
 - After cleaning, the processing or packaging line should be inspected by a management representative to verify the effectiveness of the cleaning process.
 - It is recommended that periodically an allergen antibody test be performed on the processing line after cleaning to verify the effectiveness of the cleaning process.
- 4 Document all cleaning and verification activity.
 - Carefully account for all allergens and products containing allergens.
 - All cleaning and verification activities must be recorded and retained as proof that allergenic material was removed from the line before the line was used again for non-allergenic processing.
- 5 Train all employees on Allergen Control Program. Allergen contamination control is a key component of an effective Good Manufacturing Practice program. As such, all employees are to receive training at the time of employment and annually thereafter. A record of each training session must be maintained.

Resources (Located under “Regulations and Guidelines”)

- [Food Allergy Issues Alliance - Food Allergen Labeling Guidelines](#)
- [Food and Drug Administration - Statement of Policy for Labeling and Preventing Cross-](#)

Good Manufacturing Practices



contact of Common Food Allergens, Guide to Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients

- Food Allergy and Safe Nut Processing available at <http://ianrhome.unl.edu/treenuts> This webinar is intended to increase knowledge about the seriousness of tree nut allergy by discussing methods of allergen control that can prevent inadvertent exposure and reduce food safety hazards in the food supply.
- FAAN www.foodallergy.org
- FAARP www.farrp.org

9. Quality Control

Grower Certification

Work with growers to ensure on-farm food quality and safety programs and GAPs are implemented. GMPs are more effective when growers have implemented on-farm food quality and safety programs. Growers who utilize safe and effective agricultural practices will minimize the potential for food safety contamination in the field and ultimately at the processing facility.

Verify grower's quality and GAP programs through written documentation and on-site inspection.

- Survey your growers to determine the level of GAPs in use.
- Maintain a copy of the survey or the grower's GAP program.
- Conduct on-site inspections to verify that growers are utilizing GAPs. You can have your own GMP manager do the inspection or hire a third party.
- Have each grower sign a Grower Agreement (Appendix page 10). This agreement should outline 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, farm animals, and domestic pets out of the orchard as much as possible.

References (Located under "Regulations and Guidelines")

- Food and Drug Administration - 21 CFR 110.80(a)(2)-(4) (Raw materials)

Product hold and release

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 (QC) Department. Each department should notify QC personnel of any "HOLDS" and prepare the tags for the product. HOLDS should be clearly labeled (e.g., with a red "HOLD" tag) on the containers or pallets (Appendix page 12).

All incoming product to 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 do not 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 (Appendix page 12).

Procedures for "HOLDS"

- HOLD notices are completed with all necessary information. The HOLD notice is issued to all departments involved.
- The product on hold will be labeled with a completed HOLD tag and the lot number will be recorded.
- Product pallets will be removed to the HOLD area pending disposition.

Good Manufacturing Practices

- Disposition of the product will be determined by senior management or the QC Manager.
- HOLD tags may only be removed by QC personnel.
- All HOLD tags must be accounted for by QC.

Grading and Inspection

USDA inspection and grading of incoming almonds is mandatory and must be conducted by USDA licensed inspectors. Grading and certification of finished packed almonds varies by handler.

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 stated standards if there are claims on invoices, product labels or advertising as to the grade of the final product. Maintain files of your plant's grading and inspection forms for review by customers and government agencies.

Resources (Located under "Regulations and Guidelines")

- Food and Drug Administration - 21 CFR 110.80(a)(1) (Raw materials inspection)
- US Department of Agriculture - US Standards for Grades of Shelled Almonds, reprinted 3/24/97, US Standards for Grades of Almonds in the Shell, reprinted 3/24/97

Net weight control

Labels must accurately state 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, negatively regard under weights. Over weights can result in a loss of income. An effective GMP program includes a well-managed net-weight

control plan. Sample Control Chart for Weights form in Appendix (page 13).

Institute a program of random sampling to ensure labeled net weight reflects actual net weight. Document the weights of all random samples. When a discrepancy occurs, document the corrective action taken.

Resources (Located under "Regulations and Guidelines")

- Food and Drug Administration - 21 CFR 101.105(g) (accurate quantity), and 21 CFR 101.105 (q) (quantity variation)

10. Food Security

Food products have been identified as subject to risk of tampering or criminal or terrorist actions. All food processors – including almond processors – are responsible for the protection of all food products produced and warehoused in their facilities.

The preventive measures listed below are relevant to all sectors of the food system, including farms, transportation, processing, packing and warehouse facilities.

The FDA guidelines are divided into seven sections. Not all seven sections may be appropriate for every almond operation. To determine which sections may apply, an Operational Risk Management (ORM) assessment may be useful. ORM guidelines can be found on the FDA website (www.cfsan.fda.gov).

FDA Food Security Preventive Measures Guidance Summary

Management of food security

- *Security procedures* – Assign responsibility for security to qualified people. Encourage all employees to be on the alert and immediately report any signs of product tampering or other unusual situations.
- *Investigation of suspicious activity* – When suspicious activity is observed or reported, management should immediately initiate an investigation of the incident. Should criminal activity be suspected, alert local law enforcement.
- *Supervision* – Provide an appropriate level of supervision for all employees at all times. Conduct routine security checks with focus on product or equipment tampering.
- *Mail/Packages* – Secure incoming mail and packages. Be alert to any signs of tampering.

Physical facility

- *Visitor control* – Restrict access to your facility – especially food processing, packaging and warehouse areas. Screen incoming and outgoing vehicles for suspicious or inappropriate activity or cargo.
- *Physical security* – Use fencing or other barriers to control access to facility. Keep gates and doors locked whenever possible. Use security patrols or video surveillance where appropriate. Provide adequate lighting of perimeter area.
- *Laboratory safety* – Restrict access, keep lab materials in the lab and away from production areas, secure and account for sensitive materials,
- *Storage and use of hazardous chemicals* – Isolate and secure all hazardous chemicals. Limit access to hazardous storage materials and storage areas. Account for all hazardous materials and investigate losses or irregularities.

Employees

- *Pre-hiring screening* – Screen employees and conduct criminal background checks for all employees including seasonal, temporary and contract employees. Check immigration status when appropriate.
- *Daily work assignments* – Know who is working and where.
- *Identification* – Establish a system of positive identification such as photo ID badges. Collect ID badges when an employee is terminated either voluntarily or involuntarily.
- *Restricted access* – Control and restrict access to production areas, allowing only personnel necessary to perform a job or function.
- *Personal items* – Restrict all personal items from the processing facility

Good Manufacturing Practices

- *Training* – Train all employees in food security at time of employment and periodically thereafter
- *Unusual behavior* – Watch for any employee behavior that is out of the ordinary.

Computer systems

- *Restrict access to computer system and protect with password or other methods.* Backup computer data and use a system that traces critical computer transactions.

Raw material and packaging

- *Use only known and qualified suppliers.* Inspect incoming materials for any signs of tampering.

Operations

- *Water security* – Test for potability regularly, secure wells, storage and handling facilities.
- *Plant air security* – Secure access to facility air intake points.

Finished Products

- *Finished product security* – Keep track of finished products. Lock and seal vehicles used to transport finished products.

Resources

Food and Drug Administration (21 CFR 10.115; 65FR 56468; September 19, 2000)