CHAPTER 7

GOOD MANUFACTURING PRACTICES
AND
INDUSTRY BEST PRACTICES

FOR

PEANUT PRODUCT MANUFACTURERS

Revised 2016

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Sections from the Grocery Manufacturers Association's
Guide for Control of *Salmonella* in Low Moisture Foods, Feb. 4, 2009
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DEFINITION OF TERMS:

Adulterated - food manufactured under such conditions that it is unfit for food or prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Aflatoxin - a naturally occurring mycotoxin that is produced by many species of Aspergillus, a fungus, which are toxic and carcinogenic.

Allergen - a substance that causes an inappropriate and sometimes harmful response of the immune system in at least some individuals.

ATP Test - a technique used to monitor overall hygiene levels

A_w - Water Activity, a unit of measure reflecting the amount of moisture that is readily available for the metabolic activity of microorganisms.

Buffer/Vestibule Area - a separated area set aside for appropriate hygiene procedures prior to entering a controlled area.

CCP - Critical Control Point, a step in a process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

COA - Certificate of Analysis, a document that reports and attests to the quality of a material or product.

D-value - the time required at a certain temperature to kill 90% of the organisms being studied.

FDCA - the United States Federal Food, Drug, and Cosmetic Act

GMA - Grocery Manufacturers Association

GMP - Good Manufacturing Practices, often refers to the United States Good Manufacturing Practices, which are regulations promulgated by the U.S. Food and Drug Administration covering the manufacture of food, drugs, and cosmetics. The term is also used to describe a set of practices for specific industries.

HACCP - Hazard Analysis and Critical Control Point, a systematic approach to food safety

Hazard - a potential physical, microbiological, or chemical problem with a food that could have a negative impact on human health if consumed.

Hygiene - a condition promoting sanitary practices and cleanliness.

ICMSF - International Commission on Microbiological Specifications for Foods

Log Reduction - The log reduction is given in base 10 (i.e. multiples of 10), and refers to killing target microorganisms in increments of ten. One log is 10^1 or 10 bacteria cells per

gram; two log is 10^2 or 100 cells per gram; three log is 10^3 or 1000 cells per gram and so on. So reducing by one log if you start with say 10^3 cells you would end up with 10^2 cells (1000 reduced to 100). In other words, a 3 – log population equals 1,000 cells of the bacteria per gram of food. If one log is killed, the new population equals 100 cells / gram of materials, and the log reduction equals one. Thus, a six – log reduction means starting with a population of one million cells per gram, and killing all of them.

NACMCF - National Advisory Committee on Microbiological Criteria for Foods

Pheromone - a chemical secreted by an animal, especially an insect that influences the behavior or development of others of the same species, often used in traps to attract and remove pests.

Prerequisite Programs - a range of programs necessary to set the stage for HACCP -based systems.

PCA - Product Contact Surface

PSCA - Primary Salmonella Control Area Sanitize - adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Surrogate - a non-pathogenic microorganism used in process validation studies, which has at least the same treatment resistance and the organism being studied.

Tempering - a process of gradually raising the temperature of stored materials in order to prevent the formation of condensates on the material or in the containers.

Z-value - the temperature change that is required to effect a 10 fold (1 log cycle) change in the D Value.

INTRODUCTION

While the United States continues to enjoy one of the safest food supplies in the world, events over the last several years emphasize the importance of a comprehensive food safety program for every peanut product manufacturer. Consumption patterns for peanut products have shown widespread popularity from the very young to consumers of advanced years. Recently two major outbreaks of food borne illness have been associated with peanut products. Consumers continue to be concerned with potential cross contact allergen risks associated with peanut product manufacturing facilities. Peanuts are also exposed to mold that must be controlled to eliminate the production of aflatoxin above the regulatory performance standard. It is important that the potential source for any foodborne illness be eliminated through a deliberate and structured approach of risk evaluation, management, and control. This revised document seeks to provide the practices needed to establish a program that meets the needs of manufacturers of peanut products in preventing problems in these and other very important food safety areas. Consumers must be confident that every effort has been made to provide safe and wholesome products to the marketplace. The industry has a moral and legal responsibility to provide safe products and well-trained employees who follow the practices that result in safe products.

The consumer, by nature, and the FDA, by law, will hold the manufacturer totally accountable for the safety of manufactured products. Consequently, the manufacturer is expected to know the official federal and state regulations and industry requirements and guidelines that apply to purchasing, processing and product testing practices. The pertinent up-to-date information contained in this Code will help the manufacturer operate with the knowledge to produce safe wholesome products.

The Code of Federal Regulations PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD, describes some of the basics for any food safety program. The objective of the GMP regulations is to describe general rules for maintaining sanitary conditions that must be followed by all food processing facilities to ensure that statutory requirements are met.[1] These are the practices that the United States government has determined must be followed in order to produce food that is not considered adulterated or unfit for consumption. In the GMP document, terms "shall" and "should" are used in the text of these regulations. "Shall" is used to state mandatory requirements and "should" is used to state recommended or advisory procedures or identify recommended equipment. The revised document below describes good manufacturing practices with particular emphasis on conditions related to a peanut processor.

[1] Section 402 (a)(3) specifies that food may be adulterated if it has been manufactured under such conditions that it is unfit for consumption.
Section 402 (a)(4) considers that food may be adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.

This document also includes details of how to control the risks associated with microbiological hazards, particularly *Salmonella*, chemical hazards including Aflatoxin, and physical hazards such as foreign material. Hazard analysis and prevention will be emphasized over inspection. It is assumed that sufficient information will be developed about all phases of a peanut processing operation so that potential food safety problems can be identified. It is essential that procedures be in place using the best practices outlined in this document to manage any potential issue and prevent a product from becoming unsafe to consume and in violation of regulations designed to protect the consumer. Food safety must be built into the entire processing system as opposed t trying to correct deficiencies afterward.

Permission has been given by the Grocery Manufacturers Association to incorporate information from their document entitled Guide for Control of *Salmonella* in Low Moisture Foods throughout this document. The American Peanut Council (APC) expresses its sincere gratitude for this consideration. Readers can access references from this material in that document which can be found at
http://www.gmaonline.org/science/*Salmonella*ControlGuidance.pdf.
Where the American Peanut Council has modified any GMA information, the text has been bolded. The intent of any such modification is to supplement GMA information with APC's perspective and not to contradict any GMA position. Any GMA text that has been omitted includes a bolded statement to that effect.

GOOD MANUFACTURING PRACTICES

Personnel Practices

Personnel and their practices can affect the safety of the foods they handle. Through training and monitoring employee practices, the potential for the contamination of foods can be controlled. Managers of food operations have the responsibility for assuring that all personnel comply with this part of the GMPs. To accomplish this, management has been given the responsibility of training personnel in food protection principles and food handling techniques. A written training program should be established, routinely evaluated, and updated as necessary. Training must be applied as stringently to temporary personnel as with permanent employees. Contract service personnel must be trained in quality and food safety. .

There are several personnel practices with which peanut processors should be concerned:

- Disease Control - Personnel with contagious illnesses, open lesions, boils, sores, infected wounds, or any other abnormal source of microbial contamination that could contaminate foods or food contact surfaces with microorganisms should be excluded from areas where contamination may occur. This includes areas where they would contact food, food contact surfaces, or packaging materials. In some instances, e.g. norovirus infection, workers should be excluded from the entire facility. Personnel should be instructed to report such conditions to their supervisor until the condition is corrected. Personnel should also be instructed to report any exposure outside of the workplace that would pose a risk to the work environment. A comprehensive health policy outlining employee restrictions should be developed by each organization.

- Cleanliness - (a) Employees need to wear clean garments that are suitable for their activities. (b) clean footwear should be appropriate for the work environment and available for use in production areas (c) uniforms where provided should be maintained and cleaned on a regular schedule (d) it should be assured that any outside clothing be clean and sanitary if allowed in production areas (e) personal cleanliness needs to be maintained by washing hands prior to work, when hands are soiled, after eating, and after using restrooms.

- Jewelry or other objects that are insecure (such as objects in shirt pockets, necklaces, earrings, etc.) need to be removed. Hand jewelry can be a source of microorganisms or a source of foreign material (such as when stone settings come loose) and should not be worn where peanuts are processed.

- Effective hair covering and beard covering should be worn where products, food contact surfaces, and packaging materials are exposed. Mustaches may also be required to be covered.

- Foods, chewing gum, beverages, tobacco products, medicine, coins, and like products need to be confined to areas such as break rooms, offices, or other designated areas of the facility so as to prevent product contamination. Lockers or other isolated storage areas should be provided for workers to store personal items.

- Precautions should be taken to prevent contamination from foreign substances including, but not limited to, perspiration, cosmetics, chemicals, fingernail polish, and medicines applied to the skin.

- Education and training - Personnel responsible for identifying sanitary failures or food contamination should have training, education, experience, or a combination thereof, to provide the level of competency necessary for production of clean, safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices. Special training should take place on food allergy and for the need for special care to prevent cross contamination/mislabeling. All training that is conducted should be documented for each worker, and be designed to meet all federal, state, and local requirements. This training should apply to temporary and contract workers as well as permanent employees. See Establishing a Training Program below.

- Each worker's responsibility and accountability should be documented in a clearly understandable manner as to job expectations.

- Personnel practices should be monitored through internal audits.

- Visitors should follow the same rules as employees and be so instructed when entering a facility.

- No glass should be allowed inside a production area.

- Only impermeable gloves should be used and be kept clean and sanitary during use. It is recommended that they be changed every 2 hours with proper hand washing at time of change.

- Cross contamination between 'dirty' and clean areas should be strictly controlled through segregation of equipment and personnel.

Establishing 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, but it reduces the potential for contaminating peanuts, which, if 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. 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 updates or follow-up training sessions may be needed.

Educate workers on the importance of proper hand washing techniques

Thorough hand washing before commencing work and after using the restroom is very important. Employees must wash and dry their hands before working with peanuts. Any employees having contact with food should also wash and dry 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. Do not 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 eight-step process:
1. Wet hands with clean warm or hot water

2. Apply soap
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
7. Sanitize hands with an appropriate sanitizer (e.g. no touch dispensing systems).
8. Dry hands

Building and Facilities

Plants and Grounds

To comply with the GMPs, all food processing and storage operations should be designed to facilitate maintenance and sanitation operations. This includes the exterior of the operation, the structure of the building, and the interior facilities. Plant and grounds schematics should be available and up to date. Process flow charts are also helpful to have available.

- Exterior Grounds - The exterior grounds around a peanut operation need to be maintained so as not to be a pest harborage or a source of contamination, such as dust, dirt, or water. Pests around the exterior of buildings may be controlled by frequently cutting weeds and grasses, maintaining waste disposal areas, eliminating standing water, using shrubs and trees that do not attract insects and birds, and properly storing idle equipment and parts that are left outside away from manufacturing buildings.

  Roads, parking lots, and yard areas need to be maintained so as not to be a source of airborne dirt or other contamination that could enter the operation, or a source of mud that could be tracked into the facility.

  Provide for "no vegetation" strips around the exterior building walls and cover the strip with crushed stone or similar material.

  Routine inspections or audits should be made and documented with all necessary corrections.

- Facility Construction - Buildings that house food operations should be of suitable size, design, and construction to allow the operations to be conducted in such a manner that food safety will not be compromised. To fulfill this, the facility needs to:

  1. Be of sufficient size to adequately move equipment in the course of production, maintenance and sanitation activities. Storage areas need to be of suitable size to facilitate good housekeeping practices.

  2. Be designed to reduce the potential contamination of foods, food-contact surfaces, and food packaging materials. Examples of ways to accomplish these are: Enclosing systems, physical separation (walls or space), logical traffic flow patterns, appropriate air flow such as positive pressure in finished product area, line covers, adequate interior and exterior lighting, etc.

  3. Be designed to control condensate, leaks or drippage from walls, ceilings, pipes, ducts, and roofs especially over product zones. Be designed to control water from any source in production areas in order to prevent the risk of *Salmonella* growth and potential product contamination.

4. Eliminate or protect (enclose) glass in lighting fixtures, skylights, insect light traps, etc. while providing adequate lighting to maintain an acceptable level of sanitation.

5. Be constructed with materials and in a manner that will allow walls, ceilings, and floors to be adequately cleaned and kept in good repair.

6. Provide adequate ventilation to control fumes such as from roasters and odors such as in trash disposal rooms.

Sanitary Operations

- General Maintenance – Buildings, fixtures, and other physical facilities of the plant should be maintained in a sanitary condition and kept in repair sufficient to prevent food from becoming adulterated within the meaning of the Federal Food Drug and Cosmetic Act.

- Storage of substances used in cleaning and sanitizing toxic materials – The only toxic materials allowed in a food plant are those necessary for use in the plant (e.g., for cleaning, pest control, and equipment maintenance, or for use in lab testing procedures or the plant's operations). The ways in which toxic substances must be labeled and stored also are specified in the FDCA and other state and federal regulations.

- Sanitation of food contact surfaces – All food contact surfaces should be cleaned as frequently as necessary to protect against contamination of food. Chemicals used on food contact surfaces must be food grade. When choosing sanitizing agents appropriate experts should be consulted to identify the most effective sanitizers for each purpose and to learn how they are applied.

- Special attention should be applied to portable equipment such as stepladders and fans that they are properly cleaned and sanitized before use.

- Workers should be properly trained in the use of sanitizing agents.

- Proper disposal of containers should be documented.

- Material Safety Data Sheets (MSDS) should be available for all chemicals used.

- On the following pages are sanitation best practices from the Grocery Manufacturers Association (GMA) Guide for Control of *Salmonella* in Low Moisture Foods, February 4 2009, found on page 26, bullets 2 through end of page 32 and pages 38 through 44. Please note that PSCA stands for Primary *Salmonella* Control Area, which GMA suggests as an area for specific attention for control of *Salmonella*.

- Establish a master sanitation schedule to assure timely and effective sanitation for the basic GMP and transitional areas (if one is established).
  - Use wet or dry cleaning procedures as appropriate.
  - Dry cleaning involves the use of tools such as vacuum cleaners, brooms, and brushes. Dry cleaning in the basic GMP and transitional areas may be followed by a wet cleaning as appropriate.
  - To be effective, a wet cleaning should include complete cleaning and sanitizing cycles (for equipment, etc.). Partial wet cleaning without sanitizing should be avoided because a sanitizing step is critical to inactivate microorganisms after cleaning. Whenever water is introduced into the facility, thorough cleaning must be followed by sanitizing and drying as appropriate.

- Establish appropriate cleaning and hygiene procedures for the PSCA and the buffer/vestibule area at the entrance to the PSCA.
  - Use dry cleaning as the routine cleaning practices in the PSCA.
  - Use dry cleaning and controlled wet cleaning **(see Table 4-1 later in this document)** for the buffer/vestibule area leading to the PSCA. Keep the area as dry as possible.
  - Keep the PSCA dry, including floors, ceilings, equipment, products, and all other objects in the area. It is preferred that no drains are installed in this area; if there are drains the floor surrounding them should be properly sloped for drainage and kept dry under normal conditions.
  - Maintain the PSCA to avoid cracked or damaged floors, hollow unsealed objects and poorly installed equipment.
  - Keep the air used in the PSCA dry, including air entering the area and used to dry the product. If compressed air is used, steps should be taken to continuously dry the air, as moisture may be trapped in the compressed air.

- Product accumulation (i.e., on walls, ceilings, conveyor belts, lids and walls of batch tanks or mixing tanks, and the bottom of a bucket elevator) should be removed in a timely fashion through routine housekeeping. This is particularly important for products that are hygroscopic or in environments of high humidity leading to moisture absorption and localized condensation.
  - Poor equipment design may lead to residue accumulation and should be corrected to eliminate the problem where feasible (see more discussion in Element 3).
- An example of steps for implementing barriers and other controls in the PSCA is shown in Table 2-2. All or some of these steps may be used as appropriate, depending on the product and process.

Table 2-2. Example of steps for implementation of barriers and other controls to maintain enhanced stringency of hygiene in the Primary *Salmonella* Control Area (PSCA)

Step 1	• Form a multidisciplinary team.
Step 2	• Define different areas within the facility in relation to hygienic requirements (e.g., PSCA, basic GMP area, transitional area). Establish required level of product protection using a hazard analysis or a risk assessment approach. The first priority is to prevent product contact surface contamination with *Salmonella*. • Map all circulation of people, incoming materials, waste, rework, etc. on a flow chart. Access to the PSCA should be limited to essential persons or activities only. • Establish barriers where appropriate and clearly define their purpose. Barriers should be acceptable and practical for all persons who enter the area regularly or for specific purposes (e.g., sampling, maintenance, etc.) • Take into consideration elements such as drainage and floor slopes; drainage and equipment positions; personnel and material routes; rework handling; storage of spare parts, maintenance tools and cleaning equipment; fire protection devices; conveyors; Clean-In-Place circuits; waste collection; air conditioning; air handling system; etc.
Step 3	• Define construction and equipment design standards to meet hygiene requirements. • Protect the PSCA during equipment installation to ensure that uncontrolled items/personnel and potential contaminants of concern cannot pass.
Step 4	• Establish routine procedures that describe what can and cannot pass the barriers and procedures for passing them. • Establish procedures to monitor and document barrier efficiency. • Establish procedures for maintenance, including routine and unscheduled maintenance.
Step 5	• Establish a master sanitation schedule to assure timely and effective sanitation of equipment and the processing environment.
Step 6	• Train all personnel who enter the PSCA and others concerned about the barriers and procedures, their purpose, use and maintenance. Retrain operators as often as necessary to maintain sanitary practices.

(Continued from page 10)

Pest Control

Pests should be prevented from entering any area of a food plant. The term, *pests*, can be interpreted to mean rodents, insects, birds, or other types of animals. Many of these pests are capable of movement and it is essential that an effective pest control program be developed and implemented to prevent pest problems from developing.

To accomplish this, an effective documented program to prevent pest entry into a building is needed. Within the building, prevention programs such a trapping, elimination of harborage locations, using pesticides in accordance with labeling directions, and monitoring the pest control devices will help to insure compliance.

Recommended elements of an effective pest control program are as follows:

- Ensure all exterior doors are weather stripped and maintained on a continuing program. Keep exterior doors closed when not in use. Install automatic closures on exterior doors.
- Maintain adequate surface drainage.
- Windows should be properly screened.
- Exhaust fan louvers should be installed and maintained.
- Ensure that pesticides and other toxic chemicals are properly stored (under lock and key), handled, marked and used according to all federal, state and local regulations. Permit their use only by properly trained and certified personnel.
- Use tamper-proof, covered bait stations of a type and location to minimize spillage. Utilize bait stations for exterior use only; space such stations at approximately 50-foot intervals; use mechanical traps for interior spaces and place at 25-foot intervals along walls. Monitor mechanical devices at least weekly and bait stations at least monthly.
- Pheromone traps may be used for monitoring purposes.
- All rodent devices should be numbered and the service date listed on inside cover, where applicable. A map of exact locations of these devices should be kept current and on file.
- Document all insecticide treatments to include date, operator (license), compound, concentration of active ingredient(s), amount used, where used (specifically), and how applied (specifically).
- Written inspection/service reports should be submitted after each service call and kept on file.
- Keep on file specimen labels and Material Safety Data Sheets on all pesticides used.
- Maintain 18-inch inspection zone between wall/floor junctions and goods/items in storage.

- Monitor effectiveness of outside service on a scheduled basis to check for: rodent burrows in nearby grounds; activity at floor/wall junctions and doorways; evidence of insect activity

- Exterior grounds should be kept well maintained including minimal use of shrubs, ivy, and other plants, frequent grass mowing, free from debris and stored materials near walls of the facility and any other objects that could be used to harbor pests. An inert barrier next to exterior walls is recommended.

- Where feasible, seal load levelers at docks to prevent trash accumulations and rodent harborage and entry. Load levelers pits should be cleaned regularly,

- Look for insect activity in long- term supply and stock storage areas.

- Use black light, supplemented with means for distinguishing from other chemicals that fluoresce, to check for rodent urine stains.

- Establish effective audit and training programs.

- Locate processing plants away from livestock and poultry operations. Processing plants in the vicinity of livestock and poultry operations are especially vulnerable to pathogen contamination by pests. Studies have revealed that pests such as rodents, insects and birds have much higher rates of carriage of food borne pathogens such as *Salmonella* and *Campylobacter* when in the vicinity of live animal operations than those living in areas removed from livestock operations.

Sanitary Facilities and Control

Food plants should be equipped with adequate sanitary facilities and accommodations. Several of the sanitary facilities that are required are included but not limited to the following:

- A sufficient water supply of adequate sanitary quality and temperatures to meet the needs of processing, cleaning, and employee sanitary requirements.

- Plumbing must carry sufficient quantities of water throughout the operation and properly convey sewage and liquid waste from the facility. Backflow prevention into sanitary water systems must be provided. Cross connections between discharge wastewater or sewage and sanitary water are not permitted. Avoid as a source of contamination to food, water, supplies, equipment or creating an unsanitary condition.

- Toilet facilities need to be accessible, of adequate number, and maintained in a sanitary condition. Reminders for hand washing after toilet use should be prominently posted in each facility.

- Hand wash stations need to be located in production areas so employees can conveniently wash their hands. The hand wash stations need to be supplied with water at a suitable temperature. Antibacterial soap with an E2 rating in a sanitary dispenser, and sanitary

hand towels should be readily available. A trash receptacle should be provided for disposal of used towels. Care should be taken that water does not carry over into critical dry areas from hand washing activities.

- Trash and production waste are to be handled and transported in a manner that will not be a source of contamination or an attractant to pests.

- Equipment and Utensils - Equipment design, construction, installation and maintenance must contribute to cleanliness and non-contamination of products. Utensils should be designed for adequate cleaning and minimum potential for product contamination.

- Food contact surfaces and utensils should be corrosion resistant, non-toxic, cleanable, and capable of withstanding the production environment.

- Protection should be provided where there is potential of indirect contamination of food-contact surfaces. For example, a cover may be needed over a conveyor moving open containers.

- Seams in food-contact surfaces of equipment need to be continuous and smooth to minimize the potential for food contamination.

- Freezers and refrigerated rooms need calibrated thermometers (non glass) or temperature recording devices in refrigerated rooms or compartments. Refrigerated storage rooms should be provided with humidity recorders.

- Compressed air or other gases that are introduced into foods or onto product contact surfaces can be a source of contamination with water, oil, or microorganisms. Adequate safeguards should be applied to avoid potential contamination.

Equipment

Peanuts are constantly in contact with the surfaces and utensils in the facility. General sanitation practices are listed below. Sanitary design principles for equipment are found on following pages as outlined by AMI in GMA's Control of *Salmonella* in Low Moisture Foods, February 4, 2009 pages 36-37.

- All peanut contact surfaces should be made of non-toxic materials, appropriate to their use, resistant to deterioration by cleaning and sanitizing agents and materials that can be easily cleaned and maintained.
- Equipment and utensils should be designed so as to provide access for cleaning and be cleanable.
- Equipment should 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.
- All cold storage facilities in the plant should 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.
- If compressed gases are used in the facility, a certificate of purity should be obtained

from the vendor and kept on file

- Develop a preventative maintenance program for equipment, utensils and plant infrastructure to ensure that all are properly maintained in order to avoid potential contamination of product and maximize efficiency. A preventative maintenance program should include a list of all equipment and 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.
- 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, results and certification that calibration has been performed against a certified standard.
- Seams and welds on equipment must be smooth so as to prevent contamination.
- Forklift control. It is highly recommended that an area be dedicated to forklifts. If forklifts must be used both outside and inside a processing facility or go between the raw and processed locations in a plant, they must be thoroughly cleaned and disinfected.

Production and Process Controls

Raw Materials

All arriving vehicles carrying raw materials (including ingredients and packaging) should be inspected:

- Ensure all transporting vehicles used for peanuts are not used for chemicals, livestock, waste products, or other contaminants.

- Examine all incoming vehicles carefully to determine if doors, hatches, and seals are intact and no evidence of tampering exists.

- Record the seal numbers of the doors and hatches prior to their removal. Note any broken or damaged seals and report such findings to the carrier and shipper.

- Upon opening and prior to unloading of the product, examine the exposed interior of the container for evidence of any potential contaminants and adulterants including but not limited to non-peanut food allergens, insects, rodent, mold or undesirable odors. Continue this examination during the entire unloading operation.

- Check for rodent activity evidenced by droppings and urine stains. Use of "black light" is recommended to find urine stains on containers, in vehicles or on contents.

- Ensure materials from cold storage are inspected for evidence of improper "tempering" (mold, mildew, dampness). If evidence of moisture is noted, perform microbiological assays to assure safety, as needed.

- Ensure each shipment of peanuts or other raw nut products arrive with a grade certificate or certificate of analysis, if required.

- All sensitive ingredients (known to potentially be contaminated with Salmonella, including peanuts and other nut meats) should be sampled and tested prior to use. Aflatoxin, moisture, grade and microbiological testing (where cross contamination potential exists) are inspections

and tests that may be applied. Approved AOAC testing methods should be used.

In the event contaminants and/or adulterants are noted

- Notify carrier to make an inspection and provide an inspection report.
- Notify shipper for disposition.

- Where the shipment contains damage or material that could lead to contamination of the receiver's establishment, do not permit the product to enter the building; in other cases, separate damaged or contaminated product from the remainder of the load.
- Keep a record indicating the type and disposition of damaged, adulterated, and deteriorated product, and of the vehicle. Photographs may be useful in providing documentation.
- Additional best practices are listed below from GMA's guide for Control of *Salmonella* in Low Moisture Foods, February 4 2009. (Bullets 3 and 4 on page 19, and Establishing a Raw Material/Ingredients Control Program beginning on page 45.)

- Establish controls to segregate ingredients known to be contaminated with *Salmonella* such as raw nuts, flour, baker's yeast, spices, raw cocoa beans, grains, and meat and bone meals. Establish a supplier control prerequisite program to review and approve (raw) material suppliers. For ingredients that will be added to the finished product without a further inactivation step, more controls may be necessary, and these are elaborated in Element 5.
- Prevent or minimize cross contamination through procedures and activities such as the following:

    - Raw or unprocessed foods should be separated from processed/ready-to-use or ready-to-eat foods. Packaging materials should be protected from contamination during shipment, storage and use. Packaging should be inspected immediately prior to use to ensure that it is not contaminated or damaged.

    - Wherever possible, use dedicated forklifts, utensils, and maintenance tools for the Primary *Salmonella* Control Area (PSCA; see Element 2) or post-lethality area vs. raw or pre-lethality area.

    - Outline traffic patterns properly and ensure employee compliance through education and training.

    - Inspect pallets and trailers regularly, keep them in good repair, and not stored outside where they may be exposed to bird or pest activity.

    - Maintain the highest room air pressure in the PSCA or the post-lethality area and include the air handling system in the master sanitation schedule.

***Salmonella* Control Element 5:**
Establish a raw materials/ingredients control program.

Low-moisture products may be manufactured in a way that some ingredients are added after an inactivation step in the process or none of the ingredients are subjected to an inactivation step. For example, seasoning may be added to an extruded product after the heating step, ingredients for fortification may be added after milk pasteurization and spray drying, or products such as cold-pressed bars (e.g., nutrition bars) or dry blends may be produced by combining ingredients without an inactivation step. In order to prevent finished product contamination, it is essential not only to protect products from environmental contamination after the *Salmonella* inactivation step, but it is also essential to avoid introducing *Salmonella* from ingredients that are added without an inactivation step.

The addition of contaminated ingredients after the inactivation step has contributed to *Salmonella* contamination in finished products. For example, according to results from investigations of the 2007 *Salmonella* outbreak (CDC, 2007b) associated with children's snacks, FDA found *Salmonella* Wandsworth in the broccoli powder used for seasoning the product after the inactivation step. Product samples obtained from the processing plant also tested positive for *Salmonella* Wandsworth and *Salmonella* Typhimurium, while samples taken from the plant environment tested negative (Liang, 2008; Zink, 2007b). The manufacturer sourced ingredients from both domestic and

international suppliers. An outbreak associated with potato chips in Germany (Lehmacher et al., 1995) was traced to the use of contaminated paprika seasoning added after the inactivation step. In another instance, contaminated dried milk powder added to chocolate liquor after the *Salmonella* inactivation step (cocoa bean roasting) contributed to *Salmonella* in the finished milk chocolate. In the 2008-2009 outbreak of *Salmonella* Typhimurium attributed to peanut butter and peanut butter paste originating from a single processing plant (CDC, 2009; FDA, 2009a), the potentially contaminated peanut butter and paste were distributed to more than 70 companies for use as an ingredient in hundreds of different products, including low-moisture products such as cookies, crackers, snack bars, cereal and candies. Because the peanut butter or paste was used in many products without a further inactivation step (e.g., peanut butter crackers, peanut butter snack bars) or the inactivation step was not fully validated (such as in peanut butter cookies subjected to baking), hundreds of product recalls by dozens of companies ensued (CDC, 2009; FDA, 2009a). The latest outbreak and its cascade effects clearly illustrate the need to have knowledge about ingredient suppliers and their control programs and the need to verify that these programs are effective in controlling *Salmonella*.

FDA's inspection of the processing facility implicated as the source of the *Salmonella* Typhimurium outbreak found a number of deficiencies (FDA, 2009b), including deficiencies in GMPs (e.g., deficiencies in facility integrity and maintenance, plant construction and design, protecting equipment/containers/product against contamination, separation of raw and finished products, pest control, sanitation program) and process control (e.g., lack of validation of roasting step). Notably, FDA indicated that the plant did not clean a peanut paste line after *Salmonella* Typhimurium was isolated from the product, and continued manufacturing on the line for over three months (FDA, 2009b). FDA inspectors found that, in approximately a dozen instances, the plant released a product that initially tested positive for *Salmonella* after it was retested and found negative. Environmental samples collected by FDA inspectors at the facility tested positive for *Salmonella* Senftenberg and Mbandaka (FDA, 2009b). Such deficiencies can be uncovered by a robust supplier qualification and requalification process. Common industry practices outlined in the seven *Salmonella* control elements in this guidance may be used in evaluating whether a supplier has a comprehensive *Salmonella* control program in place.

Salmonella-sensitive ingredients are ingredients that have been historically associated with *Salmonella* (tested positive for the pathogen), have been implicated in past outbreaks, or are used to make products that are intended for at-risk individuals. When such ingredients are added to the finished product without further lethality, procedures should be in place to assure the control of *Salmonella* in these ingredients to avoid finished product contamination.

A supplier approval program should be developed to assess the adequacy of control measures the supplier has implemented for *Salmonella* control in sensitive ingredients. It is well known that the absence of *Salmonella* in sensitive ingredients, dry-mixed ingredients, or finished products cannot be assured through testing alone (FAO/WHO, 2006; EFSA, 2008). Absence of *Salmonella* cannot be assured through acceptance or rejection of a lot according to requirements stated in a specification. The supplier approval program may include initial approval of the supplier, supplier audits, periodic requalification that takes into consideration key factors such as whether the supplier conducts microbiological monitoring of their process

environment, and periodic raw material/ingredient testing upon receipt.

Common Industry Practices:

- Create a list of *Salmonella*-sensitive ingredients, with an emphasis on those that are used without a further inactivation step in the finished product. Table 5-1 shows a list of *Salmonella*-sensitive ingredients commonly used in low-moisture products.
  - Sensitive ingredients should be held under adequate hygiene conditions to avoid recontamination. Where feasible, sensitive ingredients should be stored in a segregated area.
  - Before sensitive ingredients are brought into the PSCA, procedures should be in place to minimize cross contamination from packaging materials or containers used to transport bulk ingredients. For example, removal of the outer layer of multiple-layer bags prior to bringing the bags into the PSCA may be employed.
- Obtain sensitive ingredients from an approved supplier. An approved supplier is one that can provide a high degree of assurance that *Salmonella* is not likely to occur in the ingredient through the implementation of appropriate process controls. Establish a supplier approval program to ensure the adequacy of the supplier's food safety programs. The approval program should include components such as the following.
  - Conduct an initial comprehensive audit of a supplier's food safety program.
  - Use common practices outlined in the seven elements of this guidance where applicable as a basis for supplier approval. Industry practices from the GMA's Food Supply Chain Handbook (GMA, 2008) can also be applied as appropriate.
  - Evaluate the supplier's food safety program for areas that include, but are not limited to, the following:
    - A pathogen environmental monitoring program.
    - Sanitation practices.
    - Raw materials/ingredients storage.
    - A finished product hold and release testing program.
    - Traceability.
    - Process validation.
    - A corrective action plan if positive *Salmonella* results are found, and an evaluation of the potential significance for other products or ingredients manufactured in the processing facility or on the line being evaluated.
  - Supplier approval should be specific to an individual facility or processing line.

- Supplier requalification should be conducted at a frequency based on risk. Consider that the supplier's history may not be a guarantee of future product safety and quality.

- Develop guidelines for adding and removing a supplier from the approval list based on the adequacy of their food safety program and their compliance to the program.

- Provide the supplier with ingredient specifications and ensure the supplier is in agreement with the requirements. The specification should be lot-specific and include a requirement that the lot be *Salmonella*-negative. A complete microbiological criterion (sampling plan, methodology, etc.) should be defined. ICMSF or FDA BAM sampling plans (ICMSF, 2002a; FDA, 2003 and 2007) are commonly used as part of a criterion. Samples taken should be as representative as possible of the entire production lot.

- Develop a program for testing and using sensitive ingredients to be added to products without a lethality step or ingredients added after lethality step. This is particularly important for situations involving new or unknown suppliers or where there is a lack of confidence in the supplier's *Salmonella* control program. The program should include components such as the following:

    - Wherever possible, obtain a Certificate of Analysis (COA) from the supplier that includes results of *Salmonella* testing and sample size analyzed.

    - Implement a hold and release testing program for COA verification or for ingredients that were obtained without a COA.

    - Use approved testing labs (in-house or external). Laboratory approval should evaluate the ability of the laboratory to conduct *Salmonella* tests for the food(s) of interest. It may of value to conduct this evaluation as an on-site laboratory audit. The laboratory must follow Good Laboratory Practices, which ideally should include proficiency testing (e.g., for *Salmonella* testing). Laboratories may or may not be certified (e.g., ISO 17025). These considerations should also be extended to the supplier's laboratory to ensure their COA results for sensitive ingredients are reliable.

    - The FDA BAM or an ICMSF sampling plan (e.g., cases 10-15) may be used, depending on the ingredient and the robustness of the supplier's food safety program. The frequency of sampling may vary, e.g., once every lot (such as for a new ingredient from a new and unknown supplier), once every 6 lots, or less frequently, depending on the supplier.

    - Make clear in the program that if a product sample tests positive for *Salmonella*, the tested lot is considered adulterated and it should not be released into commerce. It is important to note that retesting should not be conducted for the purpose of negating the initial test results (Rainosek, 1997; ICMSF, 2002c; see further discussion in Element 7). Conduct an evaluation of risk for *Salmonella* contamination to determine disposition of adjacent lots.

- Wherever possible, source an entire lot and strongly discourage being supplied with a split lot that has been distributed to multiple customers

or multiple manufacturing plants. (This has the potential for one company's verification test to implicate another company's products.)

- All materials being tested for *Salmonella* should remain under manufacturer's control and be released for use **only** after acceptable test results are received.

Table 5-1. Examples of *Salmonella*-sensitive ingredients used in low-moisture products*

Chocolate, chocolate liquor, cocoa powder, chocolate chips, cocoa products
Nuts/nut products
Coconuts
Seeds/seed products
Grains/grain products (excluding starches)
Dried egg products
Fruits/fruit products (excluding candied or alcohol-packed fruits, jams or jellies)
Dairy ingredients and blends
Spices/herbs (excluding extracts), blended seasonings
Soy products
Gums/thickeners (excluding xanthan gum)
Yeast/yeast extract
Gelatin
Dry vegetables
Enzymes/rennets
Dry meat or meat byproducts

* This list is not inclusive of all sensitive ingredients.

(continued from page 17)

Peanut Storage

- Raw peanuts should be stored to protect them from deterioration and possibility of contamination. Storage should be separated from other ingredients, packaging materials, in-process, and unprotected finished product to ensure against cross contamination.

- During storage, raw peanuts and other ingredients, whether in bulk or in containers, must be protected against contamination. Temperature and relative humidity need to be controlled if these materials are susceptible to extremes. Good housekeeping practices and monitoring for pest problems are important in storage areas. Particular care should be taken to prevent moisture exposure to peanuts. Roofs should be routinely inspected to prevent leaks. Any product exposed to water should be disposed of.

- Care should be taken to avoid cross contamination of food allergens during storage.

Manufacturing Operations

- All food processing and packaging operations should be conducted in a manner that minimizes the potential of microbial growth and the potential for contamination. Peanut product processors can control these through the proper cleaning and sanitizing of equipment, protecting product from foreign matter contamination and applying proper food handling practices. It may be necessary to have separate processing lines and or rooms to eliminate cross-contamination of potential food allergens.

- The FDA's Good Manufacturing Practices describe ways to avoid contamination of product by microorganisms. Roasting should destroy harmful microorganisms such as *Salmonella*. The roasting step must be validated as a kill step. Contamination after roasting must be avoided. Such control may be accomplished by physical separation of raw and processed areas and products, a positive air pressure system in areas where roasted peanuts are exposed, air filters on air intakes or circulating systems and heaters, or other effective air quality control measures. Post processing contamination can also occur as a result of using the same trucks or containers for raw or blanched and roasted peanuts. It should also be assured that in the event of process disruptions that result in any portion of the unprocessed peanut stream not being exposed to specified roasting conditions, product be removed from the process system and destroyed or reprocessed at specified conditions that have been validated to destroy harmful microorganisms. See Validation section later in this document.

- Since peanut particles or finished product left in equipment and in contact with moisture enable microorganisms to grow, proper cleaning of equipment is essential. Sealing the lines or covering them with tightly fitted plastic will protect them from water and microorganisms. A dry cleanup is recommended. However, if wet cleanup is necessary, it is desirable that equipment be moved outside the production area to a wash area where disassembly, cleaning, sanitizing and thorough drying can be accomplished. If movement of equipment is not possible care should be provided during cleanup, sanitizing and complete drying. Cracks, crevices, pipelines, corners and inaccessible areas in both the equipment and production area will accumulate microorganisms if not cleaned, sanitized

and thoroughly dried. Periodic inspection and cleaning of non-product contact equipment (air handling equipment) is also important since this equipment could be a source of contamination. If water is used in the process, e.g. for cooling, ensure the water does not leak to the peanut material as bacteria can grow from such conditions.

- Sanitizing should be done on clean surfaces only. Selection of the correct sanitizer is important. Treatment should not adversely affect the equipment, the product, or health of the consumer and should meet regulatory requirements. The concentration of sanitizer used should be monitored to insure effectiveness and that recommended concentrations are not exceeded. In all cases, assure equipment is thoroughly dry before start-up.

- Once all materials to be used in the finished product have been approved for use in production and the processing system is clean, production can proceed.
  (ATP swabs are a good tool to determine a clean line)

- Recommended Operating Procedures

  1. A raw material assurance program should be in place (see guidelines from GMA's Control of *Salmonella* in Low Moisture Foods dated February 4, 2009 earlier in this document).

  2. Manufacturers should be familiar with the American Peanut Council's Good Management Practices including the Good Agricultural Practices.

  3. Raw material storage should be physically segregated from finished product storage and should assure that no dust or particulate matter of any type be transferred from raw commodities to finished product. Separate handling equipment should be used in these areas to prevent cross contact by allergens as well as cross contamination with pathogens such as *Salmonella*. Color-coding of equipment should be considered as a means of facilitating segregation.

  4. Peanuts should be processed to ensure removal of any remaining foreign material.

  5. Bar magnets should be used to remove ferrous metal. Such devices must be cleaned of tramp metal frequently to assure functionality.

  6. Use of photoelectric equipment and handpicking are additional methods to be used to remove foreign material, damaged and immature peanuts.

  7. Hand sorting should be done in a well-lighted area with proper facilities. Personnel should be rotated on a regular basis. Operators should rigorously follow GMPs for personnel.

  8. Photoelectric equipment to detect dark or damaged peanuts more likely to contain aflatoxin should be in place and properly maintained and sensors and light sources cleaned regularly. Monitoring output from photoelectric sorters should be done regularly.

  9. Rejected peanuts from sorting should be isolated from edible peanuts.

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10. Temperature of peanuts just prior to roasting should be taken and recorded and it should be assured that initial temperature meets any requirements identified during validation of process conditions. An alarm and/or diversion mechanism should be considered for situations where required conditions are not met during processing.

11. Recording devices should be in place to record critical processing conditions including temperature and time of roasting, belt speed, and bed depth, cooling temperatures, color, and moisture.

12. All measuring and recording devices should be calibrated at appropriate intervals.

13. Records of "lots" of peanuts processed and certificates of analysis should be maintained.

14. Records of critical information should be appropriately authorized.

15. All processing steps should be validated to assure they are capable of performing the required action, including roasting of peanuts for a specified time and temperature. On following pages is the chapter from GMA's Control of *Salmonella* in Low Moisture Foods dated February 4, 2009, beginning page 50 regarding the validation of inactivation of *Salmonella*

16. Verification activities including all tests required to be performed should be carefully specified and procedures documented. Following the above referenced chapter is the chapter from GMA's Control of *Salmonella* in Low Moisture Foods dated February 4, 2009, beginning page 59 regarding the verification of *Salmonella* control.

17. USDA commodity microbiological requirements are listed in the table below:[2]

Microbiological Standards	
Salmonella	Negative
E. Coli	<3.6/g MPN
Coliform	<10/g MPN
Aerobic Plate Count	<10,000/g
Yeast	<100/gram
Mold	<100/gram

18. Special circumstances may exist for peanut butter conveyor lines composed of enclosed piping. The following corrective action may be considered to purge the piping in the event of *Salmonella* contamination:
    - Remove all residue from interior piping. Experts recommend disassembling the line, cleaning, sanitizing with peroxyacetic acid, rinsing, and then thoroughly drying all surfaces.
    - Purging lines with hot oil has been used by processors. (If this is considered, conditions of at least 61 minutes at minimum 90°C. should be used.)

[2] USDA Commodity Requirements PP11 Peanut Products for use in Domestic Programs 5/15/08.

This is based on a study yielding the following results: "42±8 min at 90 degrees C achieved a 5-log reduction of a mixture of three outbreak-associated *S.* Tennessee strains in peanut butter (49±12 min were needed to inactivate a composite of other *Salmonella* isolates). (Doyle and Ma, 2009) and more than 260 min were needed to reduce *Salmonella* by 7 log.units at 70 degrees Centigrade in peanut butter (Shacher and Yaron, 2006)."*
It is important to validate conditions chosen for this treatment procedure to assure that they are capable of inactivating Salmonella in the specific process equipment to which they are applied. Verification steps such as environmental sample testing or finished product testing should also be applied after such procedure to assure effectiveness of treatment.

* Control of *Salmonella* in Low Moisture Foods, Grocery Manufacturers Association, February 4, 2009**.**

19. A defined rework policy should be documented for the specification of handling all types of rework (i.e. roaster, grinder, finished product, etc.).

20. All finished products must be identified by a lot or code number. A lot as defined by the Confectionery and Cacao Products GMP 118.C is (revised per 21 CFR 110):

    "A collection of primary containers of units of the same size, type and style containing finished product produced under conditions as nearly uniform as possible, designated by a common container code or marking, and in any event, not more than a day's production."

    It is suggested a lot I.D. include the plant, product, line, batch number, date, time (hh.mm.ss).

21. It is recommended that finished product lots be identifiable with raw peanut lots wherever possible. Appropriate production and shipping records are necessary to facilitate location of finished products in the trade if recovery of product should prove necessary. The processor is advised to prepare or use a recall program such as those recommended by the GMA.

22. Where practical, consideration should be given to a clean break for materials that are bulk stored or in-process components that are continuously processed. This is done in order to determine intervals where this component or material has a definable break in the sequence of storage or manufacturing and is therefore traceable. The effectiveness of the separation method should be validated and verifiable. A sanitizing step should be used where appropriate. Risk assessments based on lot size and historical environmental test data can be used to determine the time interval between breaks.

23. Clean room techniques should be used for storage of in-process ready to eat components until packaging is applied.

24. Packaged finished product should be sampled, tested, as a verification step for aflatoxin, foreign material, and microbiological contamination.

25. Packaged finished product should be properly labeled according to FDA guidelines reflecting all ingredients used in descending order. It is important that products containing peanuts be labeled properly due to the potential for allergic reaction. Methods for clearly identifying shipping units that contained mixed lots should be in place.

26. Metal detectors are recommended for finished lots to assure absence of metal. Test and calibration procedures should be documented and recorded. Rejects should be investigated.

***Salmonella* Control Element 6:**
Validate control measures to inactivate *Salmonella*.

When a lethality step is needed to inactivate *Salmonella* in a low-moisture product or ingredient, the processing parameters used should be adequate to inactivate the level of the organism likely to be present. According to the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), validation encompasses collecting and evaluating scientific data and technical information to demonstrate that the control measures and associated critical limits at the lethality step, when followed, will result in a safe product (NACMCF, 1998). In addition, it is necessary to demonstrate that the chosen control measure and critical limits can be applied in production at a critical control point. Validation of lethality steps for low-moisture foods involves determining an appropriate log reduction for *Salmonella*, determining the critical limits in the process required to achieve the reduction, and confirming the process equipment consistently delivers the critical limit parameters in the operation (NACMCF, 1998; Scott et al., 2006).

In general, NACMCF's definition for pasteurization (NACMCF, 2006) can be used to guide the determination of an appropriate level of log reduction. With respect to a low-moisture product, NACMCF's definition translates into applying any process, treatment, or combination thereof, to reduce the most resistant *Salmonella* serotype to a level that is not likely to present a public health risk under normal conditions of distribution and storage. NACMCF also indicated that a control measure aimed at inactivating the target pathogen does not protect the consumer if the product is subsequently decontaminated during manufacturing. The effective approach to prevent recontamination is through good hygiene practices verified by environmental monitoring (see Element 7) to ensure that recontamination is not likely to occur.

The level of reduction required will depend on the potential levels of *Salmonella*, if present, in the raw ingredients. Efforts have been made to set an appropriate level of log reduction for a specific low-moisture product based on a risk assessment. For example, a risk assessment (Danyluk et al., 2006) conducted to assess the risk of salmonellosis from almond consumption was used to determine that a 4-log reduction of *Salmonella* in raw almonds is adequate to ensure safety of the finished product (AMS, 2007). In some instances, historical knowledge is used as the basis for validation (Scott, 2005). For example, pasteurization at 72 °C for 15 sec is considered adequate to inactivate expected levels of vegetative pathogens of concern in raw milk. These parameters may be used as the critical limits or the basis to establish other process parameters as critical limits at the lethality step to inactivate *Salmonella* in the fluid milk ingredient for a dried milk product; preventing recontamination after pasteurization during drying and subsequent handling would be essential to protect the finished dried product from recontamination. Both industry guidelines (Froning et al., 2002) and FSIS regulations in 9 CFR 590.575 (CFR, 2008a) set parameters for the pasteurization of dried egg white, which include heating the product in a closed container to at least 130 °F (54.4 °C) for 7 days or longer until *Salmonella* is no longer detected (As a practical matter, the egg industry routinely uses a more severe heat treatment in order to eliminate the avian influenza virus as well as *Salmonella*).

Both thermal and non-thermal control measures can be used for *Salmonella* inactivation to achieve the target log reduction. Various processing steps

(e.g., cooking, frying, roasting, baking, heat extruding, fumigation) may be used to inactivate *Salmonella* in a low-moisture product. Thermal processing is the most commonly used control measure to inactivate *Salmonella*. For example, the Almond Board of California's Technical Expert Review Panel (ABC TERP) determined that oil roasting at or above 260 °F (126.7 °C) for 2 min will result in a 5-log reduction of *Salmonella* on the surface of whole almonds (ABC, 2007). The ABC TERP also provided minimum time and temperature combinations required for blanching processes to deliver a 4 or 5-log reduction of *Salmonella* on almonds (ABC, 2007). These parameters were determined based on heat resistance data for *Salmonella* Enteritidis PT 30 as the target organism.

It is useful to review available scientific data for the processing method of interest, including high temperature short time or low temperature long time when desirable for maintaining product quality. In order to assure appropriate validation, it is also necessary to evaluate scientific and processing equipment data and information specific to the processing technology under consideration. A process authority should be consulted where necessary. For example, the ABC TERP, which consists of experienced microbiologists and processing experts, evaluates the adequacy of various treatments to inactivate *Salmonella* in raw almonds and develops guidelines for validating individual processes, including propylene oxide (PPO) treatment for raw almond kernels, PPO treatment for in-shell almonds, blanching, oil roasting, dry roasting and other processes that may be proprietary (ABC, 2007).

Heat resistance of *Salmonella* is affected by factors during heating, as well as the *Salmonella* strains used (Harris, 2008). Heat resistance observed in an aqueous system may not be applicable to a low-moisture product. For example, a study by Ng and colleagues (1969) found that *S.* Senftenberg 775W was the most heat resistant among 300 strains evaluated in an aqueous solution, while this strain was found to be less heat resistant than *S.* Typhimurium in chocolate (Goepfert and Biggie, 1968). *S.* Enteritidis PT 30, the target organism for raw almonds, was implicated in a food borne illness outbreak and was found to be more resistant to dry heat than many of the strains evaluated on almonds (ABC, 2007; Wang, 2008).

A number of studies have been published on heat resistance of *Salmonella* in various low-moisture products (see Annex section on heat resistance). Available D- and z-values for heat resistance of various *Salmonella* strains in low-moisture matrices are shown in Table 6-1 for food matrices and in Table 6-2 for model systems. These data indicate that heat resistance in a product with low a_w is much greater than that in a high-moisture product. For example, while reaching an internal product temperature of 160 °F (71.1 °C) without a hold time would eliminate *Salmonella* in raw poultry (FSIS, 1999), the same temperature would result in little inactivation of *Salmonella* in milk chocolate, in which the D-value for *S.* Typhimurium has been reported as 816 min at 71 °C (Goepfert and Biggie, 1968).

Table 6-1 shows D-values for *Salmonella* in wheat flour (Archer et al., 1998), milk chocolate (Barrile and Cone, 1970; Goepfert and Biggie, 1968), almonds (Harris, 2008), corn flour (Van Cauwenberge et al., 1981), and dry animal feeds (Liu et al., 1969). In addition, recent research (Doyle and Ma, 2009) found that, based on the non-linear Weibull model, 42±8 min at 90 °C achieved a 5-log reduction of a mixture of three outbreak-associated *S.* Tennessee strains in peanut butter (49±12 min were needed to inactivate a composite of

other *Salmonella* isolates). Liu et al. (1969) determined the heat resistance of *S.* Senftenberg 775W in meat and bone meal and chicken starter at moisture levels from 5% to 30%, where the investigators found that the method used to prepare the inoculum (growing the cells in a laboratory medium vs. in meat and bone meal suspension) affected the heat resistance. Akinleye (1994) reported that D- and z-values were affected by water activity of a salt solution model system. D- and z-values relevant to low-moisture heat conditions from this study are shown in Table 6-2, along with data from another study using sucrose as a model system (Sumner et al., 1991). It should be noted that comparison of inactivation kinetics data from different studies can be difficult and it is crucial to review the raw data and experimental procedures, as well as the D- and z-values reported, so as to apply the data appropriately.

Heat-inactivation of *Salmonella* in low water activity matrices was found be non-linear in many cases, such as in peanut butter (Ma et al., 2008), oil-roasted almonds (Abd et al., 2008), flour (Archer et al., 1998), and in laboratory media (Mattick et al., 2001). The *Salmonella* inactivation curve in low water activity foods can be complex, often showing a concave upwards curvature, and significant tailing has been observed (Mattick et al., 2001; Harris, 2008; Marks, 2008). Thus, the rate of inactivation may not be constant throughout the heating process and caution needs to be taken when interpreting and using heat resistance data to support the adequacy of the process parameters.

In a study by Archer et al. (1998) on the heat resistance of *Salmonella* Weltevreden in wheat flour, the investigators observed that death kinetics were non-linear, with approximately a 1-log reduction in the first 5-10 minutes of heating, followed by a slower, linear decrease in survivors. To be conservative, the investigators calculated the D-value based on the second, slower phase of the inactivation curve. Sumner et al. (1991) reported the D-value of *Salmonella* Typhimurium ATCC 13311 increased by more than 100-fold as the a_w was reduced from 0.98 to 0.83 in sucrose solutions; this trend was observed in the treatment temperature range of 65 to 77 °C (149-170.6 °F; the study did not investigate temperatures below 65 °C for *Salmonella* inactivation). In laboratory media with a_w adjusted using glucose and fructose, Mattick et al. (2001) reported that *Salmonella* Typhimurium DT104 inactivation was non-linear in the range of 55 to 80 °C (131-176 °F). At temperatures ≥70 °C (158 °F) the heat resistance increased as the a_w decreased from 0.90 to 0.65; however, this trend was not observed for heat treatment at 65 °C (149 °F) or below, where decreasing a_w from 0.90-0.65 either had little effect or slightly decreased the heat resistance of the *Salmonella*.

Some studies have also been published on the inactivation of *Salmonella* by non-thermal processing. For example, the efficacy of low-energy X-ray irradiation was examined for inactivating *S.* Enteritidis PT 30 on almonds at different water activities (Jeong et al., 2008). The organism was found to be more resistant at a_w 0.65 (D_{10}-value ~ 0.34 kGy) compared to a_w 0.23 (D_{10}-value ~0.26 kGy). Irradiation, for products where its use has been approved, can also be an effective control measure. Irradiation with a dose up to 30 kGy (21 CFR 179.26) has been approved for use to inactivate microorganisms in dry aromatic vegetable substances such as herbs, spices and vegetable seasonings (CFR, 2008c). Danyluk et al. (2005) reported that a greater than 5-log reduction of *S.* Enteritidis PT 30 on almonds occurred after the product was treated with PPO (0.5 kg/m^3) for 4 hours followed by storage for 5 days.

Ethylene oxide is effective for treating spices and herbs to eliminate *Salmonella* (Pafumi, 1986; Vij et al., 2006). While its application as a control measure is being phased out in some cases (such as for basil), it remains an effective measure to eliminate *Salmonella* in spices and herbs where approved, especially for treating high risk ingredients that otherwise would not receive a lethality treatment for *Salmonella*.

Validation testing can be carried out using *Salmonella* (appropriate strains), using a surrogate organism that has been validated for the product and process under consideration, or using a non-microbial method such as an enzyme that has been validated for use in such applications. When the time and temperature profiles of a process can be mimicked in the laboratory (e.g., oil roasting), a challenge study with appropriate *Salmonella* strains can be conducted in the laboratory to validate the process (Larkin, 2008). This approach has been used to validate a dry-air roasting process for peanuts, where a lab-scale roaster was used to mimic the actual processing times and temperatures and the process was found adequate to deliver a 4-log reduction of several *Salmonella* strains (Tuncan, 2008).

When it is difficult to mimic the processing conditions in the laboratory with sufficient accuracy, a surrogate organism or a non-microbial substance may be used for validation. When a surrogate organism or substance is used, a relationship between the target *Salmonella* strain and the surrogate needs to be established, and the surrogate should behave in a way that a correlation can be made in a conservative manner (Larkin, 2008). In practice, a surrogate that has heat resistance comparable to or greater than the target *Salmonella* strain (to build in a margin of safety) is usually selected. For example, studies in several laboratories were conducted to select a surrogate organism for *S.* Enteritidis PT 30, the pertinent pathogen for almonds (Wang, 2008). Correlation between *S.* Enteritidis PT 30 and a surrogate organism, *Enteroccocus faecium* NRRL B-2354 (also known as *Pediococcus* spp. NRRL B-2354), has been established for dry heat in the 250 to 310 °F (121.1 to 154.4 °C) range for almonds. *E. faecium* NRRL B-2354 was found to have inactivation characteristics comparable to *S.* Enteritidis PT 30 under dry heat conditions (Ceylan et al., 2008; Wang, 2008). In fact, the D-values for the surrogate were slightly higher than those for the pathogen in the 250 to 310 °F (121.1 to 154.4 °C) range for almonds subjected to dry heating.

Alternatively, particles containing enzymes can be passed through a plant processing step and tested for residual enzyme activity, thus providing an indication of process lethality. The use of enzymes for process validation has been described for different thermal processes (Tucker et al., 2002; CCFRA, 2008). Testing for phosphatase has been used to verify that the pasteurization of milk has occurred.

Common Industry Practices:

- Determine the target level of *Salmonella* reduction in the product and process under consideration.
    - The determination can be based on the rationale outlined by NACMCF (2006). The target level of *Salmonella* reduction should be such that the treated product presents a reasonable certainty of no harm to the consumer.

- A targeted 2- to 5-log reduction is commonly selected based on a hazard analysis that includes historical association of ingredients with *Salmonella*, prevalence and extent of contamination (i.e., the incoming load of *Salmonella*), and the intended use of the final product. The selected log reduction should include a margin of safety, e.g., an additional 2-log reduction beyond the extent or levels of contamination expected to occur in the ingredients (NACMCF 1997a and 1997b; FSIS, 2006).

- Where regulatory or industry standards for log reduction have been established, these should be applied. For example, based on a comprehensive risk assessment a 4-log reduction of *Salmonella* in raw almonds has been established in the US to ensure safety of the finished product.

- Determine the adequacy of the selected control measure and associated critical limits for processing.

  - Critical limits should be developed based on thermal parameters (e.g., D- and z-values, thermal death times) or non-thermal parameters of the most resistant and pertinent *Salmonella* serotype, based on occurrence in the product ingredients, processing environment, and/or association with an outbreak involving the product or similar products.

  - In many cases, processing conditions are initially driven by quality attributes and it is essential to determine whether these conditions can deliver the target log reduction (several quick trials in the lab can be done for a feasibility assessment; literature data can also be used). Working with process engineers to optimize the process to deliver the target log reduction while still maintaining product quality is a common approach used in the industry.

  - In practice, several approaches can be used for validating the adequacy of process parameters. As noted previously, if the process can be mimicked reasonably well in a laboratory (e.g., for oil roasting), then *Salmonella* can be used in process validation in a laboratory setting to confirm that the critical limits, when achieved, consistently result in the target *Salmonella* log reduction. If the process is too complex to mimic in a lab setting (e.g., heat extrusion), other approaches for validation may be used, such as determining lethality based on the processing conditions (e.g., integrated lethality based on time and temperature profiles) or using a suitable surrogate for validation on the processing line. In addition to process parameters, other critical factors such as the initial temperature and initial moisture level of the ingredient(s) should also be considered in lethality validation studies.

  - A non-pathogenic microbial surrogate or a non-microbial surrogate such as an enzyme can be used after appropriate validation. For example, *E. faecium* NRRL B-2354 has been determined to be an appropriate surrogate for *Salmonella* in the validation of processing methods for almonds (ABC, 2007).

- Use published data to guide the determination of whether a challenge study is needed for control measure validation.

- The utility of literature data depends on the food or model matrix and the design used in the study to generate the data. According to the rationale outlined by NACMCF (2006), the value of a particular set of literature data will be enhanced if the matrix and conditions used to generate the data are similar to the product and process to which the data are being applied.

- Available heat resistance data may be used to estimate log reduction by thermal processing in a low-moisture product. The ideal approach is to use available heat resistance data collected in the same food matrix, such as using D- and z-values obtained in wheat flour to calculate log reduction in wheat flour during heat processing. Care should be taken when using D- and z-values, as inactivation may not be linear. In some cases a non-linear heat resistance model may have been developed for a product (e.g., peanut butter, almonds) and this can also be used. When D- and z-values are not available in the food at the water activity under consideration, data in a product with similar composition may be used, e.g., data obtained in wheat flour or corn flour for cereal products. When data for a food matrix are not available, data obtained in a model system (e.g., sucrose solution) with similar a_w may be used to estimate lethality. When using this approach, it is important to keep in mind uncertainties inherent in applying available data and assumptions made.

- In most cases, literature data are used to guide efforts in identifying parameters specific to a product of interest, whether a challenge study is needed, and how a challenge study may be designed. Whether published data are sufficient to support the adequacy of the lethality of a chosen control measure and associated critical limits depends on several factors. According to rationale developed from industry experience (Scott et al., 2005), if an evaluation based on literature data shows survival of *Salmonella* is not likely to occur, with a reasonable margin of safety, challenge studies would not be needed. For example, analysis of the time and temperature profiles for a heat extrusion process may indicate that, based on the a_w of the ingredients and the product, the process is expected to deliver *Salmonella* inactivation that would greatly exceed 5-log. On the other hand, if there is less confidence in using published data, then limited challenge studies may be needed to verify estimated log reduction based on literature data. If the evaluation shows that there is limited lethality for the product/process based on available heat resistance data, then additional studies or process re-design would be warranted.

- Use available scientific guidance, such as the NACMCF guidance on parameters for performing an inoculated pack/challenge study (soon to be published), for validation of control measures through microbiological challenge testing.

- Microbiological expertise is necessary to determine the relevance and validity of applying published data to a specific product and process. An experienced microbiologist or process authority should assist in the use and interpretation of published data.

- Consider both thermal and non-thermal control measures, with validation, to eliminate *Salmonella*.

- Thermal processing can be used under dry or moist conditions. Moist heat treatment is followed by a drying step in the manufacturing of many low-moisture products. Where appropriate (e.g., for some spices and seeds) a combination of steam treatment (pressurized or non-pressurized) and drying may be used to inactivate *Salmonella*. In such cases, validation should focus on determining the lethality of the steam process alone as a conservative scenario or, if heating after the steam process is included in lethality calculations, the combined effects of the multiple processing steps should be validated.

- Focus validation on the CCP used to deliver the target log reduction, when one of multiple steps effecting lethality is chosen as the CCP. Cumulative effect from multiple inactivation steps may be used to achieve the target log reduction, even though individual steps alone are not sufficient to achieve the target lethality, as long as the individual processing steps and the combined lethality are validated. Be aware that not all heating steps in a process will provide *Salmonella* inactivation. For example, spray drying is an evaporative cooling process that does not result in an appreciable inactivation. Another example of minimal to no *Salmonella* inactivation may be a finishing dryer following the heat extrusion process.

- For a low-moisture product (e.g., spray-dried milk) that starts with high-moisture ingredients (e.g., milk), the heat treatment process prior to drying should be readily verifiable and efforts should be concentrated on preventing post-lethality contamination during drying and the subsequent steps through finished product packaging.

- Examples of non-thermal control measures are treatment with an approved chemical for fumigation such as propylene oxide or ethylene oxide and treatment with irradiation.

- Once the lethality of the process is validated by scientific data, ensure the operation can deliver the critical limits and that the parameters are consistently met through in-plant validation, which is an integral part of the validation process. Subsequently, verification of process control may include activities such as records review, calibration of instruments, and periodic finished product testing or other type of independent checks.
- Also make sure raw material/ingredient suppliers validate their process and the control measures.

***Salmonella* Control Element 7:**
Establish procedures for verification of *Salmonella* controls and corrective actions.

The adequacy of the *Salmonella* control program should be verified on an ongoing basis to assure effectiveness and drive continuous improvement. Verification should focus on implementing a robust environmental monitoring program that has been designed to identify transient and/or resident *Salmonella* in the processing areas. Appropriate corrective action procedures must be developed to address positive *Salmonella* findings with the intent of containing the contamination, identifying the potential source, and

eliminating the problem.
This section focuses on environmental monitoring and corrective actions to be taken when *Salmonella* is found in the environment, since this is one of the most important verification activities in low-moisture product manufacturing. Other verification activities, such as those for critical control points in a HACCP system, are well covered elsewhere (NACMCF, 1998; CAC, 2003; ISO, 2005; Scott and Stevenson, 2006).

Environmental monitoring is an essential component for *Salmonella* control, as it provides a microbiological assessment of a plant's environment and an assessment of the effectiveness of sanitation and the overall *Salmonella* control program (Zink, 2007a; McNamara, 2007; Hall, 2007). Environmental monitoring is not, in itself, a control measure. Rather, it is a tool to verify the effectiveness of the overall *Salmonella* control program. Monitoring results provide critical information to improve *Salmonella* control in the plant environment. This information should be used to correct problem areas before they pose a risk to finished product. With this understanding, it is critical that the program be designed and implemented in a way to maximize detection of *Salmonella*. A robust environmental monitoring program is one of many prerequisite programs that together provide a firm foundation for effective food safety management.

The target organism for environmental monitoring for low-moisture foods should be *Salmonella*. Scientific literature suggests the pathogen is more persistent in the environment than other organisms such as coliforms and Enterobacteriaceae. A suitable indicator for *Salmonella* has not been identified (EFSA, 2007). Testing with enumeration of Enterobacteriaceae, however, may help assess moisture control in areas in the processing environment intended to remain dry (ICMSF, 2002b). Enterobacteriaceae is a useful indicator of process hygiene and it may be monitored in parallel as a hygiene indicator for verification of general sanitation effectiveness. However, it cannot be a substitute for the direct monitoring of *Salmonella* because, while high levels of Enterobacteriaceae suggest an increased risk for the presence of *Salmonella*, low levels of Enterobacteriaceae do not guarantee the absence of the pathogen (EFSA, 2007; Cordier, 2008).

Environmental monitoring for *Salmonella* is generally conducted on non-product contact surfaces (non-PCSs). Non-PCSs in the Primary *Salmonella* Control Area (PSCA) should be the main focus of routine monitoring for *Salmonella*. However, environmental monitoring for *Salmonella* should also be conducted in other areas of the facility (e.g., wet processing or handling of raw materials). Monitoring in these areas can provide insight into the potential for *Salmonella* to be present and potentially spread into the PSCA. Within the PSCA, non-PCS areas adjacent to PCSs should be monitored with relatively high frequency. If these areas are not maintained in sanitary condition, they may pose a risk of product contamination. Non-PCSs within the PSCA that are more distant from PCSs should be sampled with medium to high frequency, and non-PCSs outside the PSCA, should be sampled with low to medium frequency (Table 7-1). Each facility should determine the frequency adequate for its product and process. In general, high, medium and low frequency would correspond to daily/weekly, monthly, and quarterly testing, respectively.

Testing of a PCS and finished product may be done under some circumstances as part of the overall verification of *Salmonella* control. PCS testing may play an important role in hygienic qualification for equipment prior to use or for investigation of positive *Salmonella* findings. Periodic product testing can be useful in verifying that the food safety system for *Salmonella* control is

working. Sampling plans used by the industry for product testing include those described in the FDA BAM (FDA 2003 and 2007) and those described by ICMSF (ICMSF, 2002a). However, because it has well-known limitations in finding low levels of contamination, product testing alone is not a reliable means for assuring the absence of *Salmonella* (ICMSF, 2002a).

An adequate number of samples should be taken at appropriate frequencies for the environmental monitoring program to be effective. The number of samples and the frequency of sampling depend on the operation and facility. The sampling frequency can, in part, be based on current industry practices.

The first step in developing the frequency of testing and the test sites in an environmental monitoring program is to establish a solid baseline. Weekly monitoring may be considered as a starting point and the frequency revised based on the results over time. For example, in a facility that has historical testing data that show consistent *Salmonella* negatives in the environment based on a rigorous sampling program, the monitoring frequency can be reduced. On the other hand, a facility should be prepared to increase monitoring when changes in the operation warrant more monitoring, e.g., ingredient changes, leaky roof, drain back up, construction events, equipment installation, or finding *Salmonella* during routine environmental monitoring.

An official or validated method, such as the FDA BAM *Salmonella* method (FDA, 2007) or ISO 6579 (2002), should be used for testing. For some products methodology may need to be modified and validated, as some food components (e.g., high fat levels) can complicate the sample preparation and pre-enrichment step and other aspects of the analysis. Both methods include a section on the testing of environmental samples. An alternative method may be used after it is validated as equivalent in sensitivity and specificity to a standard reference method for environmental samples or for the product being tested. Choosing a validated method is important because a method validated for one purpose may not be suitable for another purpose; and, similarly, a method validated for individual sample units may not be suitable for testing sample composites (McNamara, 2007).

Common Industry Practices:

- ❒ Develop a written program for routine environmental monitoring.
  - The program should include elements such as identification of sampling sites, frequency of sampling, number of samples, sampling procedure, and test method. Examples of these elements are described in Table 7-1. Corrective actions to be taken when a positive is found should also be outlined (see examples in Table 7-2).
  - Sampling devices noted in the program should be appropriate for the types of samples collected and validated as necessary. For example, if sponges are used, they must not contain preservatives and validation of *Salmonella* recovery is recommended.
  - Sampling sites should be delineated into zones to facilitate program development, provide focus to critical sampling areas, and help direct appropriate corrective actions. For example, four zones may be established:
    - Zone 1 for PCSs in the Primary *Salmonella* Control Area;

        - Zone 2 for non-PCSs adjacent to or within close proximity to PCSs in the Primary *Salmonella* Control Area;
        - Zone 3 for non-PCSs more distant from PCSs in the Primary *Salmonella* Control Area and process areas outside the Primary *Salmonella* Control Area; and
        - Zone 4 for areas outside the process area (e.g., employee entrance, locker room, warehouse, loading dock).

    - Routine environmental monitoring should target testing non-PCSs under normal operating conditions. Samples taken post-sanitation provide sanitation verification only and would not meet the true intent of environmental sampling. A 'seek and destroy' philosophy should be adopted in environmental monitoring. This means the monitoring program is designed to aggressively search for *Salmonella*, particularly in environmental sites where *Salmonella* might be expected to be present, might concentrate, or might grow and spread. Table 7-3 provides examples of potential *Salmonella*-positive sites based on food industry experience. The listing in Table 7-3 is by no means inclusive of all potential sites.

    - Using only preset sample sites is not recommended since it significantly limits the scope of sampling and will likely miss emerging areas of concern. However, some sites may be sampled on a continuing basis to assess trends. Sampling data should be reviewed on a routine basis. The sampling program should be dynamic and responsive to the data generated.

    - A rotation schedule should be developed to allow all areas of the plant to be sampled on a periodic basis, e.g., weekly monitoring with rotation of sites between different areas of the plant, with all sites sampled within a specified time period (e.g., monthly or quarterly). However, this should not be set-up in a manner that excludes the sampling of an area of concern identified in a "non-scheduled" area. The sampling plan should be flexible and allow for additional samples to be collected where appropriate.

- ❒ Increase environmental monitoring (frequency and/or number of samples), as well as other control measures, in response to plant events such as during and after construction, and after equipment installation and major repairs are completed. An example of intensified control and monitoring is shown in Table 7-4.

- ❒ Develop a policy on whether and when to test PCSs and/or finished product and a program for this testing.

    - Testing of PCS, if included in the program, should be done only after a policy has been established with regard to the impact of a PCS-positive on finished product and the actions to be taken. Routine testing of PCSs is not particularly meaningful in verification because, given an effective *Salmonella* control program, contamination, if any, is likely to be sporadic and sampling is unlikely to find positives on PCS.
        - PCS testing may be done as part of corrective actions for an environmental positive, e.g., in sampling for investigational purposes following positive *Salmonella* findings in areas that

may pose a risk for PCS contamination on the line (see Table 7-2). PCS testing may also be valuable under other circumstances such as hygienic qualification of a piece of equipment prior to use in production, e.g., for new equipment or newly-acquired equipment that has been used in another facility.

- Manufacturers should decide whether or not to conduct finished product testing based on an evaluation of risk. New regulatory or customer requirements (i.e., Certificates of Analysis) may also dictate the need for finished product testing. **It is recommended that finished roasted peanuts and peanut containing finished product testing for *Salmonella* be carried out according to the procedure outlined for category II foods in Chapter 1 of the FDA BAM manual Food Sampling and Preparation April 2003. http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm. Automated sampling techniques may be applied whereby small increments of a lot are obtained throughout packing to assure effective representation.**[3]
    - Whenever finished product testing is performed, the tested lot should be isolated, placed on hold, and only released into commerce if the product tests negative for *Salmonella*.
    - If a product sample tests positive for *Salmonella*, the tested lot is considered adulterated and should not be released into commerce. **(a retesting statement in GMA document has been removed).**
    - **The lots immediately prior to and after the positive lot should be held and re-tested as a category I food. It is essential to do a root-cause investigation. The final disposition of lots that test negative should depend on the results of this analysis, as well as the testing.**
    - Retesting of the original positive lot for investigational purposes only (i.e. to try to determine level or incidence of contamination in the sample) may be appropriate. The lot associated with a positive sample may be reworked using a validated inactivation step. In addition to product disposition, other corrective actions may be taken as appropriate (see below)

- ❒ An official or validated method should be used to test samples taken from the environment or finished product.
    - The FDA BAM method (2007) and the ISO 6579 method (2002) apply to various products described in the methods, as well as to environmental samples. The FDA BAM method and the ISO 6579 method are considered the official method in the US and EU, respectively. A method that has been validated to be equivalent in specificity and sensitivity to one of these official methods may also be used. According to the FDA (2007), a validated rapid method is generally used for screening, with negative results accepted as such, but positive results require cultural confirmation by the appropriate

[3] Type in bold print has been added by APC and is not GMA content.

official method. Isolate subtyping with a method such as serotyping or genetic fingerprinting may be used for tracking and troubleshooting purposes.

- Compositing environmental samples (combining multiple sponges or swabs into one pre-enrichment) or pooling (combining 2-5 post-enrichment samples into one test sample to be run on a rapid method) is generally not recommended. A positive finding on a composited sample cannot identify the specific location of the positive and results in broader, less focused corrective actions. However, there may be some situations where compositing may be appropriate, e.g., samples taken from multiple drains in the same processing area, where it is less important to pinpoint the site. If a "pooled" sample comes up positive, the individual enrichments that made up the pooled sample can be immediately retested separately to pinpoint the positive sample(s). However, this process adds delay in determining the location of a positive compared to testing samples individually. The ability to composite or pool samples is method dependent and must be validated. Implications of compositing or pooling should be carefully considered.

- Corrective actions must be taken when *Salmonella* is detected in an environmental monitoring or finished product sample. In most cases, corrective actions are triggered by presumptive *Salmonella* test results since waiting for the final confirmation could take up to a week.

  - If a positive is found in any of the four sampling zones, the site should be examined and potential causes investigated. It may be advantageous to have a pre-assigned team to assist in the investigation and to help direct corrective actions.

  - Corrective actions to be taken should be based on an assessment of the potential for finished product contamination given the location of the positive site in the environment. (A positive in Zone 2, 3, or 4 (non-PCS) does not automatically implicate finished product.)

  - Corrective actions should include appropriate procedures, such as those described in Table 7-2, and be accompanied by re-sampling of the initial positive and adjacent areas.

  - **Consideration must be given to stop production and a complete process equipment disassembly/breakdown, cleaning, sanitation and drying cycle when a positive is found in zone 2 or finished product unless the source of the contamination is positively identified to one location where directed cleaning and sanitation can be applied to that point forward.**[4]

  - All corrective actions taken, including re-sampling results, should be documented.

[4] This point (bolded print) from the American Peanut Council

Table 7-1. Example of an environmental monitoring program for production of low-moisture foods

Sampling Zone	Definition	Examples of Sample Sites *	Test for	Frequency	Number of Samples**
Zone 1	Product contact surfaces (PCS) in the Primary *Salmonella* Control Area	Conveyors, filler hoppers, scrapers/utensils, packaging equipment, etc.	Indicator Organisms (e.g. Aerobic Plate Count; Enterobacteriaceae); ***(Salmonella statement removed from GMA table here)***	Post-Sanitation or as needed for investigational, validation, or verification purposes	Line Dependent
Zone 2	Non-PCS within close proximity to PCS in Zone 1. - areas that, if contaminated, could reasonably lead to PCS contamination (i.e., under normal operational practices)	Exterior of equipment, legs/frameworks, motor housings, catwalks, control panels, scrap carts, floor drains, HVAC vents, vacuum cleaners if used near PCSs, air filters, weight scales, floor mats at packaging, etc.	*Salmonella*	Weekly, Biweekly, or Monthly	5-10
Zone 3	Non-PCS within process area but more removed from PCS. - areas that, if contaminated, could <u>not</u> reasonably lead to PCS contamination without mechanical or human intervention (i.e., employee using compressed air to clean floors or a piece of equipment being moved)	Cleaning tools (brooms, squeegees), floor scrubbers, forklifts, floor drains, traffic pathways into process area, ceiling drain pipes, wall/floor junctures, wash stations, ingredient storage areas, etc.	*Salmonella*	Weekly or Monthly	3-6
Zone 4	Non-PCS outside processing areas. - areas that, if contaminated, could spread to the processing area via foot or equipment traffic (i.e. waste carts picking up contamination in compactor room)	Compactor areas, employee entrances, locker rooms, storage rooms, labs	*Salmonella*	Monthly or Quarterly	2-4

* It is recommended that a facility assessment be done to identify sampling sites, in order to include potentially problematic areas. Weekly monitoring may be considered as a starting point to establish a solid baseline and the frequency may be revised based on results over time.

** In general, a greater number of samples are taken in Zone 2 than Zone 3 and in Zone 3 than Zone 4 – a ratio of 5:3:2, 6:3:1, 7:2:1, 8:1:1 have been used depending on the product and process, although other approaches may be effective. A larger facility with multiple process lines may take a greater number of samples than those indicated for the zones.

Table 7-2. Examples of corrective action procedures following positive *Salmonella* findings in the plant environment

Zone 2, 3, or 4: Response to a Single Positive

Corrective actions must be taken when a *Salmonella* positive is found in any zone. Corrective actions should be initiated based on presumptive positive test results. The actions should aim to eliminate potential sources of the contamination.

Corrective actions common to Zone 2, 3, and 4 may include the following:

- Initiate pre-assigned response team to conduct a preliminary investigation to determine potential cause or source for the contamination (e.g., water leaks, maintenance activity, construction, etc.). The suspect site and surrounding areas should be examined as part of the investigation.
- Take immediate actions to correct any GMP deficiencies based on findings. These may include:
  - Quarantine the suspect area and limit access to the area.
  - Reinforce hygienic practices with appropriate employees (retrain if necessary).
  - Re-examine cleaning frequencies and revise as appropriate.
  - Eliminate water and water collection points, if present.
  - Repair damaged floors/walls and other structural damage as appropriate.
  - Re-examine traffic patterns. Where necessary and feasible, limit traffic flows (both employees and mobile equipment) through the area, restrict fork truck movement, redirect high risk traffic patterns from adjacent areas, etc.
- **Conduct investigational sampling of the suspect and surrounding areas prior to cleaning can help identify a source of contamination.** Precaution should be taken to avoid spreading potential contamination from the suspect area to other areas in the plant.
- Thoroughly clean/sanitize and dry the positive site and the surrounding area. Use dry, controlled wet, and/or wet cleaning as appropriate according to guidelines described in Element 4.
- Re-sample the implicated area and other sites within the surrounding and traffic pattern areas. If the positive is found in Zone 3, Zone 2 sites in the implicated area should be sampled and tested to verify that contamination has not spread to areas closer to PCSs; if the positive is in Zone 4, all Zone 3 sites close to the implicated area should be sampled and tested to verify that contamination has not spread into the process area.

- Increase sampling frequency, e.g., from weekly to once every two days in Zone 3, from weekly to daily for Zone 2. After 3 consecutive negatives, the routine sampling frequency and rotation plan for the *Salmonella* monitoring may be resumed.

Zone 4 areas are remote from production and generally present low risk to product. However, results from Zone 4 do provide information about the non-production environment and traffic flow. Although it is expected that *Salmonella* may be found occasionally in Zone 4, a positive finding should prompt additional actions beyond routine sanitation.

A Zone 3 positive, in the absence of a Zone 2 positive, is an early indicator of a sanitation program that is not robust enough. The implicated process may or may not be suspended based on the positive location and its proximity to product contact surfaces.

Zone 2: Additional Actions for a Single Positive

- Stopping production for sanitation may be appropriate under certain circumstances where finished product or PCSs may be at risk.
- Whether or not to disassemble the line depends on the equipment associated with the positive site and how close the site is to finished product. Breaking down the line may not always be warranted if cleaning and re-sampling can be conducted without affecting PCSs. For example, the outside of a cooling tunnel and support frames may fall into a Zone 2 sampling category and these sites should not affect product contact surfaces or cause the line to be broken down. However, if deemed necessary, break down the line from the positive site on, and disassemble equipment as necessary to ensure all PCSs are accessible for cleaning and sanitation. Thoroughly clean, sanitize, and dry the line and the surrounding areas starting from the positive site through the end of the line.
- Conduct pre-operational inspections on the line equipment and in the area as applicable. Include Zones 2 & 3, and possibly Zone 1, as necessary in the sampling plan to re-qualify the line. Pre-operational test results should be obtained and confirmed negative prior to start-up if Zone 1 samples are included.
- Product testing may or may not be necessary depending on where the positive site was located. If finished product testing is already conducted as part of the overall food safety program (e.g., products with a *Salmonella* specification), intensified product testing may be initiated following any Zone 2 *Salmonella* positive finding. For example, the stringency of the sampling plan may increase from a plan with 3 samples of 25 g each to a case 11 (n=10), case 14 (n=30), or case 15 (n=60) depending on the situation, with c=0 in all cases; or from testing a 375 g composite to testing 2x 375 g (750 g) or 4x 375 g (1500 g). Whenever a product lot is subjected to testing, the lot should be held and only released if the test result is negative for *Salmonella*.

Special Circumstances: Consecutive Positives (all Zones)

When a sound control program for *Salmonella* is in place, finding multiple and/or consecutive positives may indicate that the primary source is a harborage site, where the organism may have become established and is multiplying. This can lead to an increased risk for spreading the organism and ultimately process line contamination. Corrective actions outlined below may be followed for problem resolution.

- Map the contamination sites on a layout of the facility to aid in locating the source of contamination, or at least suggest additional sites to sample. It is critical that a harborage site, if one exists, be found and eliminated. This usually means taking more samples than those taken during routine monitoring in the affected and traffic flow areas.
- Reinforce GMP training and hygienic practices and provide additional attention to sanitation procedures.
- Visually inspect areas for potential niches. Intensify cleaning activities around these areas.
- Visually inspect handling practices (production, sanitation, maintenance, material handling) and correct non-hygienic employee practices.
- Review equipment cleaning and preventative maintenance protocols and revise if necessary.
- Examine processing equipment and consider equipment redesign if necessary.
- PCS or product testing may be necessary or need to be intensified for Zone 2 consecutive positives. In some operations, testing may involve testing of worst-case samples on the line, e.g., sifter tailings on a spray dryer system. Line samples may be taken at various times and/or from various locations to help pinpoint potential contamination sites. Investigational samples should be analyzed individually, not as composites.
- Depending on the location of the positive, consideration should be given to testing Zone 1 sites. For example, consideration should be given to testing Zone 1 sites (i.e., PCSs) as a response to multiple positives in Zone 2. Consideration may also be given to Zone 1 testing under other circumstances such as qualification for new equipment or relocated equipment, product tests positive, or products are implicated by epidemiologic investigations in an outbreak.

Table 7-3. Examples of locations and situations in facilities that can serve as potential sources for spread of *Salmonella*

Process area
- Aspirator line
- Dust collection system
- Filter sock
- Air conveyance system, e.g., rotary air lock, cyclone, air locks, duct work, pneumatic conveyance system
- Inside a pump that was disassembled
- Inside an air duct
- Exposed insulation
- Eroded flooring
- Space between walls
- Poorly sealed wall/floor junction
- Leaky roof
- Leaky drain pipe
- Conveyor
- Bucket elevator
- Fork lift
- Employees
- Fans
- Cat walks
- Central and/or portable vacuums
- Maintenance tools
- Floor scrubber
- Floor squeegee
- Mop head
- Drain
- Insects, rodents, and other pests
Outside of process area
- Fire exit, for example, used by construction crew to enter and exit the facility
- Entrance to employee locker room
- Pathway to trash compactor
- Receiving dock
- Insect light traps
- Areas where employees may congregate, such as a designated smoking area

* This list is by no means all-inclusive.

Table 7-4. An example of intensified environmental monitoring and control in response to special plant events

Plant events include construction, new equipment installation in the processing areas, or other events that may affect the Primary *Salmonella* Control Area. Plant traffic controls, room air pressure, sanitation activities, etc. should be assessed during construction activities. Intensified environmental control procedures and action steps may be required, including:

- Reinforce GMP practices and traffic patterns with outside contractors.
- Set-up temporary control barriers within the plant as applicable.
- Increase cleaning frequency of adjacent areas during construction, after equipment installation, and after major repairs are completed.
- Sampling and testing for *Salmonella* should be performed in the construction and adjacent areas during construction.
- Increase environmental monitoring (frequency and/or number of samples) after construction, equipment installation, or major repairs are completed. The sampling sites and frequency should be determined based on a team evaluation of the following: plant location of construction activities; type of construction (e.g., installation, demolition, material removal); duration of construction activities; types of environmental controls implemented, etc.

Warehouse and Distribution

Storage and transportation of finished food should be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container. It is especially important that peanuts be protected from contacting water. Roofs should be inspected on a routine basis to prevent leaks. If processed peanut come in contact with water a written corrective action plan should be in place to eliminate the product a risk by disposing of affected peanuts.

INDUSTRY BEST PRACTICES

Microbiological Control

Microbiological testing of finished product should be done as a verification step to ensure the process works and that products do not contain microorganisms of public health significance. Bacteriological testing of finished product can also be done to monitor the overall sanitation level of the processing system.

An environmental monitoring program is recommended to determine the effectiveness of plant sanitation procedures. Microbial testing should be done on selected food contact surfaces and other support equipment, air intake units, evaporative coolers, etc. Environmental monitoring should be on a regular basis. Pathogens should be the target organism for non-food contact surfaces. Indicator organisms should be monitored from startup samples.

As referenced in earlier sections of this document The Grocery Manufacturers Association has published an excellent guidance document for the control of *Salmonella* entitled "Control of *Salmonella* in Low Moisture Foods" dated February 4, 2009. The document focuses on low moisture foods that are often the type produced from peanuts (peanut butter and peanut paste, for example). However, many of the principles and details outlined apply generally to a well-managed microbiological control program. Referenced below are specific sections of the GMA seven control elements that highlight activities and practices that should be followed by a peanut product processor or manufacturer.[5]

Prevention

- Prevent or minimize cross contamination through procedures and activities such as the following:

  - Raw or unprocessed foods should be separated from processed/ready-to-use or ready-to-eat foods. Packaging materials should be protected from contamination during shipment, storage and use. Packaging should be inspected immediately prior to use to ensure that it is not contaminated or damaged.

  - Wherever possible, use dedicated forklifts, utensils, and maintenance tools for the Primary *Salmonella* Control Area (PSCA; see Element 2) or post-lethality area vs. raw or pre-lethality area.

  - Outline traffic patterns properly and ensure employee compliance through education and training.

  - Inspect pallets and trailers regularly, keep them in good repair, and not stored outside where they may be exposed to bird or pest activity.

[5] Introduction (in bold type) by APC

- Maintain the highest room air pressure in the PSCA or the post-lethality area and include the air handling system in the master sanitation schedule.

- Establish a program for water quality to minimize the risk of water as a potential carrier of *Salmonella*.
  - Establish procedures for sourcing and handling potable water within the facility.
  - Ensure that the water distribution system is properly maintained to prevent any leakage, especially in the PSCA. Use backflow prevention devices where needed.
  - Establish verification procedures to ensure that water brought into the facility is of adequate quality (ICMSF, 2005c) and is not a source for *Salmonella*. This is also important for water for jacketed temperature controlled equipment, such as holding or mixing tanks that are double walled and filled with water to control temperature in the processing of chocolate, peanut butter, fat-based confections, etc. If the water in the system is not adequately maintained, contaminated water leakage through microfractures in the equipment could occur and result in the contamination of product being held or processed in the equipment.
  - When water usage is necessary in the processing area (e.g., for cleaning and sanitizing equipment), use minimal amounts. In particular, water usage in the PSCA should be avoided or kept to the very minimum. See Element 4 for further discussion.
- Construction and major maintenance events should be coordinated so that the area under construction is contained.
  - Construction includes activities such as layout modifications requiring displacing pieces of equipment, resurfacing floors, cutting drains, cutting through walls, installing or removing exhaust ducts, etc. Due to the ability of *Salmonella* to survive in dry environments for long periods of time, construction activities may release *Salmonella* from unknown harborage sites and contribute to the spread of the organism throughout the plant (CAC, 2008).
  - Control measures during construction may include the following: isolate the construction areas, prevent/minimize dust and aerosols, control traffic patterns, use temporary partitions as appropriate, maintain negative air pressure in the construction area, intensify cleaning procedures, and enhance environmental monitoring during these activities, as described in Element 7.
- Put in place a training program to educate employees on the potential sources of contamination, adherence to traffic patterns, and proper hygienic practices to follow in order to minimize the ingress or spread of *Salmonella* in the processing area. Such training is particularly important for those who work in the PSCA, including personnel who enter the area on a temporary basis (e.g., maintenance crew, contractors).

Hygiene Practices and Control

pages 23 -32 GMA document.

***Salmonella* Control Element 2:**
Enhance the stringency of hygiene practices and controls in the Primary *Salmonella* Control Area.

The Primary *Salmonella* Control Area (PSCA) in a low-moisture product facility is the area where handling of ingredients and product requires the highest level of hygiene control. In a facility where products receive a pathogen inactivation treatment, the PSCA is the area subsequent to the terminal lethality step. In a facility where no inactivation step is employed, e.g., dry-blend mix, the entire process area may become the PSCA. Although there is a clear need to establish stringent hygiene control in the PSCA, practices in other areas of the facility should not be neglected, as they impact the hygiene conditions in the PSCA. In fact, maintaining stringent hygiene control in the PSCA depends on effective hygiene control in the rest of the processing area of the facility, which for comparison are designated the basic GMP area and, if one is established, the transitional area. The PSCA is sometimes referred to as the high hygiene zone or the high-risk area (e.g., in Europe). The PSCA is also referred to as the ready-to-eat area, the critical side, or the dry side of the operation. The basic GMP area is also referred to as the basic hygiene area, the non-critical side or wet side of the facility.

The separation of one manufacturing area in a facility from another is generally done to minimize contaminant transfer from one area to another, e.g., wet to dry areas, 'dirty' (relatively speaking) to clean areas, raw materials to finished products, or a basic hygiene area to a high hygiene area. Compartmentalization or segregation of the facility into specific areas is a common practice in food processing (FAO/WHO, 2006; Holah, 2005). The separation of the low-moisture product manufacturing plant into areas of different hygiene levels with the establishment of a PSCA that is separated from the rest of the processing area is one of the first steps leading to effective *Salmonella* control (Figures 2-1, 2-2, and 2-3). Depending on the product and process and the intended consumer (e.g., general public, infants), the number of hygiene areas established in a facility in addition to the PSCA may vary. The objective is to minimize to the greatest extent the spread of *Salmonella* into the PSCA where preventing product contamination is the most critical.

Clearly defining the control measures necessary in the different areas is important to effectively control *Salmonella* in the processing environment, especially in the PSCA, and thus prevent contamination of finished products. As indicated previously, in the PSCA, processed products (and components of the products) not subjected to a further inactivation step are exposed to the environment and are vulnerable to contamination with *Salmonella* if the organism is present. As product contamination could have serious consequences for consumers, maintaining enhanced hygiene stringency in the PSCA area is extremely important. To ensure this high level of hygiene control in the PSCA, maintaining hygienic control of the basic GMP and the transitional areas must also be exercised. In comparison to the PSCA, the basic GMP area in the processing environment and the transitional area (if one is established, see below) are areas

where *Salmonella* may occasionally be present. The occasional *Salmonella* contamination in these areas has a low likelihood of leading to finished product contamination provided that the problem is detected and corrected in a timely manner. GMPs must be applied and adequate sanitation must be carried out (with wet or dry cleaning procedures as appropriate) in the basic and transitional areas to minimize potential *Salmonella* harborage sites that could become a source of contamination into the PSCA.

The degree of hygiene control in the facility may depend on the type of the operation and the analysis of the potential for *Salmonella* introduction. Generally, the stringency of hygiene control should increase from the basic GMP area to the transitional area to the PSCA. Particular emphasis should be placed on control measures for (physical) separation, passage of traffic (personnel, equipment, materials, etc.), airflow, cleaning processes (whether or not wet cleaning is permitted and how water is used - discussed further in Element 4), and verification (discussed further in Element 7).

The degree of separation between the different hygiene areas within a facility may vary depending on the product and process (Holah, 2005). Barriers are placed between the different hygiene areas to restrict traffic and prevent vectors (potential sources of *Salmonella*) from passing between the basic GMP area to the PSCA. Examples of vectors include dirt on shoes or clothing, pallets and packaging materials, pests, dust, and sometimes water. Examples of physical barriers are walls, doors, split conveyors, filters, etc. Examples of other barriers are pallet exchange, shoe-change, removal of outer bag packaging, marked limits on floors, etc. Whenever possible and necessary, there should be no direct connection between the PSCA and the basic GMP area. Access to the PSCA should ideally be through a buffer area (i.e., a vestibule or anteroom, hygiene juncture) where personnel take steps to minimize carrying contaminants into the PSCA. In addition, hygienic facility design and plant layout to direct the flow of personnel and traffic is another effective control measure to minimize the transfer of contaminants from one area to another (ICMSF, 2002b). The air supply to the PSCA should be suitably filtered to prevent airborne contamination. Ideally, the PSCA should be maintained under positive air pressure to prevent the entry of contaminated air from the outside or surrounding areas of the manufacturing facility (CAC, 2008; FAO/WHO, 2006; Holah, 2005).

The determination of whether a location in the facility belongs to the PSCA, the transitional area or the basic GMP area should be based on an evaluation of risk. An area can be evaluated based on the probability of *Salmonella* being present and the proximity of the area to the finished product. For example, a location that is medium or high on the probability axis and near on the proximity axis would fall into the PSCA (Figure 2-4), while a location that is far away on the proximity axis, or medium distance on the proximity axis and low on the probability axis would fall into the basic GMP area. By using this approach, a facility may be designated into areas with different levels of hygiene control. An evaluation of risk and mitigation strategies can also be used to determine the appropriate control measures for the PSCA. For example, in a facility that uses raw materials known to be contaminated with *Salmonella* presence or in the event that persistent *Salmonella* is found, more stringent controls would be needed.

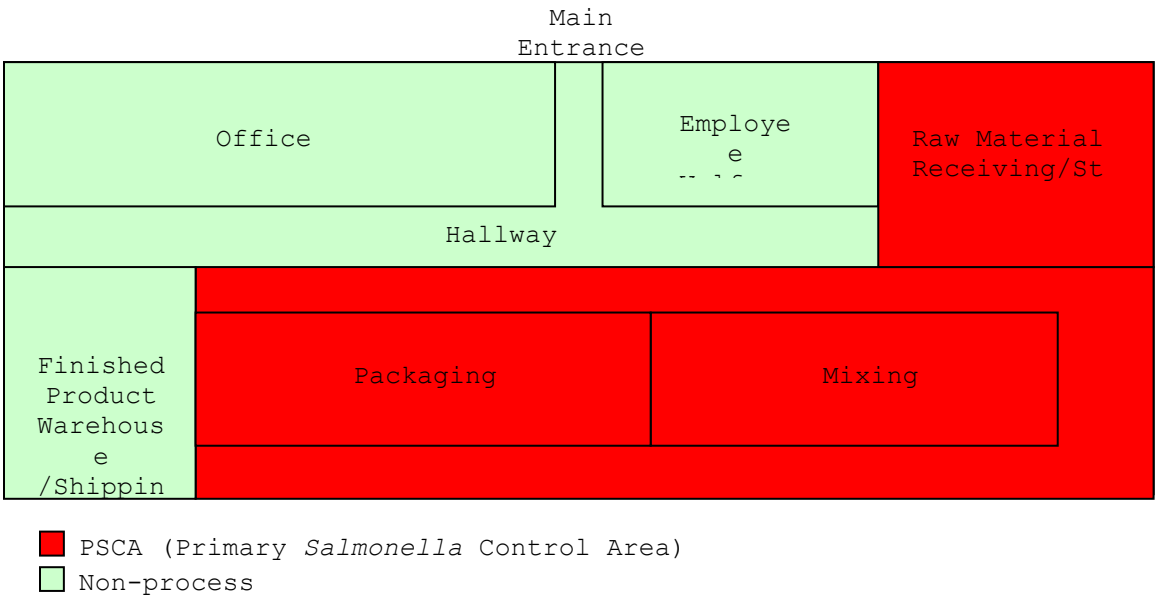


Figure 2-1. Example of a conceptual plant layout showing the entire process area as Primary *Salmonella* Control Area (PSCA) in red. The non-process area (e.g., warehouse and office) is in green. This layout may be applicable to products such as dry blends and snack bars.

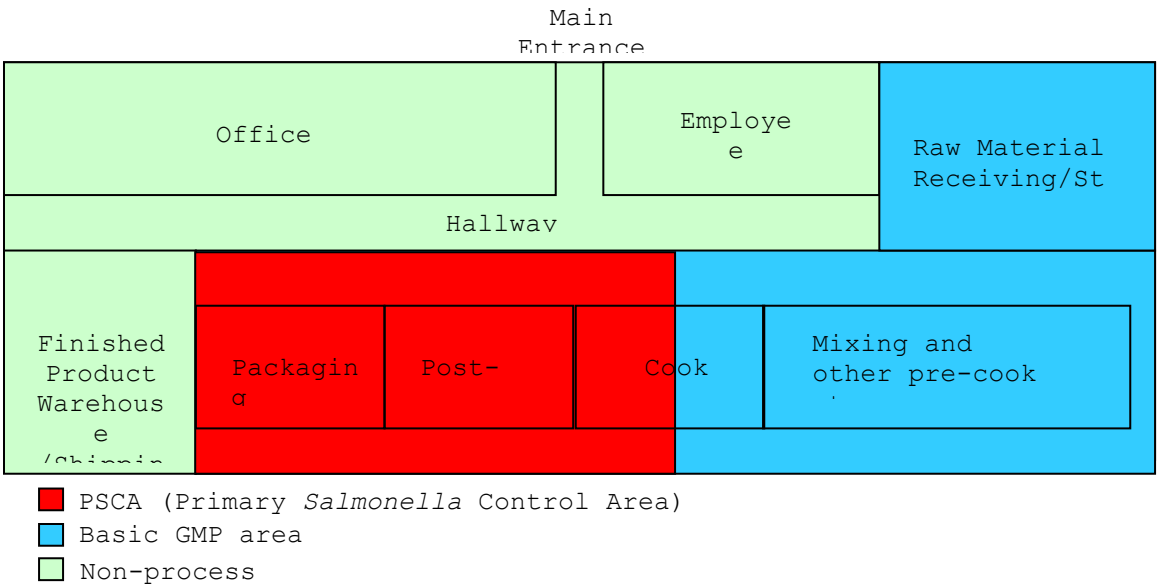


Figure 2-2. Example of a conceptual plant layout showing two process areas with different hygiene control: a Primary *Salmonella* Control Area (PSCA) in red and a basic GMP area in blue. This layout may be applicable to products such as corn snack chips, cereals, and peanut butter.

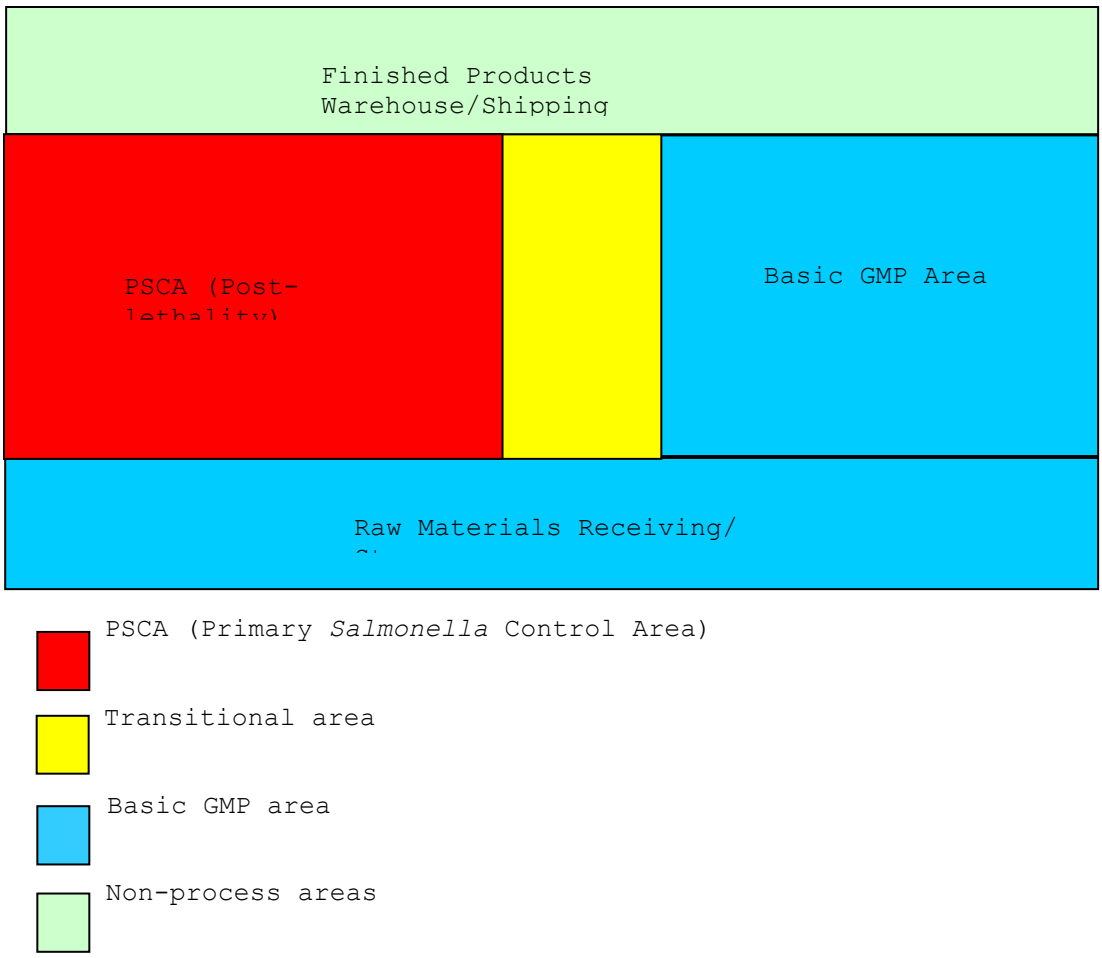


Figure 2-3. Example of a conceptual plant layout showing three process areas with different hygiene control: a Primary *Salmonella* Control Area (PSCA) in red, a transitional (area leading from one zone to another) area in yellow, and a basic GMP area in blue. The non-process area (e.g., warehouse, shipping) is in green (offices and employee welfare areas are not shown). This layout may be applicable to products such infant formula.

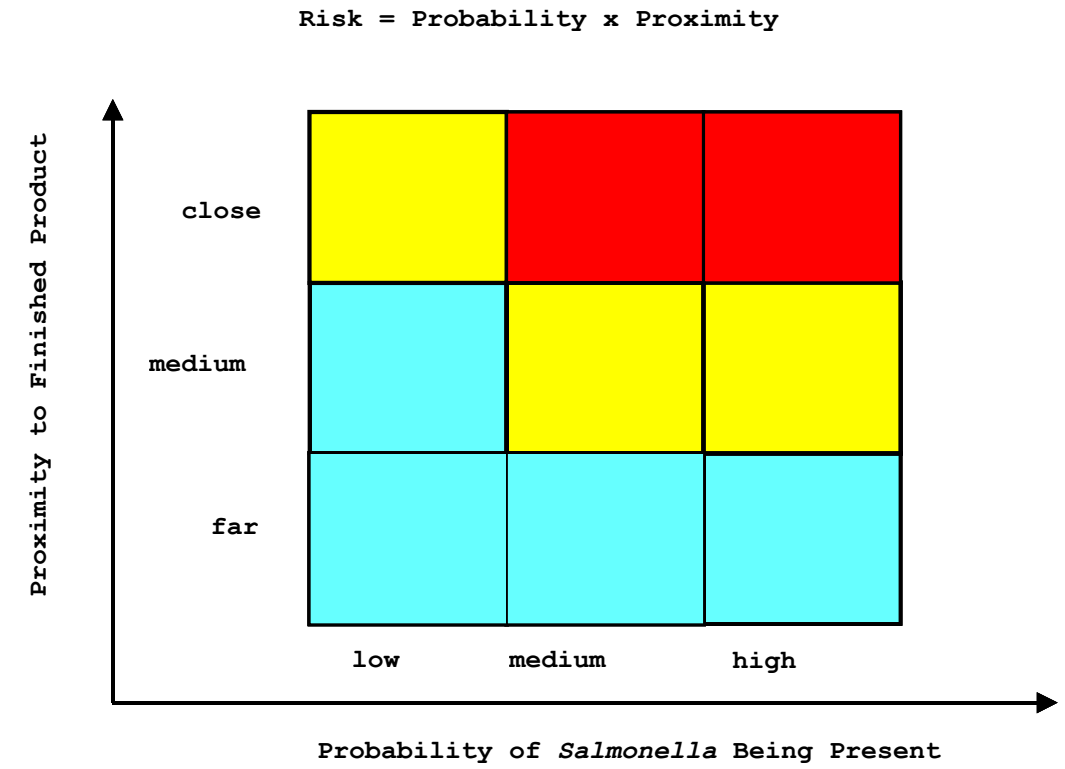


Figure 2-4. An example of using a risk evaluation approach for determining hygiene areas in a facility. In this approach, the risk of *Salmonella* contamination in finished product is proportional to the probability that *Salmonella* is present in the process area and the proximity of the area to the product before packaging.

Table 2-1. Example of desirable features for a buffer area at the entrance to the Primary *Salmonella* Control Area (PSCA)

Entry and exit doors of the buffer area to the PSCA are tightly fitted, internal cores are filled, and if necessary equipped with self-closing devices.

Insect light traps, if used, are installed outside the entry door to the buffer area (i.e., the door facing the non-critical side).

Floor is properly sloped for drainage and sloped towards the non-critical side. Preferably no drains are installed in the area.

A bench is provided for shoe change. Two sets of open shelves are provided: one for 'dirty' shoes worn before entering the buffer zone, and the other for clean shoes worn in the PSCA. Air exhaust is used (if necessary such as when the buffer area is small) to remove shoe odors

Hands-free hand washing sink is provided and it is located on the non-critical side of the buffer area or just outside the buffer area on the non-critical side. Drying hands with paper towels is recommended. Hand washing is done on the non-critical side because wherever there is a hand washing station, the surrounding floor may become wet. Moisture on the floor should be minimized to the extent possible in this area, and care should be taken that this moisture not be transferred to the PSCA.

After shoe-change and other changes, hands may be treated with a disinfectant spray.

Common Industry Practices:

- Establish designated areas in the facility with different levels of hygiene controls to minimize the spread of *Salmonella*.
  - Establish a Primary *Salmonella* Control Area (PSCA) within the process area of the facility.
  - Depending on the type of operation, a facility may generally be divided into one, two, or three processing areas (in addition to the non-processing areas). For example, an operation that does not employ an inactivation step may designate the entire processing area as the PSCA, e.g., a spice blending operation, a snack bar or nutrition bar operation, and other mix and pack operations (Figure 2-1). An operation that employs an inactivation step may designate the processing area after the inactivation step as the PSCA and the rest of the processing area as the basic GMP area, e.g., a corn snack chip operation (Figure 2-2). In addition to the basic GMP area and the PSCA, an operation with an inactivation step may employ a transitional area to further enhance hygiene control in the PSCA, e.g., a powdered infant formula operation (Figure 2-3). In general, the more sensitive the product or the consumer, the more important the separation of the facility into different hygiene areas to facilitate the implementation of enhanced controls in the PSCA.
  - Depending on the type of operation and the hazard analysis, it may be desirable to establish a buffer area upon entrance into the

facility and/or upon entrance into the PSCA. The buffer area is where traffic restriction can be implemented and different types of hygiene procedures can be applied. The buffer area, if established, should be designed to reduce the potential for introducing contamination into the PSCA, either through workers or through other items such as packaging materials, cleaning tools, and equipment. Examples of desirable features for buffer areas at entrances to the PSCA in an infant formula facility are listed in Table 2-1.

- Establish barriers for the PSCA. Barriers can be established upon entrance and exit to the PSCA, from exiting the basic GMP and transitional areas. The barriers serve to completely or partially separate the PSCA from the rest of the facility. Physical separation between the PSCA and the rest of the processing area is particularly important for operations that use raw ingredients in which *Salmonella* is unavoidable (e.g., raw cocoa beans, raw nuts and grains).

    - Upon entrance to the facility, traffic may move between the basic GMP area and the transitional area without additional barriers. Movement of personnel and materials into the PSCA is controlled to various degrees depending on the type of operation. The riskier the product the greater the need to have a physical separation. For example, in powdered infant formula production, it is desirable to have a physical separation of the PSCA (walled off from the rest of the operation).

    - Another example is peanut processing, where the raw side of the process is separated from the rest of the facility. The area in which raw peanuts are dumped into the roaster is physically separated from the roaster exit. A hygiene juncture is maintained at the entrance of the raw side of the process where gowning and boot changing, which may be color-coded, occurs. These are removed when exiting the raw side and a new set of attire is worn on the finished side. This is also the case for cocoa bean handling and processing.

- Control all traffic between the PSCA and the rest of the facility, including the movement of personnel and materials. Avoid activities that may lead to contamination of the PSCA. The following list of activities should be considered:

    - Direct traffic between the raw side and the finished product side. Movement of personnel and materials (e.g., ingredients used in dry-mixing, packaging materials, pieces of equipment, carts, and cleaning tools) into the PSCA should be minimized and strictly controlled. Prior to entering the PSCA, personnel should follow established hygiene procedures in a buffer area or vestibule. These may include removing clothing/boots worn in the raw side of the process area and replacing them with clothing/shoes and other protective garments designated for use in the PSCA. Washing and drying hands prior to entering the PSCA is also important. **All boots or shoes should be dry when entering into dry processing or packaging areas. Boots should be scrubbed and sanitized with an EPA-registered sanitizer as directed by the product label at shift end and allowed to dry**

before next shift, or be scrubbed and dry before entering the processing area.[6]

- Dedicated workers may be assigned to hygienic areas at the facility.

- Dedicated equipment, pallets, utensils and other tools should be used in the PSCA.

- Bringing products and ingredients into the PSCA without appropriate decontamination/treatment should be avoided. Additional controls are outlined in Element 5 for ingredients that are mixed into the finished product without a lethality step. (Procedures for handling dry ingredients to be added to the finished product without a further inactivation step are elaborated in Element 5.)

- ❑ Prevent or minimize dust moving into the PSCA from the other areas by physical separations such as walls and by other means such as using air filters and maintaining positive air pressure in the PSCA relative to the other areas of the facility.

    - Air filters should be installed and maintained in the ventilation system. The type of filters may vary from simple dust filters to High Efficiency Particulate Air (HEPA) filters, depending on the product, process and the intended consumer.

  Where necessary and depending on the product and hazard analysis, further steps may be taken to filter air used in direct contact with product (e.g., for product cooling or powder transport) by using a HEPA filter applied at a point close to the line. When using HEPA filtered air in direct contact with product, it is more efficient to apply the filtration close to the point of use rather than filtering all air entering the PSCA with a HEPA filter.

Hygienic Design of Buildings and Equipment

pages 33-37 GMA document.

***Salmonella* Control Element 3:**
Apply hygienic design principles to building and equipment design.

It is probable a food manufacturing facility will be challenged with the introduction of *Salmonella* through numerous vectors, including contaminated ingredients, employee or equipment traffic, or infrastructure issues (breached roofs or drainage). The application of appropriate hygienic design standards to building design and layout, equipment, process and infrastructure is essential to ensure that if *Salmonella* is introduced it does not find a niche and become a resident/endemic strain but rather remains transient.

Optimal hygienic design of equipment and infrastructure is recognized as critical to the business by manufacturers of microbiologically perishable foods. Optimal design and equipment maintenance for these processes is

[6] Text in bold print added by APC. See appendix for sanitizers.

directly related to achieving desired product shelf-life, minimizing consumer complaints and enhancing company profitability. Conversely, manufacturers of low-moisture products have too often not had hygienic design and maintenance of equipment and infrastructure as a primary focus, given product shelf-life is not dictated by microbial growth. The industry hygienic design mindset has been shaped by the belief that microbial issues are not a concern given the stability of low water activity foods. Indeed, microbial growth will not occur in foods maintained at water activity below 0.60.

Highly visible recalls associated with these low water activity foods have convinced manufacturers of low-moisture products to recognize their foods are susceptible to post-process contamination by infectious, pathogenic microorganisms. These pathogens will not grow within the food, yet may survive for the duration of the product shelf-life and cause foodborne illness if consumed.

The manufacture of foods is accomplished by processes within areas of the manufacturing facility with differing requirements for water. The requirement for water during processing or sanitation typically defines the equipment and process hygienic design standards. These differing design standards do not reflect a lower hygienic expectation; but rather, the appropriate approach to maintaining the equipment and process in a hygienic state given the risk water presents for microbial growth. The equipment, surroundings and infrastructure that remain in a dry state (e.g., grain silos, dry blending, chocolate processing) generally will not be exposed to water and therefore have design standards that differ from those requiring water for food processing or sanitation.

Since limiting water is the primary means to control *Salmonella* in low-moisture food manufacturing it is imperative that the relationship of each process point and installation to water sources be evaluated. Simply put, the type of cleaning necessary at each process point will determine water usage. Food allergens often complicate this evaluation as installations may need to be designed to remove food allergens using water that otherwise would not be required. The selection of the appropriate hygienic design standards begins with identification of the method of cleaning that will be employed at each process point. It is important that the key stakeholders define the hygienic needs (i.e., type of cleaning) of an installation and forecast the future usage of the manufacturing line and process. New manufacturing line installation is very expensive and the desire for manufacturing flexibility is very high. The cost of retrofitting a manufacturing line and surrounding infrastructure designed to operate in a dry state to one that accommodates water is much higher than if the process was initially designed to accommodate water.

A multidisciplinary food safety team should determine the current and, to the extent possible, future plans for the manufacturing line and surrounding infrastructure. From these plans, the team should identify the new line’s and infrastructure’s relationship to water. The hygienic design standards will focus primarily on accessibility for dry cleaning and dust control if the equipment and process will remain in a dry state and receive only dry sanitation. Conversely, if the installation requires water, the focus on the installation and infrastructure will require a design that accommodates water, prevents microbial growth niches and receives microbiologically focused sanitation.

Common Industry Practices:

- Building design and layout should be based on hygienic principles, using common practices such as those outlined in the literature (CAC, 2008; EHEDG, 2001, 2003 and 2008; Graham, 2005).
- A common approach should be applied to sanitary design that keeps the equipment design as simple as possible and strives for a minimum number of parts, with all parts and assemblies accessible for inspection and cleaning. A program should be established for design review of equipment based on sanitary design principles, including some or all of the principles outlined in Table 3-1 as appropriate.
    - Review new equipment prior to purchase for sanitary design and layout. The proposed layout and placement in the facility should be evaluated to confirm that access necessary for proper cleaning is not compromised. The presence of the new equipment should not compromise the cleanability of existing machinery.
    - A similar review should be conducted for equipment that is relocated from one facility to another.
    - Plans to modify existing equipment should be reviewed by the plant food safety team prior to beginning the alteration.
    - Existing equipment should be periodically reviewed to verify that it still meets sanitary design principles and has not been altered in a manner that would compromise the sanitary design or cleanability of the equipment. Existing equipment should be modified when necessary to eliminate difficult-to-clean areas (such as unsealed hollow components, scratched surfaces, crevices, poor sanitary welds, etc.) and design features that may lead to residue build-up or stagnant products. Examples of poor design features are shown in Figures 3-1 and 3-2.
- If water will be used, the infrastructure and equipment must be designed to accommodate water. Development of microbial growth niches must be prevented. Water drainage from the process in the facility must ensure rapid drying. Additionally the infrastructure must be designed to prevent entry of unwanted water from surrounding processes or from outside the facility.
- Particular attention should be given to sanitary design, layout and maintenance of equipment located in the Primary *Salmonella* Control Area (PSCA) to ensure that moisture can be excluded from the processing environment, including the utilization of dry cleaning procedures (see more details in Element 4). Conditions leading to the formation of condensate should be eliminated or minimized to the greatest extent possible.
- Hygienic design standards and strict adherence to sanitation performance specifications must be applied to construction and major maintenance activities. These activities can dislodge microbial growth niches and lead to widespread contamination of the facility. The plant food safety team should evaluate this work and conduct an evaluation of the risk of introducing physical, biological or chemical hazards into

the facility. Based on this evaluation they should define and implement the appropriate preventive measures, such as temporary isolation of the construction or maintenance sites, rerouting of employee and equipment traffic, proper handling of waste material egress, maintaining negative pressure in the work site, etc.

- Equipment maintenance should follow hygienic procedures such as those described in Elements 1 and 2 as appropriate. Unscheduled maintenance is particularly risky, and hygienic procedures should be strictly followed.
- A wide range of accessory tools such as supports and ladders may be located inside large equipment or inside the PSCA. Hygienic design is critical and these tools/structures should not have features such as hollow bodies, loose parts or uncleanable surfaces.
- Elevated infrastructure should be designed to minimize dust and dry material accumulation, especially when pipes, overhead structures and platforms are directly above exposed products or production lines.

Table 3-1. Sanitary design principles for equipment [ξ]

1. **Cleanable.** Equipment should be constructed to facilitate effective cleaning that is verified by environmental monitoring.
2. **Made of Compatible Materials.** Construction materials used for equipment must be compatible with the product, environment, and dry cleaning and, when needed, wet cleaning and sanitizing.
3. **Accessible for Inspection, Maintenance, Cleaning and Sanitation.** When needed, equipment should be easily disassembled for sanitation without requiring special tools not normally used in food facilities.
4. **No Liquid Collection.** No stagnant product build-up or liquid collection areas. Equipment should be self-draining to assure that residues do not accumulate or pool on the equipment.
5. **Hollow Areas Eliminated or Sealed.** Hollow areas of equipment must be eliminated whenever possible or permanently sealed. Items such as bolts, studs, mounting plates, brackets, junction boxes, nameplates, end caps and sleeves should be continuously welded to the surface and not attached via drilled and tapped holes.
6. **No Niches** (e.g., no pits, cracks, corrosion, crevices, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets, or dead ends). Welds should be ground and polished smooth.
7. **Sanitary Operational Performance.** During normal operations, the equipment must perform so it does not contribute to unsanitary conditions or the harborage and growth of bacteria.
    - 7.1. **Hygienic Design of Maintenance Enclosures.** Human/machine interfaces such as push buttons, valve handles, switches and touch screens, must be designed to ensure product and other residues (including liquid) do not penetrate or accumulate in or on the enclosure or interface.
    - 7.2. **Hygiene Compatibility with Other Plant Systems.** Equipment design should ensure hygienic compatibility with other equipment and systems, such as electrical, hydraulic, steam, air and water systems.
8. **Validate Cleaning and Sanitizing Protocols.** Procedures for cleaning and sanitation must be clearly written, designed and proven effective and efficient. Chemicals recommended for cleaning and sanitation must be compatible with the equipment and the manufacturing environment.
9. **Separate Processes Wherever Possible.** Operations of different processes in food manufacturing plants should be properly separated to prevent cross contamination and or adulteration.
10. **Meet Personnel Hygiene and Sanitation Requirements.** All plant personnel, contractors and visitors must be trained and required to follow plant hygienic and sanitation requirements - NO EXCEPTIONS

[ξ] Adapted from an American Meat Institute document (AMI, 2002) targeted to *Listeria* control in high-moisture products. In many cases the general principles for sanitary design for high moisture are appropriate to low-moisture products.

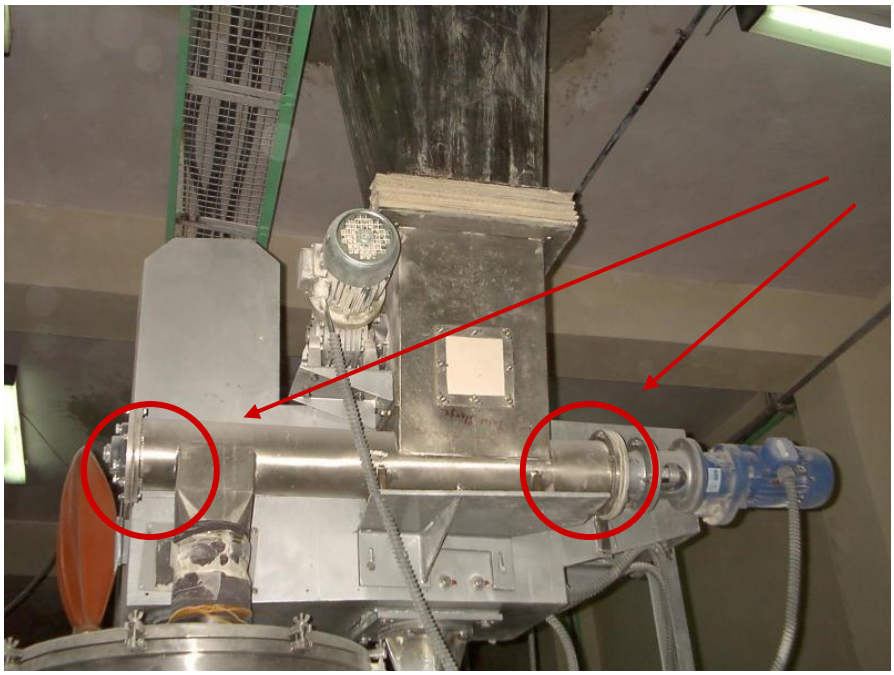


Figure 3-1. Ends of a horizontal screw conveyor – always a potential area of stagnant product build-up.

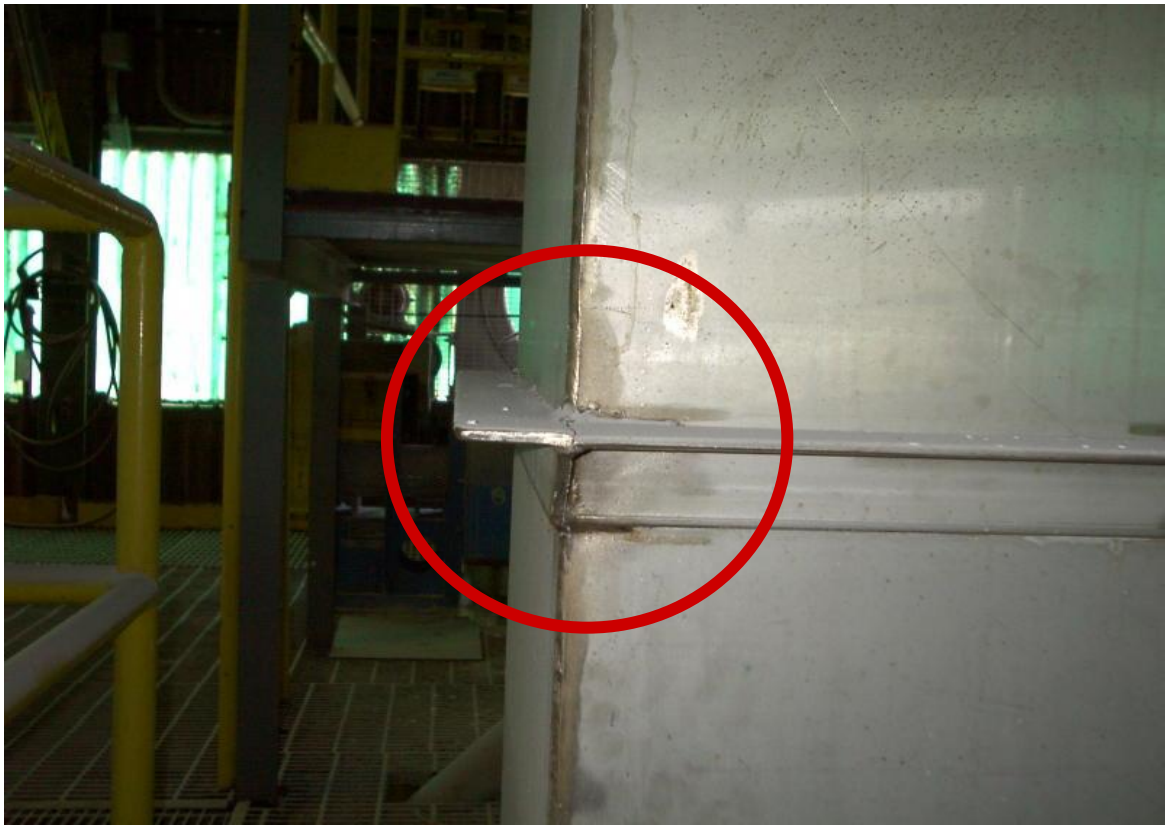


Figure 3-2. A flat surface that can collect product (This should be eliminated or sloped).

Moisture Control and Minimizing Growth

pages 38-44 GMA document (including effective dry and wet cleaning practices)

***Salmonella* Control Element 4:**
Prevent or minimize growth of *Salmonella* within the facility.

Moisture control is critically important in preventing *Salmonella* contamination in low-moisture products (ICMSF, 2005b). Water in the dry processing environment is one of the most significant risk factors (perhaps the single most important factor) for *Salmonella* contamination, as water allows for pathogen growth, significantly increasing the risk for product contamination. Industry experience indicates that the presence of water, even in very small amounts present for short, sporadic time periods, may allow *Salmonella* to grow in the environment. At times, moisture is obvious in the form of water droplets or puddles; or it may be from sporadic sources such as roof leaks. However, many sources of moisture, such as high relative humidity or moisture accumulating inside of equipment, are not visually apparent.

Salmonella can, to varying degrees, be introduced into low-moisture product manufacturing facilities and become established in those environments. Harborage sites may develop and become a source of product contamination unless these sites are identified and eliminated (CAC, 2008). A harborage site, or niche, is a site in the environment or on equipment (junctions, cracks, holes, dead-end areas, etc.) that enables the accumulation of residues (food debris, dust, and water) and permits the growth of microorganisms such as *Salmonella.* These sites may be difficult to inspect or access and therefore can protect *Salmonella* during routine cleaning and sanitizing.

Growth of *Salmonella* is only possible in the presence of water. Since food particles and dust are normally expected to be present in processing areas, adequate nutrients are always available to microorganisms. Growth cannot occur, however, if the plant environment is sufficiently dry. The potential *Salmonella* harborage sites become more significant when water is present for a sufficient period of time.

The presence of water in the dry processing environment can result from improper use of water during cleaning, which has been linked to the occurrence and spread of *Salmonella* (CAC, 2008; see Annex). Other events resulting in the presence of water in a dry area include condensate formation, leaking water or steam valves, infiltration of water following heavy rains (e.g., leaky roofs), the use of water showers in the case of fire emergencies, etc. (CAC, 2008). Efforts must be made to remove water immediately from the PSCA in such events in order to keep the plant environment as dry as possible. Dry conditions must be maintained at all time in the PSCA, except for the occasions when controlled wet cleaning is deemed essential. Potential problems arise when there is visible water present in the dry areas or when there are areas in which standing water has dried out. *Salmonella* may be found not only in wet spots but also spots where standing water has dried (Zink, 2007a). The latter situation may present an additional risk of spread via the generation of airborne contaminated dust.

Dry cleaning is typically employed when conducting sanitation in the PSCA. The objective is to eliminate water from the area so that despite the presence of food and other substrates, microorganisms (including *Salmonella*) will not grow. Without growth, *Salmonella*, if present, remains at very low levels, thus reducing the risk of product contamination. Dry cleaning has been successfully applied for many years in production of low-moisture foods such as dried milk and infant cereals to prevent product recontamination with *Salmonella*.

Dry cleaning is especially important in older facilities or older areas in a facility that were not originally designed based on current sanitary design principles. In such facilities, in spite of regular maintenance, there may be a potential for the presence of cracks or other harborage sites that may be difficult to eliminate. Even if dust or food residues may enter such a site, potential problems can be minimized if the residues and the sites are dry. Once water enters the harborage site, microbial growth can occur and the potential risk of contamination to the environment and eventually to the product is increased. Many years of industry experience shows that, even though the environment may appear a little dusty after dry cleaning, this is a far more hygienic condition (on a microbial level) than a wet-cleaned environment without visual dust. Serious *Salmonella* problems may develop when wet cleaning introduces moisture under equipment supports, into floor cracks and other difficult-to-clean or hidden spots where complete drying is not achieved.

Product accumulation should be removed as soon as possible (ICMSF, 2005b). Occasionally there are special circumstances, such as finding environmental sites positive for *Salmonella*, which requires that equipment not designed for wet cleaning be wet cleaned. Extreme care must be taken to understand the risks and to formulate a plan that will successfully eliminate the contamination without spreading and enhancing the problem. Dry and controlled wet cleaning may be required, including clean-out-of place with disassembly, cleaning and sanitizing, drying and reassembly. It is recommended that a multidisciplinary team be formed that has the appropriate expertise to plan and oversee this type of high-risk operation.

Common Industry Practices:

- Minimize the use of water in the entire plant environment.
- Specify the type of cleaning practices to be used in different hygiene areas, i.e., the basic area, transitional area, and PSCA. There are three types of cleaning (Table 4-1): dry, controlled wet and wet cleaning. Dry, wet and controlled wet cleaning in the different hygiene areas should be used at appropriate frequencies, which may be modified based on the specific product and process.
- Choose dry cleaning as the routine cleaning practice in the PSCA. Use controlled wet cleaning infrequently in a prudent manner and on an as-needed basis. Do not use wet cleaning or only use it in very rare cases in the PSCA, e.g., in response to a product contamination incident.
- When controlled wet cleaning is necessary care must be exercised such that only the minimum amount of water is used. Table 4-2 lists common

procedures for controlled wet cleaning. It is recommended that the environment of the wet-cleaned area be tested for *Salmonella* to verify sanitation effectiveness (see Element 7). Areas/situations where controlled wet cleaning may be necessary include the following:

- In the case of an unusual event, such as a roof leak or a faulty sprinkler that may lead to potential product contact surface contamination in the PSCA, production should be stopped. The leak should be fixed, and the area cleaned, sanitized, and dried before production resumes.

- Wherever possible, remove parts of equipment and conduct controlled wet cleaning on them in a room dedicated to cleaning.

- When controlled wet cleaning is done in a certain area of the PSCA, the area should be segregated and care must be taken so that the cleaning activities do not adversely impact the adjacent areas.

- Other examples of situations where controlled wet cleaning is needed include when the buffer area upon entry to the PSCA becomes dirty and requires cleaning, when there is a need to remove sticky build-ups and to remove allergens, etc.

- Eliminate water in the PSCA. Water distribution systems (piping, etc.) should also be limited to the greatest extent possible.

  - In order to maintain the PSCA as dry as possible, the use of dry drains (i.e., drains that are physically capped with an impermeable barrier when not being used to collect water) is recommended.

  - In production where hygroscopic products are made, procedures should be in place to remove as soon as possible accumulated product to avoid moisture build-up and localized condensation.

- Establish appropriate dry cleaning procedures for the PSCA.

  - The goal of dry cleaning is to collect, remove and dispose of residues without redistributing them or cross contaminating the environment. Examples of dry cleaning tools and their uses are described in Table 4-3. Personnel responsible for maintenance, cleaning and checking the tools should be designated and properly trained.

  - In addition to tools such as brushes and scrapers, vacuum cleaners are useful for dry cleaning. When vacuum cleaners are used, it is desirable to dedicate individual vacuum cleaners to specific areas, so that vacuumed material can be tested as part of the environmental monitoring program (see Element 7). If the material tests positive for *Salmonella*, there is a limited area to search for the source of the contamination. In addition, the contaminated vacuum has not been used in other areas around the plant and the contamination is confined. Desirable design features for vacuum cleaners are described in Table 4-4.

  - The objective of dry cleaning is to remove residues without the use of water by using tools or cleaning aids that do not entail

the application of water or other aqueous solutions. Where appropriate, blasting with dry CO_2 pellets or other dry abrasives can be an effective method for removing stubborn residues on equipment or facility surfaces without introducing water. Hot oil may also be used to flush the interior of equipment used to handle low-moisture products such as peanut butter or chocolate.

- Sanitizers that will rapidly evaporate after contact, such as alcohol-based sanitizers, provide a means to spot-sanitize equipment with a very minimal introduction of water. For example, critical or sensitive spots (such as electrical equipment control panels) can be dry-cleaned and then sanitized with an alcohol-based sanitizer. However, it is not possible to sanitize a dirty surface, such as an area with dry soils that cannot be removed effectively. These sanitizers are flammable; caution should be taken to prevent explosion or fire during application. **Use an EPA-registered food contact sanitizing wipe or alcohol-based sanitizer during production for spot sanitizing of hard, non-porous food contact processing surfaces or tools as directed by the product label. First, remove any gross soils with mechanical action using one wipe. Once visually clean, follow with another wipe as a sanitize step. Tools can also be wiped on a given frequency such as once per shift.**[7]

- Compressed air should generally not be used for dry cleaning except in special situations (e.g., to dislodge dust from inaccessible points). Moreover, if and when compressed air is used, it should be dried and filtered to exclude microorganisms and moisture prior to use. Water traps in compressed air systems can be included as part of the environmental monitoring program and be tested for indicator organisms (e.g., Enterobacteriaceae), as well as *Salmonella*.

- Dry cleaning should be monitored and verified by visual observations and environmental monitoring.

- Separation of cleaning tools used in different hygiene areas is important and can be accomplished using color-coding or other suitable means.

[7] Text in bold type added by APC.

Table 4-1. Types of cleaning in a low-moisture product manufacturing facility

Dry cleaning	No water is used. Dry cleaning is the physical removal of residues (food particles, dust, etc.) by actions such as sweeping, brushing, scraping, or vacuuming the residues from equipment surfaces and the plant environment.
Wet cleaning	Water can be applied. However, certain practices should be avoided, e.g., excessive use of water (floor is flooded with water), high pressure hoses. Instead, water should be used on an as-needed basis and should be minimized and isolated to specific areas where possible. Complete drying after the wet cleaning is essential.
Controlled wet cleaning	A limited amount of water is used. Complete drying must follow immediately after the controlled wet cleaning. Specific pieces of equipment may be moved out of the PSCA area, wet cleaned, sanitized, dried and then returned.

Table 4-2. Examples of common industry procedures for controlled wet cleaning

- Remove as much residue as possible by dry cleaning.
- Avoid overuse or careless use of water. Procedures for collecting water should be in place to prevent water spreading on the floor or following product conveyance lines or other connections to non-wet cleaned areas of the facility.
- Commercial pre-moistened sanitizing wipes may be used to spot-clean specialized areas with minimal introduction of water.
- Never use high pressure water application, even for situations such as to get rid of dry build-ups, as the over-spray will spread to other areas and contaminants can be aerosolized.
- When drains are not used for wet cleaning they must be sealed.
- During cleaning, there should be no changes in procedures for entering the PSCA all barriers still apply, e.g., entering through the buffer area and following required procedures.
- Always apply a sanitizing step following the controlled wet cleaning. EPA registered **sanitizers can be used on floors, and ready to use sanitizing and disinfecting surface sanitizers, can be used on hard, non-porous food contact surfaces. Sanitizers specifically formulated for foot baths can be used as a walk through solution prior to entry to protected production areas. Ready to use sanitizers can be used as a final sanitizing step on production equipment before thorough drying. Footbaths should be monitored and changed frequently throughout the day to maintain effective concentration.**[8]

[8] Text in bold print added by APC. See appendix for sanitizers.

- Ensure prompt and complete drying of all areas and components involved (equipment, parts, floors, the environment, etc.) after controlled wet cleaning. All equipment parts and environmental sites must be visually inspected for any remaining wet spots before the sites are released for production. Consideration should be given to evaluating the microbiological quality of the first product through the equipment to verify the efficacy of the controlled wet cleaning process.

Table 4-3. Examples of tools for dry cleaning and their uses

Tools	Design features and usage
Brushes, scrapers	- Choose tools with sanitary design that do not create hygienic problems. These tools should be cleanable, durable and without loose parts. The handles and supports should have no spaces where residues can accumulate. If the handle is hollow (e.g., to control weight for practical reasons), it should be sealed. - A tool that is used for cleaning product contact surfaces should not be used for cleaning floors, drains, and ceilings. - Provide a designated area to store cleaning tools not in use, e.g., hooks, hangers, storage cabinets, etc. - Check all brushes and scrapers regularly and replace them as needed. Do not use tools that are worn and could become potential sources of foreign materials and contamination. - Dry clean the tools. Wet cleaning is done only in designated areas and only if the tools can be dried promptly and completely; it must be done using controlled wet cleaning.
Vacuum cleaners	- Portable vacuum cleaners with appropriate design features are recommended for dry cleaning to avoid or limit the spread of dust. A vacuum cleaner has the advantage of collecting and retaining residues in a dust container. They can also reach difficult-to-reach places. For example, a vacuum cleaner is preferred to remove residues on overhead structures such as wiring supports and pipes (using a brush in this case would create and spread dust). - Desirable design features for vacuum cleaners are described in Table 4-4.

	- A vacuum cleaner used in the PSCA should not be used outside the area. A vacuum cleaner that is used for cleaning inside equipment should not be used for cleaning the floor. Dedicated accessories should be used accordingly. The dust bag should be removed in an area isolated and as far away as possible from the process line (but still in the PSCA). The vacuum cleaner dedicated to the PSCA should not be taken outside the PSCA for emptying because it could transport contaminants on its return. - A vacuum cleaner will only be an efficient tool if it is well maintained in such a way that it does not become a carrier of contamination, e.g., protected against water and moisture, making sure attachments are well fitted. If a vacuum cleaner used in the PSCA needs cleaning or maintenance, it can be done in a dedicated/isolated area in the PSCA or it can be protected by a plastic cover and transported on a pallet to a dedicated area outside the PSCA. After maintenance, the vacuum cleaner should be dry-cleaned. On rare occasions when necessary (e.g., when contamination is detected), the exterior of the vacuum cleaner can be subjected to controlled wet cleaning, sanitizing, and drying prior to use again. - Filter(s) should be properly maintained on a regular basis and replaced when necessary. - Central vacuum cleaners, if they are used, should be used with caution because these tend to have lengthy pipes that are difficult to clean and maintain. They can also harbor insects.

Table 4-4. Desirable design features for vacuum cleaners based on the location of use

For use outside the PSCA:

- Practical easy-to-empty vacuum cleaners equipped with a normal dust trap filter (for both large and small particles, but not necessarily a microbiological filter) and a removable and replaceable bag. To prevent dust from re-circulating to the air with the exhaust, a filter is installed on the outlet of the vacuum cleaner and maintained properly.

For use inside the PSCA:

- Should be made of stainless steel except certain accessories, contain a multiple-stage filtration system with replaceable bag for dust collection, and have practical and easy-to-clean or easy-to-replace accessories.

- Should have a detachable stainless steel trolley, straight stainless steel wands, flexible plastic hose, round brush, crevice cone or floor nozzle to be used as appropriate for the purpose.

- Exhaust fan and motor of the vacuum cleaner should be located above the dust collector;

- Accessories and spare parts can be easily obtained when replacement is needed;

- Accessories fit tightly when attached;

- Exterior is cleanable;

- Absence of fittings (wheels, etc.) that can accumulate dust.

- The vacuum cleaner should have a multiple-stage filtration system, which may include features such as a large main filter to ensure even airflow; a microfilter to protect the motor and acts as a barrier to small size particles; a HEPA (High Efficiency Particulate Air) filter with 99.97% efficiency in removing particles and bacteria down to 0.3 microns; and/or a ULPA (Ultra Low Penetration Air) filter that retains 99.999% at 0.12 microns. A HEPA filter should be used for at least some part of many operations (e.g., for a unit used to clean product contact surfaces). Whether a ULPA filter is needed would depend on the nature of the product and the point/area of use (e.g., equipment vs. floor in PSCA, inner surface vs. outer surface of equipment).

Raw Material Program

pages 45-49 of GMA document

Reference pages 16-22 of this document.

Validation of Control

pages 50 -58 of GMA document

Reference pages 29-35 of this document.

Verification of Controls and Corrective Action

pages 61 – 69 of GMA document.

Reference pages 35-46 of this document.

The following is a summary of very important activities that serve to prevent post-processing contamination of finished product. The list is not all-inclusive and processors are encouraged to develop their own checklists for use in inspecting and monitoring their facilities. Due diligence should be observed at all times in areas of conveyance and handling after kill step processing has occurred:

- Physical separation from unprocessed materials or components
- Proper air flow to prevent particulate matter from contaminating finished components
- Air filters properly installed and maintained in finished component areas
- Traffic control between finished and unfinished component areas, including fork lifts/trucks
- Moisture control from any source in finished component areas
- Roof integrity, frequent inspections should be performed. Cover any open products or conveyors at first sign of roof leak.
- Container control, dedicated for each area, color coding recommended
- Storage pallets should be clean and inspected regularly
- Integrated pest control program to include finished component area

AFLATOXIN CONTROL

Pre-harvest Control

Land selection is a very important factor in the prevention of aflatoxin contamination. Certain types of soils, such as light, sandy soils can favor the growth of the source fungus under dry environmental conditions while heavy soils with higher water holding capacity can contribute to the prevention of drought stress that is known to promote growth (United Nations FAO and WHO, 2004). Crop rotation is important to prevent build up of high populations of *Aspergillus* in soils. Appropriate nutrient application for promotion of healthy plants, including adequate pH, and proper calcium and potassium levels, will help insure low aflatoxin levels (United Nations FAO and WHO, 2004). Other factors to combat drought stress include proper irrigation and soil moisture, proper plant density and weed control. Prevention of fungal infections due to insect damage should include practices that limit soil insects, mites, and nematodes through the use of approved insecticides, herbicides, and fungicides (United Nations FAO and WHO, 2004).

Post-harvest Control

Moisture is a critical factor in controlling growth and spread of *Salmonella* in the postharvest environment and this can also be said for *Aspergillus* and aflatoxin production. Therefore, peanuts should be dried to a point that the moisture level is low enough that growth is not supported during storage. All containers used to store or transport peanuts must be clean, dry and free from fungal growth. Conditions that prevent condensate formation should be maintained to prevent the growth of mold. Damaged kernels are particularly susceptible to contamination by *A. flavus* or *A. parasiticus*, so care must be taken to handle peanuts to prevent damage (Graham, et al., 2009). Farmers' stock peanuts should be tested for aflatoxin and sorted according to results. Aflatoxin-free peanuts should separated from low level and high-level lots. It may be desirable to reprocess lots containing aflatoxin at low levels either by resorting or split nut blanching (the process of removing the exterior skin and splitting the whole kernels. Regulations of the applicable legal authority may dictate what reprocessing is allowable. Monitoring programs may be used on peanuts while in storage to continually assess the level of aflatoxin present. It is advisable to keep records of temperature, moisture and humidity and their effect on aflatoxin levels each harvest season. Before receiving and shelling peanuts the aflatoxin level should be determined. Any lots where aflatoxin cannot be reduced to acceptable levels by additional sorting should not be processed. Electronic sorting can be an effective measure for removing damaged or moldy peanuts especially when used in conjunction with blanching but care should be taken to segregate and destroy rejected and contaminated materials. Other important factors contributing to effective control of aflatoxin include: a strong supplier assurance program; careful inspection of incoming lots; dump pits and handling equipment that are well maintained, clean and dry; facilities that are clean, dry and well ventilated; integrated pest management program (United Nations FAO and WHO, 2004).

Testing Raw Peanuts

The USDA requires that all raw shelled peanut lots are tested fro aflatoxin before they are shipped to a manufacturer. The peanut industry established an aflatoxin tolerance of 15 parts per billion (ppb) that is lower than the FDA guideline of 20 ppb. Lots that exceed the USDA tolerance of 15 total ppb can be reprocessed to reduce the aflatoxin content. However, it is forbidden to blend lots that are high with lower level lots for the purpose of dilution. Reprocessing options include (a) sending the peanuts back through the shelling plant (re-milling), (b) sending the peanuts to a blanching facility (the blanching process is a two-step process where the skins are removed from the kernel and damaged or discolored kernels are removed from the

lot using electronic color sorters, and/or (c) crushing the peanuts for oil (Whitaker, et.al. Peanut Science, 2002). Regulatory requirements for reconditioning failed quality peanuts are described in 7 CFR Chapter IX Part 996.50. The U.S. regulations governing aflatoxin for peanuts to be certified as edible quality can be found in the Code of Federal Regulations Title 7 section 996.11 marketing agreement. It states that a lot of peanuts are deemed negative if aflatoxin is 15 ppb or less. The CFR Title 21 part 110.110 subpart G Guidance, Compliance & Regulatory Information for Chemical Contaminants and Pesticides dictates a peanut products aflatoxin Defect Action Level of 20 ppb. European regulations have a ready-to-eat product maximum limit for peanuts of 2 ppb for aflatoxin B1 (4 ppb total) and a tolerance of 8 ppb for aflatoxin B1 (15 ppb total) for peanuts that will be further processed (United States Department of Agriculture FAS, 2010). Sampling plans and sample preparation are the keys to accurate results with aflatoxin analysis. The U.S. sampling plan for raw, shelled peanuts was evaluated by Dr. Tom Whitaker at North Carolina State University and is considered to be the current best method for sampling shelled peanut lots in the shelling plant (Whitaker and Dickens, 1979) The sampling plan consists of an automatic sampler set to cut the stream of peanuts at given intervals to achieve a 160-pound sample. Sixteen pounds are used for grade analysis by Federal State Inspection Service and the 144 pound sample is divided into three 48 pound bags designated for aflatoxin analysis. The criteria for using the three-bag samples (designated 1AB, 2AB and 3AB) are as follows: test results for finished lots must be < 15 ppb total aflatoxin as follows: if 1AB <8 ppb the lot passes, if >8 ppb and <45 ppb then run the 2AB; if 1AB + 2AB average <12 ppb the lot passes, if >12 ppb and <23 ppb, then run 3AB; and if 1AB + 2AB + 3AB avg. <15 ppb then the lot passes. A more complex plan and criteria for EU sampling is governed by Commission Regulation (EU) No 178/2010 (EU, 2010).

The USDA grade certificate and the USDA aflatoxin assay certificate produced by approved laboratories must accompany any lot of raw peanuts shipped to a customer. These, however, do not relieve the manufacturer of liability for aflatoxin control. A "negative" certificate (0-15 ppb) means that the lot may be processed for edible product. The manufacturer may consider further sorting, processing, sampling, testing, and caution when processing the lot.

The Federal Food, Drug and Cosmetic Act (FDCA) forbids the sale or distribution of adulterated food products. The Food and Drug Administration has the authority by federal law to recall, seize, or otherwise prevent the distribution of such products.

The presence of aflatoxin in peanut food products in amounts demonstrable by the official procedure of the AOAC (See Section VII) is established as adulteration under 402(a) of the Federal Food, Drug, and Cosmetic Act. (See U.S. vs. Articles of Food, White Corn, etc, U.S. District Court of Kansas, Civil Action #T-4173, Order Files 1.22.71.).

Testing Finished Products

Testing for aflatoxin should rely on validated testing methods. Particulate or whole kernel products such as salted roasted peanuts pose problems of sampling error. In such a case, the processor would adopt a sampling plan similar, if not identical, to the USDA method on raw peanuts. The acceptable levels on finished product must comply with the FDA action level. Peanut granules or crunchy peanut butter pose similar sampling difficulty as whole or split kernel products. However, the sample size can be reduced since some size reduction and mixing has been done, but in no case should the sample size be less than the total contents of one jar for peanut butter. Smooth ground product such as peanut butter needs merely to be sampled with sufficient quantity to fulfill the requirements of the AOAC test procedure used.

- The manufacturer is advised to use an internal action level well below the FDA action level in order to cope with the sampling and testing variability. The testing procedure is still an imperfect technique. If only one analysis is run, a good rule of thumb is not to ship a lot unless the test level is no more than half the action level. If a single finished product test is found to be in excess of this value, the processor should increase the number of samples and shorten the sample interval to determine whether there is any product that exceeds the action level. This will provide protection due to a "hot spot" or new lot effect as described above. It also provides the processor an opportunity to check the process, particularly the sorting step to see if there are any malfunctions. It may also be expedient to change the raw material and retest the raw peanut lot being used to determine if it could be the source of contamination

ALLERGEN CONTROL

Because of the nature of peanut allergy, manufactures must take special care not to allow cross contact of their various product lines. Non-peanut products should be processed separately from peanut product lines or the production equipment must be thoroughly cleaned before processing peanut products again. The converse is also true.

Why an allergen program?
Peanuts are among the eight most allergenic foods responsible in total 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. Even if a person is not allergic to peanuts, 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 peanuts. It is highly recommended that other nuts NOT be processed in the peanut plant, particularly if using peanut processing equipment. This safety measure will protect consumers, brands and company reputations.
Cleaning reduces the possibility of cross-contamination
However, if a business requires processing nuts other than peanuts, an allergen prevention program is recommended. 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 essential for eliminating even the smallest residue of other nut products. Every time a product other than peanuts is processed it should be assured that 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.

Sampling for allergens is also recommended to minimize the possibility of mislabeling. These tests should be conducted on a regular basis to ensure product safety. Allergen testing would be driven by the ingredients used. Allergen changes within a facility should be carefully documented and validated changeover procedures should be used.

Components of an allergen control plan (ACP)

General

1) Form an allergen control team consisting of representatives from manufacturing, quality and regulatory affairs, research and development, engineering, sanitation, and food safety sectors.
2) Conduct a risk assessment to determine the choice of the specific allergen management procedures.
3) Develop an allergen map (allergen process flow diagram) to understand where allergenic ingredients and foods are in a plant and where they are introduced into the process.
4) Develop an ACP specific for each processing facility.
5) Review the ACP regularly and update when necessary.

Segregation of allergenic foods or ingredients during storage, handling, and processing

1) Store allergenic ingredients or products separately to prevent cross contact.
    a) Use clean and closed containers.
    b) Separate storage areas for allergenic and non-allergenic ingredients and/or products.
    c) Use dedicated pallets and bins.
    d) Use clearly designated staging areas for allergenic foods and ingredients.
2) Identify allergenic ingredients by a mark or tag (or color code) and isolate them from non-allergenic
products in storage.
3) When dedicated processing lines are in close proximity, build physical barriers to separate allergenic and non-allergenic production lines.
4) For production lines with crossover points, prevent allergenic foods from falling onto non-allergenic
production lines.
5) Prevent spread of aerosols during processing.

Supplier control programs for ingredients and labels

1) Require ingredient suppliers to have a documented ACP.
2) Require letters from suppliers that guarantee that purchased ingredients are free of undeclared allergens.
3) Audit suppliers on a regular basis to assess the effectiveness of the ACP.
4) Require certificates of analysis from suppliers.
5) Conduct a supplier survey that includes:
    a) The ACP of the supplier.
    b) The range of allergenic products produced by the supplier.
    c) The allergen cleaning program.
    d) Allergen training records for the supplier.
6) Ensure that allergenic ingredients are shipped in clearly marked, sealed containers and that the containers are not damaged or broken.

Prevention of cross contact during processing

1) Scheduling of processing runs.
    a) Schedule long runs of products containing allergenic ingredients to minimize changeovers.

b) Segregate allergenic and non-allergenic product production areas, or if this is not possible
process non-allergenic foods before allergenic products.
c) Schedule sanitation immediately after production of foods containing allergenic ingredients.
d) When product design permits, add allergenic ingredients as late in the process as possible.

2) Use of dedicated systems.
a) Dedicate processing equipment and lines, if possible, to prevent allergen cross contact.
b) Dedicate tools, containers, and utensils and color code or clearly mark them.
c) Minimize reuse of processing and/or cooking media (water or oil).
d) Restrict personnel working on processing lines containing allergenic ingredients from working on non-allergenic production lines.

3) Control of rework and work in progress.
a) Use color-coded tags to identify and record when reworked products with allergenic ingredients are produced, where they are stored, the products to which they are reworked into, and when these products are added back into the line.
b) Use rework containing unique allergenic foods and/or ingredients only in the same formulation (e.g., ‘‘like into like’’ practice)

4) Maintain equipment to ensure that the systems are operating as designed.
5) Design traffic patterns and airflow in the production facility to prevent allergen cross contact.

Product label review; label and packaging usage and control

1) Ensure that packaged foods regulated under the Federal Food, Drug, and Cosmetic Act that are labeled on or after 1 January 2006 comply with the FALCPA food allergen labeling requirements.
2) Ensure that product specification and formulation changes are reflected immediately on labels.
3) Discard out-of-date labels or packaging in a timely manner.
4) Implement proper inventory control procedures for packaging materials.
5) Implement proper packaging staging control procedures.
6) Educate line personnel on techniques for ensuring that product labels are switched appropriately
at product changeover.

Validated allergen cleaning program

1) Construct processing equipment and plant structure with good sanitary features including:
a) Ease of cleaning and sanitizing.
b) No dead spots that allow accumulation of food.
c) Accessibility of equipment for inspection.

2) Parts of the allergen cleaning program to be developed:
a) Sanitation standard operating procedures.
i) Protocols are clearly written and easy to follow.
ii) Define the scope (range of applications, equipment, and products) of the cleaning
procedures.
iii) Define who is responsible for the cleaning operations.
iv) Include detailed cleaning instructions.
b) Cleaning validation procedures.
i) Protocols are clearly written and easy to follow.
ii) Define the intention and scope of validation.
iii) Describe the sampling procedures.

iv) Define and describe the analytical procedures to be used.
v) Define the final acceptance criteria.

c) Cleaning verification procedures.

i) Protocols are clearly written and easy to follow.
ii) Define the intention and scope of verification procedures.
iii) Describe the sampling procedures.
iv) Define and describe the analytical procedures to be used.
v) Define the acceptance criteria.

3) Validate the analytical procedures used to validate and verify cleaning efficacy by the end user.
4) Keep records for cleaning, validation, and verification.
5) Evaluate the allergen cleaning program periodically for effectiveness.

Training

1) Provide general training on allergen awareness and control for all employees at all levels of the company.
2) Provide specific training to employees depending on their job responsibilities.

Food Fraud

Intentional, economically motivated fraudulent adulteration of food ingredients (EMA) has become a recognized food safety risk for food processors. The U.S. Pharmacopeia Convention has pre-released "Guidance on Food Fraud Mitigation," a guidance document covering EMA. Below is a web address for this guidance that will help any organization needing assistance in identifying the most fraud vulnerable ingredients and how to choose effective mitigation tools to combat EMA.

http://www.usp.org/sites/default/files/usp_pdf/EN/fcc/Notices/guidance_on_food_fraud_mitigation.pdf

Food Defense

The FDA has provided excellent resources to help companies develop a food defense program. The following web address is for a set of online courses that provide an understanding of and guidance for developing a Food Defense Plan based on a common sense approach.

http://www.accessdata.fda.gov/scripts/FDTraining

A brochure for the program may be viewed and printed at the following web address:

http://www.fda.gov/downloads/Food/FoodDefense/ToolsEducationalMaterials/UCM354547.pdf

HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS (HACCP)

The HACCP system is a management system that focuses on prevention of problems as opposed to reactive approaches. Its goal is to provide the processor with the information required to recognize potential food safety problem areas and set up a deliberate and structured plan to monitor these areas and put controls in place to prevent the problem. HACCP covers all types of potential food safety hazards – biological, chemical, and physical. A good foundation must be in place in order to develop an effective HACCP plan. This foundation is often referred to as prerequisite programs. Prerequisite programs may include areas outlined below:

Facilities
Personnel
Production Equipment
Control of Raw Materials
Sanitation Programs
Environmental Monitoring
Chemical Control
Pest Control
Allergen Management Program
Glass Control
Receiving, Storage, and Distribution
Product Tracing and Recall
Production and Quality Controls
Complaint Investigations
Labeling
Training Programs

Many of these items have been covered in previous sections on GMP's and Best Practices.

Principles of HACCP

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Verification Procedures
7. Establish Record Keeping and Documentation Procedures

Initial Tasks in Developing HACCP Plans

1. Assemble a HACCP team
2. Describe the food and its distribution

3. Describe the intended use and consumers of the food
4. Develop a flow diagram that describes the process
5. Verify the flow diagram

Conduct a Hazard Analysis

The HACCP team should meet and identify possible hazards by developing a list of potential hazards for consideration during the hazard identification phase. During hazard identification the team decides which of the potential hazards present a significant risk to the consumer. The HACCP team should identify measures to control the specific hazards.

Determine Critical Control Points

The HACCP team determines critical control points (CCPs) based on the results of the hazard analysis. Potential hazards that need to be addressed as CCPs are those that were identified in the hazard analysis as being reasonably likely to cause injury or illness if not controlled. A CCP is a point in the process at which control can be applied to prevent or eliminate the food safety hazard or reduce it to an acceptable level

Establish Critical Limits

The HACCP team establishes the maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce the occurrence of a food safety hazard to an acceptable level.

Establish Monitoring Procedures

Procedures for observations or measurements must be established to monitor the CCPs to determine and document whether these critical limits are being met.

Establish Corrective Actions

Deviations from a critical limit will result in actual or potential hazards to the consumer. Therefore, appropriate steps must be taken to address the problem Corrective actions must be established for each CCP that will result in it being brought back into control and assurance that no affected product will leave the facility.

Establish Verification Procedures

Activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan must be established. It should be shown that the plan is adequate to control hazards associated with the product when the plan is properly implemented and that the plan is being followed.

Establish Record-Keeping and Documentation Procedures

Records should be established that document the summary of the hazard analysis, the HACCP plan, support documentation, and daily operational activities. A document control and record

keeping system should be established so that all documents available reflect current revisions and that records are maintained and stored effectively. Record reviews should be planned to ensure that all requirements have been satisfied and accurately documented.

An excellent reference for developing and implementing a HACCP program can be found in HACCP, A Systematic Approach to Food Safety, edited by Virginia N. Scott and Kenneth E. Stevenson, Ph.D., Food Products Association.

The American Peanut Council in collaboration with the University of Georgia Food Science Department has developed a peanut industry HACCP course. Please contact the University of Georgia or the American Peanut Council for schedules.

MODEL HACCP PROGRAM FOR THE PEANUT INDUSTRY

Example Process Description for the Manufacture of Ready to Eat Peanut Butter

Please note that this process description is not meant to represent any specific existing process but is a generic description written for the HACCP for Peanut Processors class exercise. Validation information stated is for exercise purposes only and does not represent an actual study performed. Conditions and specifications quoted are for illustrative purposes only and may not represent correct actual process conditions.

Peanut butter is prepared from a blend of ground peanuts and other non-peanut ingredients (sugar, molasses, hydrogenated vegetable oil, mono and diglycerides, and salt). Non-peanut raw material suppliers are required to provide certificates of analysis assuring lots delivered do not exceed specification limits for pathogens or foreign material. Verification testing for pathogens confirms lots are within specifications.

Shelled peanuts are received on trucks from several sheller locations. Each sheller is required to submit a USDA certificate of analysis for negative aflatoxin and edible grade standard. Negative aflatoxin means 15 parts per billion or less average maximum for subsamples with no individual reading greater than 25 parts per billion. Peanuts are stored in a segregated storage area at 34 to 41 degrees Fahrenheit (F.) and 55 to 70% relative humidity. Other raw materials are received and stored at ambient conditions.

All processing equipment is cleaned and sanitized according to a Master Sanitation Schedule that includes cleaning and sanitizing between production runs. Peanuts are passed through equipment that removes any residual foreign material, including sticks, rocks or metal pieces. The peanuts are then conveyed through a roaster that applies forced heated air uniformly from above and below the peanut bed, which is kept at an even bed depth of 2 inches through the use of a leveling device. The peanuts are exposed to 300 degrees F. for 25 minutes. A process validation study performed on this specific process has shown that these conditions provide a minimum 5-log reduction of *Salmonella.* The bed depth, time, and temperature are all monitored during peanut

roasting.

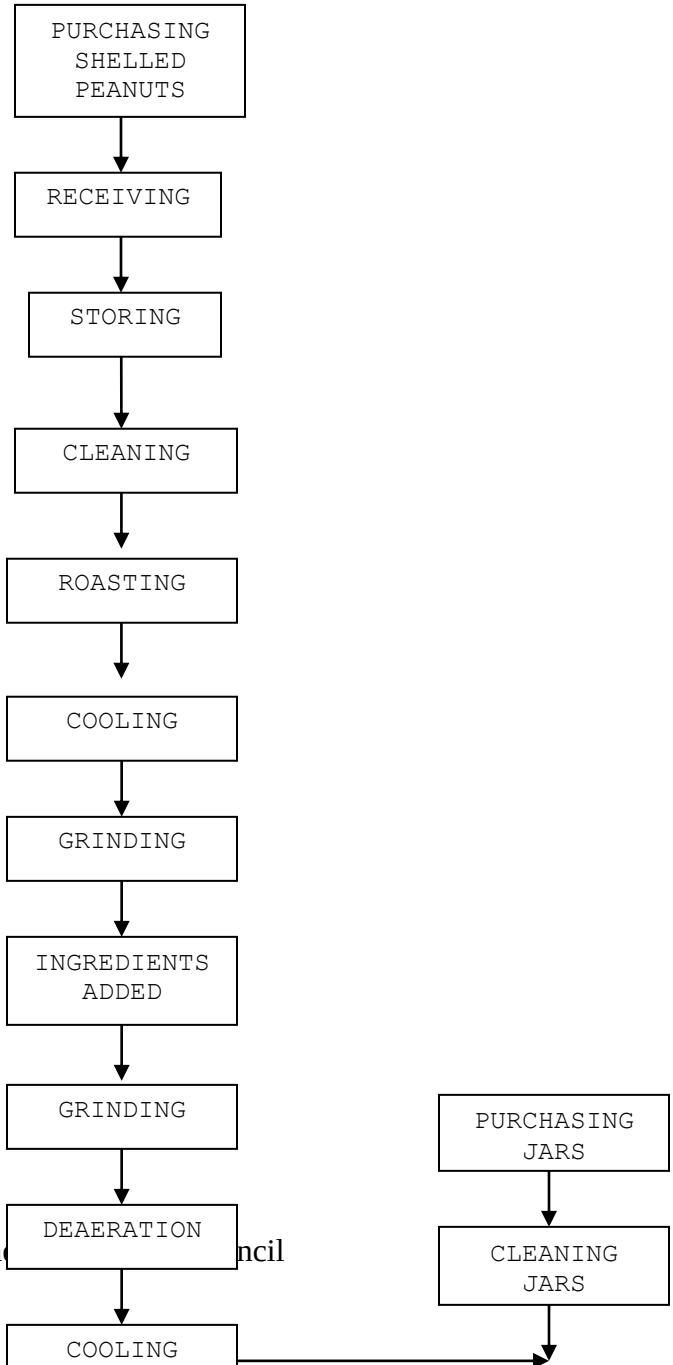
The peanuts are then conveyed into a segregated area where they are stored in stainless steel bins. The roasted peanut storage area is isolated from other materials through the use of physical separation barriers and positive airflow conditions, as well as air filtration systems. Traffic flow and equipment use is controlled and restricted in this area. A sanitary facility program is in place including regular and frequent roof integrity inspections. An integrated pest control program is also in place.

Peanuts are conveyed across a magnet for metal removal to a grinder where the peanuts are coarse ground to a paste consistency. The paste is then pump conveyed to a mixer where the other ingredients are added and mixing occurs. The mixture is then conveyed to a second grinder where the particle size is further reduced. The product is then passed through a deaerator to remove entrapped air, and then passed through a cooler into a mill where the final particle size reduction takes place. The product is then passed through a fine screen and metal detector prior to being conveyed to the filling and packaging area.

Peanut butter is packaged into plastic or glass jars. The jars are first passed through a jar cleaner where they are blown out with filtered deionized air to assure removal of any foreign material. The peanut butter is then conveyed to the filling equipment and jars are filled. Jars are passed through a metal detector and then capped and labeled with a lot identifier code printed on each jar. The label also contains a warning that this product is made from peanuts which are a know allergen. The jars are then overwrapped, palletized and stored until ready to ship. Finished product is sampled and tested for quality characteristics as well as for *Salmonella*. Product is held in control of the processor until negative *Salmonella* test results are received. The processor has a procedure in place with trained personnel which requires that any *Salmonella* positive product be destroyed and any product that has been distributed recalled immediately through their documented retrieval system. Corrective action plan procedures in this event include cleaning and disinfecting the processing facility and equipment and contact surfaces. They include an intensive environmental *Salmonella* sampling and testing protocol to identify the root cause of contamination.

Released product is shipped to customers, which include large retail chains as well as institutional users.

EXAMPLE PEANUT BUTTER PROCESSING FLOW DIAGRAM



HAZARD ANALYSIS WORKSHEET EXAMPLE

Process Step	Item	Potential Hazard	B,P, or C*	Preventive Measure	Severity	Likelihood	Need to address in Plan?	Justification
Purchase	Raw PNs	Aflatoxin	C	COA	High	Low	No	Aflatoxin is a known carcinogen but USDA required Aflatoxin testing program reduces risk of occurrence
		Salmonella	B	Roasting later	High	High	Yes	*Salmonella* has been found in raw peanuts and is associated with foodborne illness outbreaks
		Foreign Material (metal, glass, or stones)	P	Cleaning later	Med	Low	No	Hazardous foreign material NRLTO in finished product due to effective foreign material removal by screens, magnets, and electronic sorting equipment
		Infestation	B	Pest Control	Low	Low	No	NRLTO due to effective integrated pest management program
Receive	Ingredients	Infestation	B	Pest Control	Low	Low	No	NRLTO due to effective integrated pest management program
Store	Ingredients	Infestation	B	Pest Control	Low	Low	No	NRLTO due to effective integrated pest management program
Clean	Raw PNs	Foreign Material	P	FM removal	Med	High	No	Hazardous foreign material NRLTO in finished product due to effective foreign material removal by screens, magnets, and electronic sorting equipment
Roast	Peanuts	*Salmonella*	B	Thermal Inactivation	High	High	Yes	Salmonella has been associated with foodborne illness outbreaks in peanut products. This step is required to inactivate *Salmonella* present
Cool								
Grind	Peanuts	Metal	P	Magnet	Med	Low	No	NRLTO due to material screens, magnets and sorting equipment
Grind	Peanut Butter Mix	Metal	P	Screen, metal detector	Med	Low	No	NRLTO due to material screens, magnets and sorting equipment
Deaerate								
Cool								
Purchase Jars	Jars	Glass, Plastic	P, C	Air blown clean later	Med	Low	No	NRLTO because of cleaning and supplier requirements in Supplier Assurance program

Clean Jars	Jars	Glass, Plastic	P, C	Air blown clean	Med	Low		NRLTO because of cleaning and supplier requirements in Supplier Assurance program
Fill Jars								
Pack/Label								

*Bacteriological, Physical or Chemical

Good pre-requisite programs for supplier assurance, pest control, foreign material removal, and metal detection help justify the low Likelihood ratings for items listed as Low.

Severity is judged based on susceptibility of consumers to illness or effect, duration of illness or injury or known specified hazard levels. Likelihood of occurrence is judged based on experience, past outbreak data, and scientific literature.

Example Critical Control Point Decision Tree

All items on Hazard Analysis with High Severity and High Likelihood are put through decision tree. Reference Appendix A-6 HACCP: A Systematic Approach to Food Safety; Virginia N. Scott and Kenneth E. Stevenson, PhD. Fourth Edition, 2006.

Step	Hazard	Do control measures exist for identified hazard?	Is control at this step necessary for safety?	Does step eliminate or reduce likelihood of occurrence to acceptable level?	Could contamination with identified hazard occur in excess of acceptable levels or could these increase to unacceptable levels?	Will a subsequent step eliminate hazard or reduce the likelihood to an acceptable level?	Critical Control Point?
Purchase raw PNs	*Salmonella*	Yes	No	No	Yes	Yes	No
Roasting	*Salmonella*	Yes	Yes	Yes	Yes	No	Yes

Example HACCP Plan Critical Limits Monitoring Form

Process Step CCP	Control Limit	What	How	Frequency	Who	Remedial Action
Roasting	300F/25mins.	Oil temp/time	Thermometer/Timer	Continuous recording chart	Roast Operator	Quarantine and destroy or re-roast

Food Safety Modernization Act (FSMA)

The Food and Drug Administration has published rules requiring organizations to develop a food safety plan..

Following are key aspects of a food safety plan.

- Hazard Analysis: The plan must identify and evaluate hazards for each type of food manufactured, processed, packed, or held at the facility.

- Preventive Controls: The plan must identify preventive controls that significantly minimize or prevent hazards. Preventive controls include process controls, food allergen controls, sanitation controls, and a recall plan.

- Monitoring Procedures: The plan must document procedures to ascertain that preventive controls are consistently performed.

- Corrective Actions: The plan must identify steps to take if preventive controls are not adequately implemented, to minimize the likelihood of problems reoccurring, to evaluate the food for safety, and to block problem food from entering commerce.

- Verification: The plan must spell out verification activities and document that preventive controls are effective and consistently implemented.

Details of implementing a food safety plan are available on FDA's website. The Grocery Manufacturers Association (GMA) has updated its publication entitled "Industry Handbook for Safe Processing of Nuts" incorporating the new requirements of the FSMA rule for preventive controls in human foods. Training curricula and guidance documents have been developed for delivery to organizations. The American Peanut Council is directly involved in these efforts and will make resources available to help organizations comply with the new rules.

A model food safety plan for peanut butter has been developed by the Food Safety and Preventive Controls Alliance. Copies are available for purchase at http://bookstorefspca.ifpti.org/index.php/for-instructors.html.

Appendix I Sanitizers

The following list of sanitizers was provided by Ecolab. Other companies supply similar products and are welcome to provide lists of these materials to the American Peanut Council for inclusion in this Appendix.

- **Personal Hand Hygiene – Prior to entering plant**
  - Wash, Rinse and Dry Hands followed by Eco-Care 350 Sanitizer
- **Foot Hygiene – Prior to entering / after exiting dry processing areas**
  - Spray boots with RTU Sanitizer (same registration as Alpet D2)
  - Walk through foot bath mat filled with Sani-Step
- **Maintenance Tools (departmental, production, cleaning & contractor tools)**
  - Wipe down with Eco-Wipe FCS prior to use (at least once per shift)
- Eco-Wipe FCS
  - EPA-registered quat/alcohol based ready-to-use sanitizing wipes
- RTU Surface Sanitizer
  - EPA-registered, ready-to-use sanitizing and disinfecting solution
- Sani-Step
  - EPA-registered, solid, granular quaternary floor sanitizer
- Eco-Care 275
  - Green liquid, foaming hand soap with 1.0% chlroroxylenol as an active ingredient
- Eco-Care 350
  - Colorless liquid hand sanitizer with isopropyl alcohol as an active ingredient
  - Meets former USDA guidelines for E3 Sanitizers
  - Contains emollient to leave hands feeling soft

RTU Surface Sanitizer

Product Description:

- A ready-to-use sanitizing and disinfecting solution for use on hard, non-porous food contact surfaces.
- Convenient and Easy to Use
  - Ideal for sanitizing areas where water use is limited.
  - Dries quickly to help protect water-sensitive equipment.

Application:

- Any person entering the plant (employee, contractor, etc.) must spray boots with RTU Sanitizer then walk through mat filled with Sani-Step prior to entry into all production areas and upon exiting.

- Use as a final sanitize step on production equipment

EcoWipe FCS

Product Description:

- Eco-Wipe FCS is an EPA registered, pre-moistened, single use sanitizing wipe for use on hard, non-porous food contact surfaces.
  - 175 ppm Quaternary Ammonium Compounds
  - 5.48% alcohol
- 100 Pre-measured, Pre-moistened Wipes per canister

Application:

- Remove any gross soils with mechanical action using one wipe
- Once visually clean, follow with another wipe as a sanitize step
- All tools wiped at least once/shift