Industry Handbook for the Safe Shelling of Peanuts

APSA Committee on Regulatory Compliance

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This is a guidance document for the peanut shelling industry and provides examples of prerequisite and FOOD SAFETY programs that can be used in ensuring the safe shelling of peanuts.

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CHAPTER 1 – FSMA PREVENTIVE CONTROLS AND PREREQUISITE PROGRAMS

Introduction

Peanut shellers recognize that FDA has published the final regulations under the Food Safety Modernization Act (FSMA) that they must comply with to have a fully functioning food safety system. The Hazard Analysis and Critical Control Point system was used by many organizations as the basis of their food safety system. Under FSMA, peanut shellers are categorized in the Preventive Controls for Human Food and Food Safety Plans with risk assessments and preventive controls are used as their food safety systems. Prerequisite programs (PPs) are foundational operating conditions conducive to the implementation of FSMA. They are intended to keep low-risk potential hazards from being likely to occur or becoming serious enough to adversely impact the safety of the foods being produced. The Hazard Analysis and Risk Based Preventive Control (PREVENTIVE CONTROLS) rule under FSMA now requires analysis of all potential hazards regarding the likelihood and severity of occurrence and apply appropriate preventive controls, even for those areas that have been categorized as a PPs under HACCP. The biggest difference in PREVENTIVE CONTROLS and HACCP is now preventive controls may need to be developed for points other than critical control points.

In an effort to integrate HACCP and PREVENTIVE CONTROLS into a comprehensive food safety system, this document will view prerequisite programs requirements in the context of the FSMA preventive control rule. Prerequisite programs can still be documented and audited as part of food safety management system.

Good Manufacturing Practices (GMPs) are a series of general principles that must be observed during manufacturing to ensure that products are consistently produced and controlled according to safety and quality standards. Encompassed within GMPs are Good Handling Practices, Good Laboratory Practices and other best practice principles. GMPs have been revised under the FSMA rules and included as part of preventive controls. Changes include the removal of some recommendations (which will be included in guidance documents instead), and codifying some recommendations (such as training) into the requirements.

SOPs and SSOPs work in conjunction with GMPs and are prescriptive instructions on how to manufacture, sanitize and operate. Examples of an SOP would be a written procedure for sheller equipment operation, magnet check, or shipping inspection. Examples of an SSOP are sanitizing procedure for sheller/gravity or a procedure for cleaning of floors.

An example of an SSOP is on Page 10, Cleaning and Sanitation, and an example of an SOP and its format can be found in Appendix AA.

The guidance materials in this chapter are not intended to be an all-inclusive reference on FSMA or PPs. Included are a number of key PPs discussed in the context of the preventive controls rule that will provide a strong basic foundation for the shelling of safe peanut products.

This document is a compilation of information from the *Industry Handbook for Safe Processing of Nuts* and *Good Manufacturing Practices for Shelling Plant Operations*, M. Spooner, J. Trice, S. Calhoun, APC, 2009, as well as from referenced material listed at the end of the Guidelines. The *Industry Handbook for*

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List of Key Prerequisite Programs (PPs)

Facilities	Personnel Practices
Receiving, Storage, and Distribution	Training
Pest Control	Labeling
Chemical Control	Allergen Management Program
Production Equipment	Extraneous Material Control
Specifications	Use of Outside Laboratories
Supplier Control	Product Hold and Release
Cleaning and Sanitation	Complaint Investigations
Preventive Maintenance	Traceability and Recall

Keep in mind that a Food Safety Plan prerequisite program may need to be treated as a preventive control.

Facilities – Facilities are required to register with FDA under the new FSMA regulations to establish the scope of the facility. The facility must establish and implement hazard analysis and risk based preventive controls for human food.

The facility should be located, constructed and maintained according to sanitary design principles. The plant buildings and structure must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e. manufacturing, processing, packing, and holding). Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in good repair adequate to prevent food from becoming adulterated.

Facilities should be well ventilated and designed to prevent moisture and extraneous matter contamination in shelled peanuts.

Bathrooms, water fountains and hand washing facilities should be convenient to product areas, while not providing a potential product contamination source.

Receiving, Storage and Distribution – – FSMA requires that storage and transportation of finished food be under conditions that will protect food against physical, chemical, and microbial contamination, as well as against deterioration of the food and the container. FSMA rules also state that storage and transportation of food must be under conditions that will protect against allergen cross contact in addition to protecting against contamination of food.

All raw materials and products should be stored under sanitary and secure conditions, with the proper temperature and humidity conditions to assure their safety and wholesomeness.

The sheller should use designated storage areas or stock rooms to prevent damage, deterioration or tampering of material. In order to detect deterioration due to such things as pest infestation, unsanitary conditions and temperature/humidity control abuses, the condition of product in stock should be assessed at appropriate intervals.

A survey of the outside of the facilities should be made to identify any evidence of rodent harborage, burrows, potential entries for pests and other conditions which would indicate possible sources of contamination of stored products.

A "walk through" of the facility should also be made to identify possible routes of adulteration with hazardous materials or pests as well as storage areas for damaged/returned products, etc…

Evidence of problems may be found near doors and windows, along walls, between and under pallets and other "out of the way" areas and near, on, or around susceptible products.

Storage facilities should be neat, orderly, and include considerations for:

- Sanitation and pest control (e.g., spacing equipment or material storage away from walls; allow an 18 inch free access perimeter around interior; sealed doors and windows; cleanable floors, walls and overhead structures).
- Damaged bags, totes, boxes should be sealed to prevent product spillage and contamination. Raw materials damaged during the shelling process should be separated, evaluated, and a determination made as to the proper disposition. Spills should be cleaned up to prevent potential for contamination and infestation.
- Identification and tracking of shelf life of raw materials and release status of shelled peanuts. An effective stock rotation system should be in place.
- Temperature/humidity-controlled versus ambient conditions, as required per specification. Storage temperatures and humidity (where applicable) should be measured and documented using calibrated recording equipment.
- Storage off the floor on pallets or slip-sheets. Pallets, slip-sheets, racks and equipment should be maintained in good condition to prevent physical damage (free from nails, splinters, etc.). Inspections should be performed as well as on-going pest control management to ensure they are free of pest activity.
- Airflow from heaters, refrigeration units, etc., should be directed away from products. Direct sunlight on product should be avoided where possible.
- All peanut storage facilities must be dry, free of moisture build-up and leaks.
- Glass should not be allowed in storage areas. Light bulbs should be shatterproof.
- Products with strong odors should be segregated to avoid odor migration.
- Where packaging materials are not sealed in individual containers (e.g., film roll stock, cartons, etc.), the pallets should be covered and stretch wrapped, shrink wrapped, or strapped to maintain integrity and prevent potential for contamination.
- Pallets used for food products should be in good condition: clean, no broken boards, no evidence of mold or infestation, no off odors.

The transportation program should encompass the following minimum requirements:

- Procedures in place should assure that products are pre-chilled to required temperature prior to loading, and vehicles are pre-chilled prior to loading for distribution (where applicable).
- Deliveries should be on clean, dry, undamaged pallets or slip sheets, free from off-odors and wrapped according to customer specifications.
- Trucks should be verified to be in good condition, dry, clean and free of off-odors before loading. This information should be documented.
- Temperature-controlled vehicles should carry suitable on-board temperature monitoring devices. The devices should be verified at defined intervals. This information should be documented.
- When possible, all openings (doors, inspection ports, hatches, etc.) on outbound shipments (including outbound trailers) should be sealed with a numbered seal and the seal number(s) annotated on the shipping documentation.
- Inbound and outbound bulk containers should be sealed. Acceptable seals include:
    - For Federal-State tags:
        - For totes, the two ties should be "tied off" and then the Federal-State Tag (which has 2 ends) double wrapped around the ties and sealed with clear plastic poly tape.
        - The tags should have company name and logo printed on them.
    - Seals, meeting customer and regulatory requirements, should be secured on railcars and export containers.
    - Large bags such as super-sacks or totes containing plastic liners should have a bag closure that will readily reveal any tampering and will not permit removal and reinstallation without breaking the seal.

In cases where third party warehouses are used to store raw materials, packaging materials, or shelled products, periodic assessments and third party audits should be conducted to assure that the sheller's requirements are met.

Pest Control – Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

A documented pest management program should be in place to effectively monitor and control pest activity in the facility and the surrounding area. Pest control activities should be performed by certified pest control contractors or facility personnel with a valid commercial applicator's license, or operating under the supervision of a licensed pesticide applicator. In the first case, a valid contract and a copy of the license given by the relevant local authority, including insurance coverage, should be in place.

Pest management practices (i.e., strategies for exclusion and trapping of pests) or alternative methods and tools for controlling pests are preferred over pesticide use and should be employed wherever feasible and practical.

Exclusion should be the first line of defense and primary method of controlling pests. Efforts should be made to keep pests out of the building by using good exterior controls including:

- Eliminate all possible entrances into the facility (note that a mouse can enter through a ¼" (1cm) opening)
  - All doors, dock doors, windows, and screens should fit tightly
  - Doors should be kept closed
  - Pipe openings through facility walls should be sealed
- Exterior product handling systems should be covered at all times and any hoses/pipes capped when not in use.
- Areas around farmer stock storage facilities should be free of high grass, weeds, debris, and any extraneous material to prevent rodent harborage. A program must be in place to maintain the areas surrounding storage facilities (mowing and spraying).
- A clear border (approximately 3-ft wide/3-ft vertical), free of vegetation from the ground to above the roof should be maintained around the building perimeter (including tree limbs and shrubs).
- Scrap, pallets, pipes, drums, etc., should not be accumulated on the grounds or parking lot.
- Metal refuse containers should be emptied frequently and not allowed to collect debris other than metal.
- All rodent holes and burrows should be closed.
- All raw materials, equipment, and supplies received should be inspected upon receipt for rodent excreta or any signs of gnawing and chewing on the containers or peanuts. Mice often enter the facility in incoming loads.
- All openings on wall and roof penetrations should be screened to prevent insect or rodent ingress. Ventilation systems should be louvered and screened to prevent entrance of insects and birds into farmer stock storage facilities.

One rodent trap technique is to set traps in three perimeters of control (lot line, exterior of the building, and interior of the building). Rodent traps should be used on interior ground level floors of facilities. A complete and accurate map should be maintained showing the location of indoor rodent traps, glue boards, insect light traps, outdoor bait stations, pheromone traps, etc. Secondarily, food and harborage sources should be controlled through proper sanitation, housekeeping, and storage practices.

Chemicals used for pest control should be accurately labeled, inventoried and, when not in use, securely stored (by locked door/gate) with access granted to authorized and designated personnel only. Insecticides should be applied according to label. Baits should be used in situations where a specific pest is the target. Where used, bait stations should be of solid construction, tamper resistant, and secure.

Bait stations should be installed at approximately 50-ft intervals around exterior of buildings and maintained with approved bait. Stations should be secured and locked to prevent entry of unauthorized personnel. Stations should also be numbered and a master listing maintained to monitor rodent activity at each station. All stations should be checked routinely to document activity. Tin Cats (no poison) should be used in outside area exposed to product (e.g., dump pits) at approximately 25-ft intervals. In general, rodenticides used should be in block form only (rodenticide granules, pellets or powders should not be used).

Light bulbs from the insect light traps should be replaced regularly (as per manufacturer specification) for the maximum efficiency of these types of traps. The insect light traps should be installed in the receiving or warehouse areas close to entrances, but should be located so as not to attract insects into the building. Light bulbs should be shatter-resistant.

Routine inspections should be conducted at a frequency necessary to identify pest activity, harborages, and entry points. Pest activity inspection results should be recorded. Documentation of pesticide use should include: the brand name of the pesticide, traceability information (e.g., lot numbers), quantity applied, the method used to apply the pesticide, targeted pest and time of treatment. All pesticide labels and Safety Data Sheets (SDS), or equivalent material, addressing safety precautions should be available at the facility. Pest activity data should be analyzed to show trends in activity. If pest activity is noted, controls should be increased appropriately. Documentation should include a map of the facility traps and bait stations, copy of license of pesticide applicator, SDS sheets and checklists of activity with any corrective action, plus all training.

Chemical Control – FSMA states that toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

Documented procedures should be in place to assure the segregation, security and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant. All chemicals should be properly labeled and stored in a locked area separate from food storage areas, with access limited to appropriate personnel only.

All chemicals, including those used in pest control and bait for stations, must have current Safety Data Sheets accessible for review.

Production Equipment – FSMA states that (1) all plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination. (2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. (3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules, as applicable, should be established and documented for every new installation or modification. New installations or modifications should also be evaluated to determine their impact on the quality and food safety systems. All testing, recording and monitoring devices should be checked at specified intervals to assure accuracy, and there should be documented corrective actions in the event the devices are found to be out of calibration. Results should be recorded and signed.

Specifications – There should be written specifications for all incoming and shelled peanuts and packaging materials. Shelled peanut specifications should meet regulatory and customer requirements. (American Peanut Shellers Association Trading Rules)

Supplier Control – Shellers must have approved supplier control programs and should ensure receipt and review of their required food safety and quality program documentation for each load received. Shellers who receive shelled peanuts from a seed sheller, toll sheller or other contract sheller should assure that their suppliers' food safety programs are also in compliance with these guidelines.

Shellers should also ensure that they have appropriate documentation for food contact materials such as packaging, food contact equipment and consumables, lubricants, cleaning and sanitizing chemicals, etc. The documentation review for lubricants and chemicals should ensure that they do not contain allergens.

Cleaning and Sanitation – All procedures for cleaning and sanitation of the equipment and facility should be documented and followed. The procedures should be specific and detailed so that they are easy to follow. The sanitation procedures should be written using the following information:

- Description of the area to be cleaned
- Equipment needed for cleaning including tools, chemicals, PPE, etc.
- Work instructions or procedures to be followed, including any necessary safety precautions
- Person responsible for cleaning the assigned area
- Frequency of cleaning the area
- Additional information such as definitions, identified safety hazards, required trainings, and references may be included

An inspection of the area should be performed by an independent inspector to ensure the efficacy of the cleaning. Completion of the cleaning and verification activities should be documented on the Master Sanitation Schedule.

An **example of a sanitation procedure** follows:

SHELLER/GRAVITY SEPARATOR AREA SANITATION

Description of Area: The shellers are used to remove hulls from the farmer stock peanuts. Hulls are sent to an outside facility and used for animal feed. Shelled peanuts are moved forward in the process. The gravity separators are used to remove foreign material of different density from the peanuts.

Equipment needed: Broom, dust pan, trash can, air hose, shovel, flashlight.

Procedure:

Assemble all tools and materials needed for this cleaning procedure prior to beginning.

1. The sheller/gravity separator operators shall keep all trash and debris off the equipment and floor areas. Trash and debris shall be disposed of in the trash can.
2. The sheller/gravity operators shall not store parts, tools, supplies or chemicals on the unit's exterior surfaces. These materials shall be stored in a locked cabinet when not in use.
3. The sheller/gravity operator shall use the broom, dust pan and shovel to clean spills of product up frequently to alleviate slip and trip hazards.

4. The sheller/gravity operator shall, on a daily basis, use the air hose to blow down all equipment; then use the broom, dust pan and shovel to place product in the trash can.
5. The sheller/gravity operator shall, on a weekly basis, use the air hose to clean peanuts from the elevators. After using the air hose, the sheller/gravity operator shall use the broom, dust pan and shovel to clean the floor areas.
6. The sheller/gravity operator shall use the flashlight for inspection of the equipment and area after cleaning to ensure the cleaning process has been adequate.

Cleaning frequency: Daily – Floors, Spills, Equipment
Weekly – Equipment, Elevators

Person Responsible: Operator

Documentation: Master Sanitation Schedule must be signed by the person completing the sanitation procedure should be in place and should include a signature by an independent inspector to verify efficacy of the clean.

Preventive Maintenance – Equipment and materials selected for production should be suitable for the purpose intended, and well maintained. A documented, planned maintenance program should be defined for preventive and corrective maintenance. The program should include: a list of food handling equipment, frequencies and maintenance records. Priority of maintenance should be given to pieces of equipment that may impact food safety and employee safety.

The preventive maintenance program should be up-to-date for all processing equipment. Elements of the program should include a defined inspection for the evaluation of screens, filters, magnets, gaskets, etc., in addition to any potential points of metal-to-metal wear. Routine preventive maintenance for compressed air and air used in cleaning and shelling operations should be documented. This includes the inspection, cleaning or replacement of air filters, O-rings, gaskets, pumps, bearings, etc. Preventive maintenance frequency should be adjusted in accordance with the outcome of the last intervention, equipment history, and vendor specifications.

Food-grade lubricants should be used on food cleaning and shelling equipment where direct and/or indirect contact between lubricant and food products is possible.

All metal welds in product contact areas should be non-toxic, cleanable, and free from pits, folds, cracks, crevices or inclusions.
Tools should be cleaned and kept off of floors and walking surfaces (e.g., decks, stairs). Tools should be maintained in a locked toolbox or other secure container.

Equipment repairs are intended to be permanent and should be performed using proper materials. Temporary fixes that may adversely impact the food safety/quality of a product should be replaced in a timely manner (typically within 30 days) by permanent repairs. Plastic, tape and paperboard used in temporary repairs should be dated until replaced.

Appropriate measures should be in place to protect products in the event that repair or maintenance activities occur during production. A program should be in place to isolate maintenance work areas from

active shelling lines and for line release to production after completion of maintenance work (equipment and area to be cleaned and sanitized, as applicable, prior to release for peanut cleaning and/or shelling) have occurred, it should be assured that the equipment and facilities are clean, sanitized and in good repair prior to release for production. Each facility should have a program for the identification of maintenance and repair of equipment and its release back to production. The program should be tailored to the specific products or facilities.

Personnel Practices – All employees, contractors, and guests who enter the shelling plant should follow the requirements for personal hygiene and food safety practices.
From American Peanut Council GMP's, June 2009, pages 5-6, with modifications from FDA comments dated December 2009:

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 is reduced. The FDA recommends that the managers of food operations be assigned the responsibility for assuring compliance by all personnel with this part of the GMP's. To accomplish this, the expectation is that management assumes responsibility for training personnel in food protection principles and food handling techniques. A written training program should be established, routinely evaluated, and updated as necessary. It is important to note that training must be applied as stringently to temporary personnel as with permanent employees. Contract service personnel must be trained in quality and food safety before being placed into positions that may affect the product. Shellers should be diligent in enforcing the following practices:

- Disease Control - Personnel with contagious illnesses, open lesions, boils, sores or infected wounds should be excluded from areas where they would contact foods, food contact surfaces, or packaging materials. In certain cases, such as norovirus infections, 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 potential food safety risk to the work environment. A comprehensive health policy outlining employee restrictions should be developed by each organization.
- Cleanliness - (a) Employees should 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) any outside clothing should be clean and sanitary if allowed in production areas, (e) personal cleanliness should be maintained by thoroughly washing hands prior to work, after each absence whether eating, using restrooms or other times when hands become soiled or contaminated.
- Jewelry should be removed, including exposed piercings, or other objects and are not allowed in the production area with the exception of a plain wedding band, or a medical detectable bracelet. Jewelry can be a source of foreign material (when stone settings come loose), or hand jewelry a source of microorganisms.
- Effective hair coverings must fully contain all scalp hair and beard and mustache snoods must cover all facial hair and worn in the production area to prevent product contamination.
- 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, false fingernails, and medicines applied to the skin.
- Education and training - Personnel responsible for identifying sanitary failures or food contamination should have training, education or 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 and significant potential consumer impact 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. All training conducted should be documented for each worker, and show that all federal, state, and local requirements are met. This training should apply to temporary and contract workers as well as permanent employees.
- Each worker's job expectations, responsibility, and accountability should be documented in a clearly understandable manner.
- Personnel practices should be monitored through internal audits.
- Visitors should follow the same rules as employees and be so instructed when entering a facility. Visitors and contractors are required to be trained in the GMP program when entering the facility and are expected to follow the same rules.
- No glass containers should be allowed inside a shelling facility, including break areas, and food and food products should not be allowed in production areas.
- For handling any chemicals or pest control, only impermeable gloves should be used, be kept clean and sanitary during use, intact, and be disposed of after use.

Training – All employees should receive documented training in personal hygiene, GMP's, cleaning and sanitation procedures, personal safety and their role in FOOD SAFETY and other food safety and food quality programs.

The peanut sheller should:

1. Determine the necessary competence for personnel performing work affecting food safety across all functions, e.g., production, maintenance, logistics, etc., and provide training or take other actions to satisfy these needs
2. Evaluate the effectiveness of the actions taken
3. Maintain appropriate records of education, training, skills and experience

   a. Training for production employees should include a general awareness of the principles of quality, food safety plan, allergens, diseases that are communicable via food, GMPs, foreign object prevention and food defense.
   b. Refresher training should be provided annually. Training should be performed for new employees before starting work. Site-specific programs should include any necessary information and instruction for visitors and contractors prior to performing activities that may affect product safety.
   c. Employees monitoring CCPs should receive specific training including monitoring, documentation, verification and corrective actions if the critical limits are not met.
   d. Specific training to meet the requirements of this document should be provided.

Educate workers on the importance of proper hand washing techniques.

Do not assume that workers know how to properly wash their hands. Posters or procedures showing proper handwashing techniques must be posted in all restrooms, breakrooms, and other areas where employees have a facility to wash their hands. These posters/procedures should not only be in English but other appropriate languages.

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

1. Wet hands with clean warm water
2. Apply soap
3. Scrub hands and fingernails (for at least 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
8. Dry hands before or after sanitizer use, as per sanitizer supplier directions.

Labeling – The sheller should have controls in place to assure that labels are correctly and consistently applied to materials. Controls should assure that labels meet all regulatory requirements and customer specifications.

The label should accurately describe the material. It should clearly exhibit the name and address of the sheller, lot number, crop year, product type, country of origin, and/or other information, as specified.

Allergen Management Program – While it is well known that some consumers are allergic to peanuts, pecans and soybeans also produce allergic reactions in some consumers. Peanut shellers should have allergen management programs to eliminate pecans and soybeans from the raw peanut stream prior to receipt or during the shelling and cleaning process.

Extraneous Matter Control –This Section describes control measures to address extraneous matters in a prerequisite program. In the event metal is identified as a hazard reasonably likely to occur given the PPs in place, it should be controlled by a preventive control. Product cleaning, screening, separation and detection systems should be designed to remove extraneous material from incoming raw product.

Inspection programs should be established to verify that the systems are working within specifications and as designed.

The sheller should have effective programs to prevent, detect and control extraneous matter in the shelled product. A hazard analysis should be performed to determine potential sources of extraneous matter, including:

- Incoming raw material and primary packaging materials
- Equipment design, processing and packaging equipment, and utensils
- Plant environment (e.g., ceilings, walls, floors)
- Contamination from personnel or other operations such as cleaning and sanitation, contractor work, etc.
- Rework/work-in-progress
- Maintenance or repair of equipment
- Historical information of types of extraneous matter previously found or reported by consumers.

The analysis should consider all types of extraneous matter. Periodic re-analyses should be conducted, particularly following changes to the plant environment and instances of non-conformances (e.g., customer or consumer complaints, PC failure).

Based on the analysis, an appropriate strategy for minimizing extraneous matter should be developed, including:

- Designing the risk of extraneous matter out of the process (e.g., eliminating metal-to-metal contact on equipment)
- Preventing introduction of extraneous matter into the product (e.g., GMPs, equipment design, preventive maintenance, covers on bins or conveyor belts)
- Detection and removal of extraneous matter (e.g., installation of strainers, screens, filters, magnets, sieves, metal detectors, X-ray or other devices/programs deemed necessary on the line).

<u>Detection and Removal Devices</u>

A variety of devices are available to shellers to limit the presence of foreign materials.
The sheller should manage detection and removal devices in such a way to maximize the effectiveness of these devices. Focus should be put on the following points:

- Location of the devices in the production line
- Procedures to manage the devices
- Start-up set up (e.g., check if magnet is in place; screen is properly seated in its housing; metal detector is detecting and rejecting specified metal test pieces)
- Frequency of detection and rejection mechanism verification checks
- Limits of acceptable and unacceptable results
- Abnormal findings (should be reported and documented)
- Corrective actions are taken where necessary
- Devices are calibrated as per supplier specifications or sheller experience to assure optimum effectiveness

The detection devices installed throughout the production line should be adequate to address the potential hazards identified in the hazard analysis. These include the type of device and established detection limit.

Magnets

- Rare earth construction provides the strongest, most aggressive magnets
- Magnets should be tested for effective placement, coverage, and pull strength at the time of installation, and routinely thereafter
- Magnets, like all foreign material control hardware, should be routinely monitored and the results of this monitoring should be recorded

Other Devices

- Stoners
- Gravity separators
- Electric eyes, x-ray or other vision control systems

Device Operation for an end-point metal detector

The detecting limit for an end-point metal detector will depend on type of product and the detection equipment. Detection equipment settings should be determined and applied to achieve the most sensitive level possible to provide maximum protection from metal contamination. **As a guide**, the detection sensitivity under production conditions should be capable of detecting and rejecting pieces larger than 7 mm (.28in) for all metals and meeting customer/regulatory requirements.

Functionality verification for electronic detection and rejection devices should take place during production with the normal product flow. Minimum frequency for system verification should occur at the following times:

- Start up (e.g., the beginning of each shift or production start up if part way through a shift)
- End of each shift
- After a production change (e.g., product, lot or primary packaging changeover)
- Following any repairs, maintenance or adjustments
- On a regular basis as determined by the site (recommended minimum every 4 hours)

Functionality verification method should assure 100% detection and timely rejection of the test piece(s). An example of verification could be at the start of production each day and at each lot change, each test piece (ferrous, non-ferrous and stainless steel) should be passed through the detection device and detected and rejected, as defined by the particular facility's food safety program. The verification test pieces should be clearly identified and differentiated from product. If a metal detector is not working at its design limit (e.g., if it fails to detect a test piece), the material produced since the last time the metal detector was verified to be operating at its design limit should be placed on hold.

The metal reject mechanism should direct product rejects from the process flow automatically into an identified area, bin or container. An action level should be defined on the basis of historical trend analysis. If this action level is exceeded, then all diverted product (rejects) should be evaluated to determine the cause for rejection. Where no action level is defined, all rejects should be evaluated to determine cause for rejection. Action limits should be available to the responsible operator, and corrective actions described. Action limits should include unusual findings and excessive rejects that would trigger an immediate corrective action. All the findings should be documented. The responsibility and methodology for evaluating rejected product should be specified and documented.

When glass, ceramics and/or hard plastics exist in the production area, a specific program should be in

place for the management of these materials. The same should be applied to devices that can be a source of extraneous matter when damaged (e.g., screens). Appropriate and timely corrective action should be implemented in case of any source of extraneous matter with the potential of falling into the product stream.

Other materials resulting from peanut harvesting are also found in raw peanut streams, such as nut grass, wood and stems. Peanut cleaning and shelling equipment should be properly maintained and monitored to assure removal or reduction to an acceptable level of these materials.

Testing and Use of Outside Laboratories – The preventive control rule is not prescriptive for testing. It simply requires testing as appropriate to the product and the hazard identified. Laboratories are not currently required to be accredited, however this could potentially change when the FSMA rule governing accreditation of laboratories is published in 2016.

Under the preventive controls rule, the following USDA requirement would then be appropriate to the product and hazard. Shelled peanuts are required under the marketing order to be certified by lot that each meets the USDA aflatoxin requirements for edible peanuts prior to entering the market place. Shellers must use USDA-certified laboratories that are inspected by USDA and participate in the USDA quality assurance systems.

For peanuts, the following protocol is used for testing finished shelled good lots:

Finished lots $\leq$ 15 ppb

*1AB $\leq$8 ppb, or if >8 ppb and <45 ppb

Then run the 2AB

*1AB + 2AB avg. $\leq$12 ppb, or if >12 ppb and <23 ppb,

Then run 3AB

*1AB + 2AB + 3AB avg. $\leq$15 ppb Accept the lot

The new preventive control rule however states that hazards that will be controlled at a later point in the supply chain, for example inactivating Salmonella by raw peanut roasting at a manufacturer, do not need to have a preventive control at the sheller. The sheller will require written assurance from their customers that they have a preventive control in place. Shellers are currently under enforcement discretion at the time of this review and do not need the written assurance from manufacturers. Peanut shellers produce raw peanuts for further processing and do not have a kill step in the shelling plant. Shellers do not test for microorganisms nor do environmental sampling for microorganisms.

Product Hold and Release – The preventive control rule requires that a records review of monitoring and corrective actions be done within 7 working days after the records are made, or within a reasonable time frame justified in writing by the food safety qualified individual at the site. A reasonable time frame may include records for release that require testing that takes longer than a week. Review of records of calibration, product testing, and supplier verification activities within a reasonable time frame. The rule

does not require review of records prior to release of the product but to insure that the preventive controls were effective.

The sheller should assure that a written Hold/Release control program is in place with roles and responsibilities clearly established. The Hold and Release system should include the sheller's premises and any contracted facilities.

The program should include controls for non-conforming raw materials, materials pending testing or rework, packaging, labels, and shelled peanuts. Records should be maintained to enable reconstruction of each hold event's history.

Products/materials that are on hold must be controlled via a defined and effective system that is intended to prevent inadvertent movement. Inventory reconciliation must occur to verify proper control.

When any material produced for the customer is either inadvertently released from hold or is suspected of non-conformance but has already been shipped to the customer, the customer representative should be notified immediately by phone, followed by notification in writing.

Any product that will be released to customers must meet three criteria:

1. Must have valid USDA grade sheet
2. Must meet USDA aflatoxin requirements
3. Must have documentation ensuring functionality of metal detection

Complaint Investigations – Shellers should have procedures in place to receive, document, investigate, respond to and correct, if necessary, customer and consumer complaints. FDA is not currently establishing a requirement for a review of complains in the preventive controls rule as a verification activity. However, they encourage facilities to do such a review.

Traceability and Recall – Pilot projects for improving product tracing were completed by FDA and reported in March 2013. FDA plans to initiate rulemaking on record keeping requirement for high-risk foods to facilitate tracing. There is a draft methodological approach to identifying high-risk foods but no final method has been approved as of the date of this publication.

The preventive control rule requires that facilities have written preventive controls for process controls, food allergen controls, sanitation controls, and a recall plan. A recall plan is mandatory for a food with a significant hazard. The rule specifically requires the following:

1. A written plan.
2. Procedures for steps to be taken and those responsible for:
    a. Direct notification of consignees and how to return or dispose of food
    b. Notification of public
    c. Conduct effectiveness checks

d. Appropriate disposition of recalled product.

All raw materials and products should be lot-coded and a recall/retrieval system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary.

Companies should have an effective program for traceability of all raw materials used and shelled products produced including product for edible, remill, blanching, and oilstock. A recall team should be defined and contact information readily available. If requested, the sheller must provide such information to the customer, especially in the event of a product-related issue such as a product recall involving products containing this ingredient. In general, the sheller should be able to identify the warehouse in which the peanuts were stored immediately prior to shelling. The traceability program should include identification of all raw materials, process parameters (for the specific lot), rework, and primary packaging materials, as well as the customers to whom the lot was distributed or the method of disposal.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (also known as "The Bioterrorism Act" or the BT Act, accessible at http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm), requires that all food processing facilities register with the FDA.

All production runs should be identified with lot numbers that enable complete linkage from raw material receipt through final packaging. Traceability should be maintained to enable linkage back to the date of manufacture and location for all finished, shelled product.

The retrieval system should be tested within the scope of the facility's control on an annual basis and after any major system changes to confirm the accuracy of all product and contact data and the continuing effectiveness of procedures and traceability systems. The results of these tests and any corrective actions necessary should be documented.

Site Security – A key component to food safety is controlling access to food processing and storage areas. Security can be achieved through physical barriers such as perimeter fencing and locked doors as well as through administrative barriers like policies restricting visitor access and effective enforcement of site GMP's.
The following site security measures are commonly utilized by shelling plants:
(this is not a comprehensive list)

- Perimeter fencing with locking gate
- Exterior lighting
- Signage indicated restricted areas
- CCTV cameras
- Electronic door locks (coded or badge swipe)
- Locked chemical storage
- Visitor policies
- Employee background screenings
- Site-wide alarm and/or PA system
- Employee Training

- Employee ID's and uniforms
- After hours security

The site security measures should be documented, monitored and verified with regularity and all employees should be trained on these measures and instructed to immediately report any abnormalities to plant management.

Food Defense – After the September 11, 2001 attacks, the U.S. government identified the nation's food supply as a potential target of terrorist organizations. FSMA was the first regulatory law to use the term "food defense" and the final rule, *Mitigation Strategies to Protect Food Against Intentional Adulteration* (IA rule) requires that all domestic and foreign businesses registered with the FDA as food facilities develop and implement a facility-specific food defense plan. FSMA requires that facilities that engage in manufacturing, processing, packing or holding food for consumption in the United States submit additional registration information to the FDA (https://www.fda.gov/food/registration-food-facilities-and-other-submissions/online-registration-food-facilities). This registration must be renewed every two years.

While food safety programs are in place to reduce the risk of *unintentional* contamination, food defense programs are established to mitigate the risk of *intentional* contamination by a person meaning to do harm. The IA rule requires that food businesses do the following:

- Identify vulnerable parts of their food manufacturing processes
- Implement strategies to reduce identified vulnerabilities (mitigation strategies)
- Monitor and verify that the implemented strategies are effective
- Maintain records of these activities

The Food Defense Plan (FDP) is a set of written documents that should be developed by an individual or team with knowledge and expertise of the facility's operations in addition to general food defense principles. There is no defined format for the FDP, but the plan must include all components of the IA rule. The FDA website (https://www.fda.gov/food/food-defense) provides resources and tools to build your facility's food defense plan.

Food Defense Plans are required to have the following components:

Vulnerability Assessment – A vulnerability assessment is conducted much in the same way that the hazard assessment is carried out within your food safety plan. Each process or step listed on the process flow diagram is evaluated to identify vulnerabilities for intentional adulteration. For each point, step or procedure in the facility's process, the following elements must be evaluated:

- The severity and scale of the potential impact on public health
- The degree of physical assess to the product
- The ability to successfully contaminate the product

The purpose of the vulnerability assessment is to identify a significant vulnerability or "Actionable Process Step". A significant vulnerability, if exploited, could reasonably be expected to cause wide scale public health harm and are steps within the process where mitigation strategies can be applied to significantly

minimize or prevent the vulnerability.

One way to identity an actionable process step is by using the KAT method. The FDA identified four Key Activity Types (KAT) consistently ranked as the most vulnerable, regardless of the food commodity assessed, to adulteration intended to cause wide scale public health harm.

The identified activities are:

1. Bulk Liquid Receiving and Loading
2. Liquid Storage and Handling
3. Secondary Ingredient Handling
4. Mixing and Similar Activities

To conduct a vulnerability assessment using the KAT method, assess each step of the process flow diagram and determine if the step fits within the description of one of the four key activity types. If the step is identified as a KAT, this is an actionable process step, and a mitigation strategy should be implemented. If the step is not identified as a KAT, a mitigation step is not required.

Mitigation Strategies – The FDA defines "mitigation strategies" as risk-based, reasonably appropriate measures that a person knowledgeable about food defense would employ to significantly minimize or prevent significant vulnerabilities identified as actionable process steps, and that are consistent with the current scientific understanding of food defense at the time or the analysis (21 CFR 121.3).

Mitigation strategies must be identified and implemented at each actionable process step to minimize the significant vulnerability. FDA's website "Food Defense Mitigation Strategies Database" (https://www.cfsanappsexternal.fda.gov/scripts/FoodDefenseMitigationStrategies/index.cfm) is a great resource for developing and implementing mitigation strategies.

Additionally, steps must be taken to ensure the proper implementation of each mitigation strategy. These additional steps include:

- Monitoring the mitigation procedures
- Implementing corrective actions in response to improperly implemented mitigation strategies
- Verification that monitoring is being conducted and that corrective actions are implemented when necessary

Information and examples for conducting a vulnerability assessment and implementing mitigation strategies can be found in Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry (https://www.fda.gov/media/113684/download).

Training and Recordkeeping – Facilities must ensure that personnel assigned to identified vulnerable areas receive appropriate training. Individuals located in these key areas should be knowledgeable of the process as well as understand their role within the food defense plan. The FDA's webpage "Food Defense Tools and Educational Materials" contains information and resources for training personnel directly involved in mitigation strategies as well as general awareness training for all other personnel (https://www.fda.gov/food/food-defense/food-defense-tools-educational-materials).

All records for food defense monitoring, corrective actions, verification activities and employee training must be maintained.

The FDP must be reanalyzed at least every 3 years or whenever the following occur:

- A significant change to activities creates a reasonable potential for a new vulnerability or a significant increase in an existing vulnerability.
- Whenever you become aware of new information about potential vulnerabilities associated with the food operation or your facility
- Whenever you find that a mitigation strategy or the food defense plan is not properly implemented
- Whenever FDA requires reanalysis to respond to new vulnerabilities, credible threats to the food supply, and developments in scientific understanding

CHAPTER 2 – FOOD SAFETY PLAN

Introduction

FSMA

The Food and Drug Administration (FDA) published final rules for preventive controls for human and for animal food on 17 September 2015. These rules are commonly referred to as PREVENTIVE CONTROLS (Hazard Analysis and Risk Based Preventive Controls). These rules also update and revise the current Good Manufacturing Practices (cGMPs). Covered peanut organizations must have a written plan to comply with these rules in order to have a fully functional food safety system. The Hazard Analysis and Critical Control Point (HACCP) system has been used by companies for many years as the foundation of their food safety management systems. Peanut processors may choose to continue to use HACCP but must implement provisions within their food safety management program to meet the FSMA rules requirements.

Facilities that manufacture, process, pack, or hold human food required to register with FDA are covered under the new FSMA rules. They apply to both domestic and imported food. Some exemptions and modified requirements apply.

Updated cGMPs include protection against allergen cross-contact. Certain provisions containing recommendations have been deleted. Previously nonbinding provisions, such as training and education, are now binding.

Individuals in covered facilities must have the education, training, and experience necessary to manufacture, process, pack, or hold clean food as appropriate to their assigned duties. They must receive training in the principles of food hygiene and food safety, as appropriate to the food, the facility and the individuals assigned duties.

The company's food safety plan must consist of:

1. Hazard analysis
2. Preventive controls
3. Supply-chain program
4. Recall plan
5. Procedures for monitoring
6. Corrective action procedures
7. Verification procedures

Covered companies are to identify and evaluate known or reasonably foreseeable hazards to determine whether there are any hazards requiring a preventive control. Facilities are required to consider economically motivated adulteration as part of their hazard analysis. Facilities must identify and implement controls to provide assurances that any hazards requiring a preventive control will be minimized or prevented (SMOPed). Consideration of severity of illness/injury and probability of occurrence or absence of preventive controls must be included in the hazard analysis. Controls must be

included at critical control points (CCPs), if any, and controls other than those at CCPs that are appropriate for food safety specifically including:

1. Process controls
2. Food Allergen controls
3. Sanitation controls
4. Supply-chain controls
5. Recall plan
6. Other controls

Preventive controls are not required when the type of food could not be consumed without application of an appropriate control (e.g., coffee beans, cocoa beans, grains, etc.) When a hazard is controlled by another entity later in the distribution chain (e.g., customer), the facility must disclose that food is for further processing (e.g., "not processed to control Salmonella") and obtain assurances the hazard will be controlled, including identification of the procedures. Currently, shellers have an enforcement discretion from FDA that does not require them to receive this written assurance.

Facilities must have written procedures for monitoring preventive controls. Monitoring must be documented in records. The regulations expressly allow for exception records for monitoring activities, i.e. records demonstrating loss of control, rather than affirmative records demonstrating control.

Corrective action procedures are required when steps are to be taken when preventive controls are not properly implemented. . Corrective action procedures should be tailored to the nature of the preventive control, but also the nature of the hazard. Corrective action procedures do not need to be specific to a preventive control.

Corrections are defined as an action to correct a problem without other actions associated with corrective action procedures. Verification must include (as appropriate to the facility, food and nature of the preventive control):

- Validation of preventive controls
- Verification of monitoring and corrective actions
- Calibration of process monitoring and verification instruments
- Product testing
- Records review

Reanalysis of the Food Safety Plan is required at least every three years or whenever there is a significant change or new information that creates a potential for a new or changed hazard. Reanalysis should be done with a preventive control is ineffective.

Each company must have a qualified individual who has successfully completed training the development and application of risk-based preventive controls at least equivalent to that received under standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. Responsibilities of a preventive controls qualified individual include:

1. Preparation of the food safety plan
2. Validation of preventive controls

3. Review of records
4. Reanalysis

HACCP

As previously mentioned a commonly used framework for a food safety plan is the Hazard Analysis and Critical Control Point (HACCP) system. Philosophically, HACCP also involves a proactive, preventive approach to control potential food safety hazards. HACCP provides a mechanism to prevent, eliminate or reduce to an acceptable level food safety risks. When utilizing HACCP, potential hazards are identified, associated risks are assessed, Critical Control Points (CCPs) are identified, critical limits are defined, prerequisite programs (PPs) are specified, methods for control are identified and criteria for compliance are clearly defined. HACCP principles and application guidelines are described in the US by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1998) and internationally by the Codex Alimentarius Commission (CAC, 2003). According to NACMCF (1998), HACCP includes the following seven principles:

1. Conduct a hazard analysis.
2. Determine the critical control points (CCPs).
3. Establish critical limits.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish record-keeping and documentation procedures.

Principle 1 involves identifying potential food safety hazards associated with all process steps within an operation and determining what significant food safety hazards exist, i.e., hazards that are reasonably likely to cause significant illness or injury without their control. After the hazard analysis, Principle 2 involves identifying critical control points by determining the operational steps within the operation where identified significant food safety hazards can be prevented, eliminated or reduced to an acceptable level. Principle 3 involves establishing critical limit(s), which should be met to ensure the CCP is under control. Principle 4 involves establishing a system to monitor control of the CCP by scheduled measurements or observations. Principle 5 involves establishing the corrective actions to be taken when monitoring indicates a deviation from critical limit and that a particular CCP is not under control. Principle 6 is to establish verification procedures (including supplementary tests, where appropriate) to ensure that the plan is working as designed. Verification activities confirm that the HACCP system is being implemented according to the HACCP plan and that it is working effectively. Principle 7 involves establishing documentation concerning all procedures and records appropriate to these principles and their application.

Processors may choose to have a HACCP plan while providing system activities that meet the FSMA requirements. The facility's HACCP plan should be consistent with the principles and application guidelines defined by the NACMCF or Codex. At least one of the HACCP team members should be trained in HACCP. The HACCP guidelines described here are intended for use by an expert, multi-disciplinary team formed to develop a HACCP plan. The NACMCF and Codex documents and examples provided in this handbook are tools for the development, implementation, maintenance, and auditing of a HACCP plan.

They also create common criteria for assessing hazards and identifying CCPs across peanut shelling operations to assure the safety of peanuts and peanut products.

1.0 Hazard Analysis and Risk Evaluation

In preparation for conducting a hazard analysis, a cross-functional team, comprised of quality assurance, operations, maintenance, and technical specialists familiar with food safety and the shelling operation should be formed. A microbiologist should be involved during the biological portion of the hazard analysis and risk evaluation step of FOOD SAFETY plan development.

Each facility must have a Food Safety Plan with a dedicated team leader who can take responsibility for the maintenance and upkeep of the plan documents. NACMCF and Codex recommend the team take the following preliminary steps:

1. Describe the food and its distribution;
2. Describe the intended use and consumers of the food;
3. Develop a flow diagram that describes the process; and,
4. Verify the flow diagram.

These preliminary tasks will generate specific information used to focus the hazard analysis on the specific product and process under consideration.

1.1 Hazard Definition

In food safety, a “hazard” is defined as a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control (NACMCF, 1998). Product safety hazards that are significant and should be controlled in the FOOD SAFETY plan (CCPs) are identified by completing a hazard analysis.

The following steps are taken when determining whether a hazard needs to be controlled within a food safety plan:

1. Identify potential hazards, using the flow diagram as a guide (see 1.2.1 and Example 1, below)
2. From the potential hazards, determine which are significant hazards that require control within a food safety plan (see 1.2.2 and Diagram 1, below)
3. For each significant hazard, identify the Preventive Control (PC) to be used to control, minimize or eliminate the hazard (see 2.0, 2.1 and 2.2, plus Diagram 2, below)

1.2 Conduct a Hazard Analysis

During the hazard analysis, the food safety team should determine all potential biological, chemical, and physical hazards that can be introduced, enhanced, or controlled in the raw materials and during shelling operations. The hazard analysis is made up of two stages: hazard identification and hazard evaluation. It is critical that the hazard analysis be scientifically based and well documented.

1.2.1 Hazard Identification

To identify the potential hazards, the following assessments should be completed, documented, and should be available to all developers and reviewers of Food Safety Plan.

Using the flow diagram, the team identifies potential biological, chemical, and physical hazards that may be introduced, increased, or controlled at each step of the process. The team creates a potential hazard list by reviewing information about:

- Raw materials, processing aids, rework
- Packaging materials in direct contact with shelled product
- Activities conducted at each process step, including handling and environmental conditions
- Equipment used to make the product

During the hazard identification process, the food safety team should consider the potential for undeclared allergens due to contamination during harvesting and handling. It is also helpful to review plant layout to assess each area or room in the shelling facility to determine the potential for cross-contamination from dust or other environmental conditions.

Examples of potential hazards include:

Chemical:	Allergen(s) due to incoming pecan contamination Aflatoxin Ag Chemicals
Physical:	Metal due to metal-to-metal wear of equipment (e.g., sorters, sizers, screeners) or field metal Field glass Sticks, stones, nut grass, bone fragments Plastic

For assistance in **identifying potential hazards**, the food safety team may use **Examples of Questions to be Considered When Conducting a Hazard Analysis** (Example 1, below)

Example 1

Examples of Questions to be Considered When Conducting a Hazard Analysis
(modified for shellers)
Modified for peanut shellers from NACMCF J. Food Prot., Vol. 61, No. 9

The hazard analysis consists of asking a series of questions that are appropriate to the process under consideration. The purpose of the questions is to assist in identifying potential hazards.

A. Ingredients
   1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., *Salmonella, Staphylococcus aureus)*; chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
   2. Are potable water, ice and/or steam used in formulating or in handling the food?
   3. What are the sources (e.g., geographical region, specific supplier)?

B. Intrinsic factors – physical characteristics and composition (e.g., water activity) of food ingredient
   1. What hazards may result if the food composition is not controlled?
   2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
   3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
   4. Are there other similar products in the marketplace? What has been the safety record for these products? What hazards have been associated with the products?

C. Procedures
   1. Is there a controllable process step that destroys pathogens?

D. Microbial content of the food
   1. What is the normal microbial content of the food?
   2. Are there areas within the facility where pathogens can enter the product or can grow if already present in the raw product?
   3. Does the subsequent change (if any) in microbial population alter the safety of the food?

E. Facility design
   1. Does the layout of the facility provide an adequate separation of raw materials from shelled peanuts? If not, what hazards should be considered as possible contaminants of the shelled product?
   2. Is positive air pressure maintained in shelled product packaging area? Is this essential for product safety?
   3. Is the traffic pattern for people and moving equipment a significant source of contamination?

F. Equipment design and use
   1. Will the equipment provide the cleaning needed for safe food?
   2. Is the equipment properly sized for the volume of food that will be shelled and cleaned?
   3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
   4. Is the equipment reliable or is it prone to frequent breakdowns?
   5. Is the equipment designed so that it can be easily cleaned and sanitized?

6. Is there a chance for product contamination with hazardous substances (glass, metal)?
7. What product safety devices are used to enhance consumer safety?
    a. Metal detectors
    b. Magnets
    c. Sifters
    d. Filters
    e. Screens
    f. Thermometers
8. To what degree will normal equipment wear affect the likely occurrence of a physical hazard (e.g., metal) in the product?
9. Are allergen protocols needed in cleaning raw product and protecting shelled product?

G. Packaging
1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
2. Is the package clearly labeled with storage conditions, if required for safety?
3. Does the package include instructions for the safe handling and preparation of the raw product when sold directly or indirectly to a consumer?
4. Is the packaging material resistant to damage, thereby preventing the entrance of microbial contamination?
5. Are tamper-evident packaging features used?
6. Is each package, tote or case legibly and accurately coded?
7. Does each package contain the proper label?

H. Sanitation
1. Can sanitation have an impact on the safety of the peanuts being shelled?
2. Can the facility and equipment be easily cleaned and sanitized to permit the safe handling of food?
3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

I. Employee health, hygiene, and education
1. Can employee health or personal hygiene practices impact the safety of the food being processed?
2. Do the employees understand the process and the factors they must control to assure the shelling and packaging of safe food?
3. Will the employees inform management of a problem that could impact food safety?

J. Conditions of storage between packaging and manufacturer and/or end user
1. What is the likelihood that the peanuts will be improperly stored at the wrong temperature/humidity?
2. Would an error in storage lead to a microbiologically unsafe food?

K. Intended use
1. Will the peanuts be further processed (heat-treated) by the manufacturer or customer?

L. Intended consumer
1. Are the peanuts intended for the general public?
2. Are the peanuts intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immunocompromised individuals)?
3. Is the food to be used for institutional feeding or home use?

1.2.2 Hazard Evaluation

After listing potential biological, chemical and physical hazards, the FOOD SAFETY team determines which of these potential hazards present a significant risk to consumers. The two factors used in this determination are severity (seriousness of illness or injury resulting from exposure to the hazard if it does occur) and likelihood of occurrence.

Severity should be determined taking into consideration susceptibility of intended consumers to foodborne illness or injury, possible impact of secondary problems, and magnitude and duration of illness or injury. Scientific data are helpful in making this determination.

Likelihood of occurrence may be influenced by:

- Effectiveness of PPs or other PREVENTIVE CONTROLS preventive controls
- Frequency of association of potential hazard with the food (e.g., glass contamination in products likely to be low)
- Method of cleaning and inspection/detection within the shelling facility or by manufacturers during further processing
- Storage and transportation conditions
- Historical experience within the shelling facility
- Design of cleaning and shelling equipment
- Employee, contractor and visitor adherence to GMPs

In the determination of whether a hazard is reasonably likely to occur, the food safety team may consider the following:

- Likelihood of presence at levels likely to cause illness or injury
- Is the adverse effect of the hazard is a result of a single exposure (acute)
- Or it takes multiple or chronic (i.e., long-term or lifetime) exposures

The food safety team may also review applicable PPs or preventive controls that may be used to manage potential hazards. Examples of applicable prerequisite programs:

- Chemical control program ensures controlled access to hazardous chemicals
- Maintenance program requires food grade lubricants to be used on processing equipment
- Glass and Brittles policy establishes an inspection program for items within the plant

Example of applicable preventive control:

- Metal detector (Process Preventive Control or CCP) located prior to pack out removes any metal missed by magnets

Further elaboration of using the two-stage (i.e., hazard identification and hazard evaluation) approach to conduct a hazard analysis can be found in published technical papers (Bernard, et al., 2006; Bernard and Scott, 2007; Scott and Chen, 2009). In essence, a proper hazard evaluation is analogous to a qualitative risk assessment, because determination of the likelihood of occurrence of a hazard and the severity of the consequence if the hazard does occur are two main inputs in a risk assessment.

Regulatory agencies have clarified that it is inappropriate to control significant hazards using prerequisite programs. If the hazard is reasonably likely to occur in the absence of control, then a CCP must be used to control the hazard.

1.3 Design Hazards Out

The most effective method to eliminate a hazard is to design it out of the product or process. For example, shatterproof light bulbs should be utilized to reduce or eliminate the likelihood of glass in product; pecan trees that are located around peanut staging areas can either be removed or staging areas can be covered to eliminate pecan contamination; and, peanut staging areas that are exposed to bird contamination can be protected to eliminate bird roosting and associated product contamination.

Hazards that cannot be designed out and are assessed as likely to be present in the shelled product should be continuously and strictly controlled. Hazards that can be effectively prevented or are at levels not likely to cause the product to be unsafe are most effectively managed through prerequisite programs or other preventive controls:

- Plastic and glass controlled through the Glass and Brittle Plastics program or
- Sticks, stones and other field debris controlled through the Foreign Material Control program

Hazards that are reasonably likely to cause harm to a consumer may best be managed by Process Preventive Control

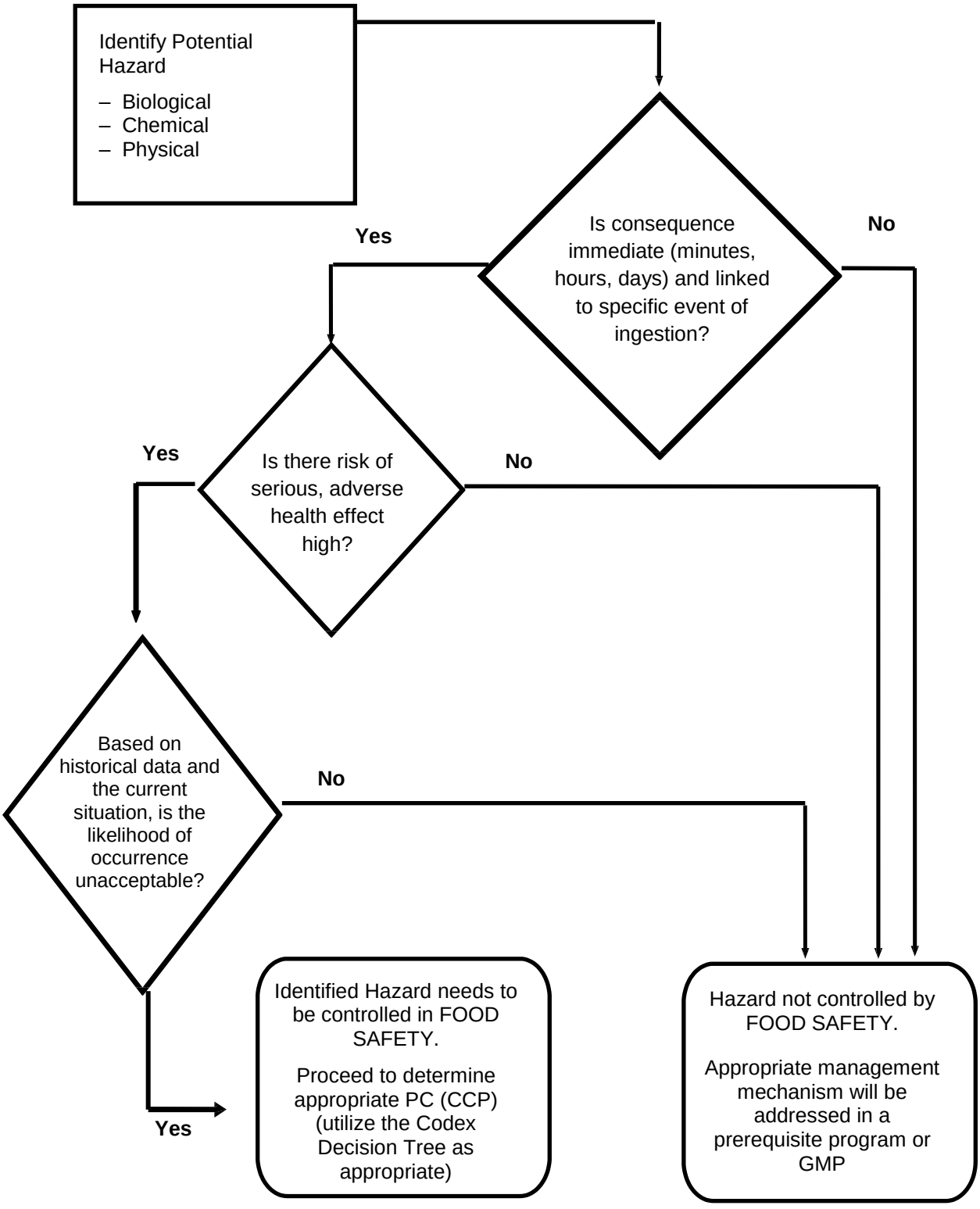
- Metal fragments controlled by use of a metal detector

1.4 Hazard Evaluation Flow Chart

How to determine whether potential hazards are "significant hazards":
After a list of potential hazards has been identified, the FOOD SAFETY team may use the **Hazard Evaluation Flow Chart** (Diagram 1, below) to aid in the determination of significant hazards that need to be controlled in the FOOD SAFETY plan by a PC (CCP), or potential hazards that can be managed by prerequisite programs.

For shelling mills, frequently the only PC (CCP) involves final metal detection (magnets, metal detectors). However, this must be confirmed through hazard analysis.

DIAGRAM 1. HAZARD EVALUATION FLOW CHART



2.0 Hazards and Hazard Management Criteria

Guidance for how to **determine whether a process step is a CCP for a significant hazard** identified during the hazard analysis is provided in the NACMCF document (NACMCF, 1998), the Codex document (CAC, 2003), and the GMA FOOD SAFETY manual (Scott and Stevenson, 2006).

2.1 Hazards Controlled by Critical Control Points (CCPs)

Pathogens, microbial toxins, some hard or sharp extraneous material and, under certain circumstances, allergens are examples of potential hazards that tend to be viewed as having the following characteristics:

- Acute illness/injury
- Occurrence of adverse effects within a predictable period of time following ingestion (e.g., minutes/hours/days)

Therefore, if these hazards are assessed as likely to be present in the product (through raw materials, handling, etc.), then they would require strict and continuous control and are most effectively managed as CCPs.

2.2 Hazards Managed by Prerequisite Programs (PPs) or PREVENTIVE CONTROLS Preventive Controls

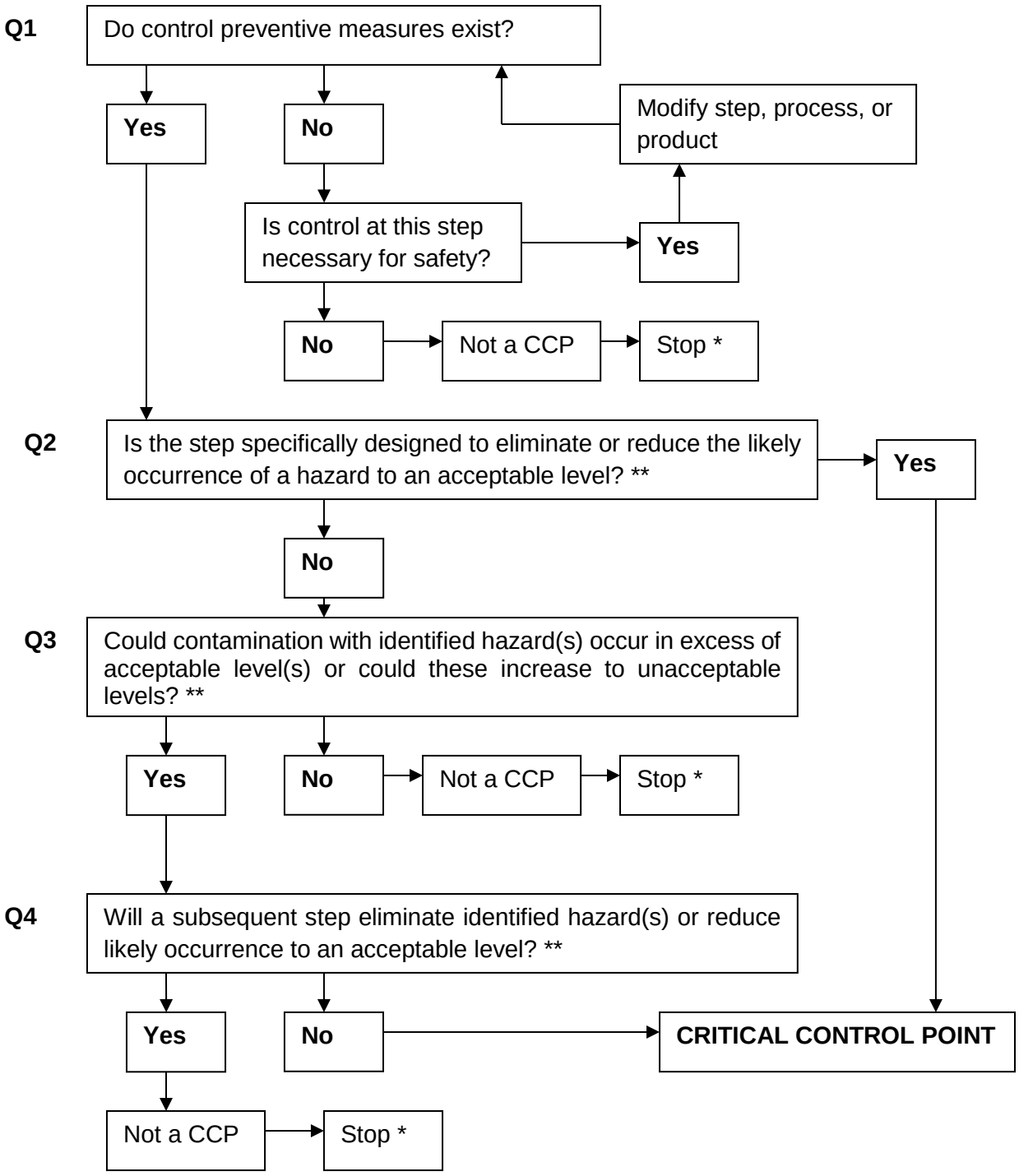
Potential hazards such as mycotoxins (e.g., aflatoxin), and under some circumstances pesticides, tend to be viewed as having the following characteristics:

- Occurrence of illness after long term, chronic exposure (perhaps years) to the causative material; and,
- Difficulty in attributing a particular adverse effect to a specific event due to the widespread occurrence of the causative agent in the food supply

These risks may be effectively managed by growers, using Good Agricultural Practices (GAPs), and shellers, using GMPs and prerequisite programs or other PREVENTIVE CONTROLS preventive controls, prior to providing the peanuts to manufacturers to produce a ready-to-eat product. Certificates of Analysis (COAs) may be requested for aflatoxin results on incoming lots to manufacturers.

The food safety team may use a decision tree, such as the Codex Decision Tree (Diagram 2, below) to aid in the determination of whether a particular step on the process flow diagram is a CCP.

DIAGRAM 2. EXAMPLE OF DECISION TREE TO IDENTIFY CCPs (CODEX DECISION TREE) (Answer questions in Diagram 2 in sequence)



* Proceed to the next identified hazard in the process.

** Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of FOOD

2.3. Examples of Hazards Addressed by CCPs, PPs, or PREVENTIVE CONTROLS Preventive Controls

Biological hazard(s)

For peanuts, the organism of primary focus is *Salmonella*, as a result of this organism's potential presence in raw nuts, the history of *Salmonella* in nut products, survival of *Salmonella* in dry environments and products, and heat resistance of *Salmonella* in dry products.

The presence of *Salmonella* in low-moisture products, like peanuts and peanut butter, is a concern because its mere presence in foods can cause illness. In the 2006-2007 outbreak associated with peanut butter, *Salmonella* was found at 1.5 organism per gram (estimated) in an unopened jar and a lower level was found in another recent peanut outbreak (Zink, 2008).

Shellers who provide raw peanuts as a non-ready-to-eat ingredient do not have a CCP to eliminate *Salmonella* in their process. However, they should have PPs or preventive controls in place to prevent *Salmonella* growth and minimize contamination.

The presence of *Salmonella* in peanuts **may be controlled at the manufacturer by a validated control step such as** roasting (e.g., oil roasting, dry roasting), as well as by implementing a program to prevent post-roast recontamination prior to packaging.

Chemical hazard(s)

Mycotoxins, pesticides, and food allergens are potential chemical hazards. In most cases, due to the low likelihood of occurrence and/or the nature of the hazard, they are best managed by PPs or PREVENTIVE CONTROLS preventive controls (aflatoxin, pesticide residue). However, in certain instances a CCP may be the appropriate control for a food allergen.

PREVENTIVE CONTROLS requires a preventive control program for identified allergens. An Allergen Control Program should be in place if pecan or other allergen contamination is likely to occur. The control steps should include eliminating the hazard prior to introduction to the peanut stream, if possible.

Physical hazard(s)

In general, extraneous matter is defined as any object/material that may become part of the product being produced that is not designed to be a part of such product. Extraneous matter does not usually present a significant risk of a severe adverse health effect; the matter may be aesthetically unpleasant but usually does not cause injuries. Extraneous matter that does not cause injury is best managed by PPs such as cleaning, equipment calibration, preventive maintenance, and employee practices. A hazard analysis may indicate that preventive controls are not necessary.
In some cases, the characteristics (size, shape and type) of the extraneous matter may potentially cause serious harm. Typically these objects will be hard or sharp, such as glass, metal, hard plastic, ceramic. Hard or sharp foreign objects that are capable of causing injury are potential physical hazards. If the hazard analysis determines that a potential physical hazard is likely to occur, it should be controlled by a FOOD SAFETY CCP and/or PREVENTIVE CONTROLS preventive control.

The food safety team can use the Hazard Evaluation Flow Chart to help determine whether or not a potential physical hazard posed by extraneous matter needs to be controlled in food safety. The following considerations or control measures may be used for the CCP(s), PP(s) or preventive controls:

Physical hazards removal/detection devices may include:

Density Detectors
Stoners
Magnets
Metal Detectors
Filters
Screens
Sieves
Strainers
Vision Systems
X-Rays
Others

For example, within many shelling facilities, the FOOD SAFETY team may determine that metal is likely to occur and, therefore, the final metal detectors or magnets are considered to be CCPs and/or PREVENTIVE CONTROLS preventive control. In some processes, more than one detection/removal device may be designated as CCPs and/or PREVENTIVE CONTROLS preventive control.

An extraneous detection/removal device that is present on a line/process is a CCP and/or preventive control if its primary purpose is to prevent, eliminate, or reduce to an acceptable level hazardous extraneous matter in the product and it is the last and/or most effective extraneous detection/removal device on that line/process.

3.0 Critical Control Point to Eliminate Metal

3.1 Objective

All peanut shellers receive farmer stock peanuts, which may have received “gross cleaning” at a buying point prior to receipt at the shelling mill. These farmer stock peanuts may contain dirt, sticks, stones, nut grass, field glass, field metal, pecans, bone fragments, etc. Infrequently, raw peanuts may also be contaminated with *Salmonella* or aflatoxin. At the sheller locations, the majority of these potential hazards should be managed through PPs and/or PREVENTIVE CONTROLS preventive controls. This section focuses on CCP(s) designed to eliminate metal fragments in an operation with a FOOD SAFETY plan where the FOOD SAFETY team concludes in the hazard analysis that metal fragments are reasonably likely to occur given PPs or other preventive controls in place and, unless controlled, are likely to cause a significant injury.

3.2 Management Responsibility

All peanut shellers should ensure that instructions are developed, documented, communicated, and followed, and that responsible employees are designated and adequately trained, in order to meet the minimum metal detection and control standards outlined by this section.

3.3. Critical Limits for Peanut Shelling CCPs

Critical limits for metal detection, described below, and final magnets are based on data in the literature or through in-house studies. These parameters are examples only and must be validated for specific types of peanuts, metal and magnets/metal detection equipment.

The scientific basis should be cited for the critical limit (e.g., regulatory guidelines, experimental studies, scientific publications). The following are examples of writing style conventions for scientific citation:

Scientific Publication

Author, Date. Title. Publication. Vol #: pages.

Regulatory Guideline

FDA (Food and Drug Administration).CPG Sec. 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects.
http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm

Experimental Studies

Company X, Inc. Engineering and QA Depts, (City, Country). Product Study. Engineer and/or QA representative, Last name, First initial, Year. Notebook # or other identification.

The detecting limit for an end-point metal detector or magnet will depend on the type of product and the detection equipment or magnet.

For metal detectors, equipment settings should be determined and applied to achieve the most sensitive level possible to provide maximum protection from metal contamination. **As a guide**, the detection sensitivity under production conditions should be capable of detecting and rejecting pieces larger than 7 mm (.28in) for all metals and meeting customer/regulatory requirements.

The FDA Health Hazard Evaluation Board "found that foreign objects that are less than 7mm, maximum dimension, rarely cause trauma or serious injury except in special risk groups such as infants, surgery patients, and the elderly."
(http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm)

The reject mechanism should direct product rejects from the process flow automatically into an identified area, bin or container. An action level, based on the number of rejects and/or the size of the metal fragments found, should be defined on the basis of historical trend analysis.

- If this action level is exceeded, then all diverted rejected product should be evaluated to determine the cause for rejection.
- Where no action level is defined, all rejects should be evaluated to determine cause for rejection.
- Action limits should be available to the responsible operator, and corrective actions described.
- Action limits should include unusual findings and excessive rejects, which would trigger an immediate corrective action.
- All the findings should be documented, including time, test results and operator's name.

- The responsibility and methodology for evaluating rejected product should be specified and documented.

3.4 Monitoring Activity/Frequency

Example of monitoring procedure for metal detection:

- Visual observation to ensure detector is working properly and product is passing through the detector will be taken at start-up and end of each shift and approximately once every 2 hours during the shift

- The reject mechanism should be tested at start-up and end of each shift and approximately once every 2 hours during the shift to confirm that it will reject metal pieces larger than critical limits.

3.5 Corrective Action Activity

In the event that a deviation is noted, the sheller should have documented corrective actions in place to manage product hold and disposition, equipment repair, calibration and verification and/or line clean-up, inspection and restart, depending upon the reason for the deviation. In the event that a deviation is noted during or after operations, all product produced since the last documented time that there was no deviation should be placed on hold pending product review and determination of product disposition. In cases where deviations from critical limits are detected during a review of records, after peanuts are shelled and packaged (bagged or cased), all affected product should be placed on hold and the designated management personnel notified to determine disposition. Hold/ Release documentation should be available.

For example, corrective action for deviations to critical limits at the metal detector may include repair or re-calibration of the metal detector or repair or replacement of the reject mechanism. In addition, product run since the last acceptable checks on critical limits should be placed on hold and evaluated for appropriate disposition. Corrective action may include 100% inspection by an operable metal detector or other approved analytical technique to ensure compliance with the critical limits. Disposition may include release of re-inspected and cleared peanuts and further cleaning (e.g., further cleaning of the peanuts through magnets and/or cleaning equipment as opposed to only rerunning through the metal detector) or controlled disposal or crushing (for peanut oil) of rejected peanuts.

3.6 CCP Verification Activities

Verification activities should be performed for each CCP or preventive control to verify that the critical limits are within control. These activities should be performed at a frequency sufficient to demonstrate control.

Functionality verification for electronic detection and rejection devices should take place during production with the normal product flow. As an example, frequencies for system verification should occur at the following times:

- After a production changeover
- Following any repairs, maintenance or adjustments
- On a regular basis as determined by the site (recommended minimum every 4 hours, length of time based on acceptable risk/value of held product and process capability experience or studies)

The functionality verification method should assure 100% detection and rejection of the test piece(s). At the start of production each day, and then at specified intervals thereafter, each test piece (ferrous, non-ferrous and non-magnetic stainless steel) should be passed through the detection device and detected and rejected, as defined by the particular facility's food safety program. The verification test pieces should be clearly identified and differentiated from product. If a metal detector is not working at its design limit (e.g., if it fails to detect a test piece), the material produced since the last time the metal detector was verified to be operating at its design limit should be placed on hold.

Examples of verification activities include:

- Designated personnel checks the sensitivity of the detector and reject mechanism by running ferrous, non-ferrous and nonmagnetic stainless steel test pieces through the geometric center of the aperture once/shift
- Management reviews and signs metal detector records daily
- Food Safety team or QA performs food safety and/or preventive controls system audit annually, reviewing procedures and paperwork for compliance and effectiveness
- Metal detector calibration per manufacturer's recommendation (e.g., annually)

3.7 Responsibility for Implementation of CCPs

Trained employees should be designated for monitoring and initiating corrective actions, and for CCP verification. It may be beneficial to involve members of the food safety team in corrective actions should a deviation to a critical limit occur, and in CCP verification as appropriate.

3.8 Record Location

All records should have a designated, secure location. Examples of records include: metal detector calibration logs, metal detector verification records, hold and release records, corrective action records, traceability records.

4.0 FOOD SAFETY Plan Administration

A completed food safety plan should contain the following components:

Product/Product Category Description
Process Flow Diagram
Raw Material/Packaging Assessment
Processing Step Evaluation
Allergen Cross-contact Production Assessment
Critical Control Point (CCP) Documentation

Food Safety Plan Approval

Forms are acceptable if they follow NACMCF and/or Codex principles and guidelines. **Example forms can be found in Appendix F.** Format of the forms is optional as long as the appropriate content is present. Retention time for food safety records should be at least as long as the shelf life of finished product, or as designated in company policies, FDA regulations, customer requirements or other appropriate regulatory standards.

5.0 Food Safety System Validation Procedures

Food safety plan validation ensures that all hazards have been identified, every hazard is being effectively controlled to the degree necessary, and only significant hazards are controlled within the FOOD SAFETY system (others are managed by PPs and other control systems). Food safety system validation involves the collection and evaluation of scientific, historical and technical information to assess whether the food safety plan, when properly implemented, effectively identifies and controls all food safety hazards associated with the product or process.

The CCP for metal detection must be validated and the validation (both supplier/industry studies and in-plant studies) should be performed by qualified personnel.

5.1 When to Validate a Food Safety Plan

- New plans or significantly changed existing plans
- Whenever there is a systematic or recurring product safety issue, or industry recall of similar product
- Existing plans (no changes), on a schedule determined by the sheller or supplier that is no longer than two years or per regulatory requirement
- When a previously unrecognized hazard is identified by regulatory, industry, or scientific sources

5.2 Evaluate the product and process to determine if changes have been made that have not been reflected in the plan

- Review product information, including raw ingredient specification, product description, and packaging material documented in the hazard analysis
- Review the process flowchart to ascertain that appropriate equipment and current process steps are included

5.3 Evaluate the product (category) safety history

- Review CCP deviation records
- Review test results from sample monitoring (e.g., physical, analytical and/or biological, if applicable)
- Review industry recalls/withdrawals for the product category
- Determine if there are any new or emerging hazards
- Review regulatory agency recommendations

- Review customer and consumer complaints related to food safety

5.4 Evaluate new developments

- New product consumption or storage methods
  - Use as an ingredient by consumer
  - New customer (manufacturer) uses or processing methods
  - Retail methods or labeling changes
- Technological advances
- Equipment supplier recommendations
- Changes in suppliers

5.5 Use the information gathered when creating the plan (refer to Sections 2.1 – 2.3.5)

Review CCP documentation for each CCP to determine:

- Are all hazards that need to be addressed in FOOD SAFETY addressed?
  - The Hazard Evaluation Flow Chart may be used (refer to Section 2.1.4)
- If addressed by CCP, is the CCP the right one?
  - The modified Codex Decision Tree may be used (refer to Section 2.2)
- Do the critical limits control the hazard? Are the critical limits still adequate?
  - Consider history and new information
- Are the current monitoring methods and frequencies adequate to identify possible deviations? Are better methods available?
- Do corrective actions effectively correct or control deviations?

5.6 Use appropriate members of the food safety team to determine if the food safety plan needs to be changed.

- Documentation of the validation process can be developed using a validation checklist (see example below from the National Conference on Interstate Milk Shipments, or NCIMS) to identify new food safety information.
- New information, if identified, should be evaluated by the food safety team and documented.
- If needed, the plant food safety coordinator should update the food safety plan, as determined by the food safety team.

It should be noted that whenever there are changes to product, package or process, as appropriate, the food safety team should be convened to review the effect on the existing food safety plan. The review during validation is intended only to verify that all changes made since the last validation are reflected in the hazard analysis and, as needed, in the food safety plan itself.

Diagram 3: Example from the NCIMS FOOD SAFETY program: FOOD SAFETY Validation Checklist

SUBJECT **FOOD SAFETY Validation Checklist** PLANT NAME ADDRESS	ISSUE DATE	PRODUCT
	SUPERSEDES	PAGE x of xx

Validation Type (check one):

☐ Initial Validation (within 12 months of implementation)

☐ Validation (Reassessment) due to changes made in raw materials or source of raw materials; processing methods or systems, including computers and their software; packaging; product distribution systems; or the intended use or intended customers (manufacturers) or consumers of the shelled product and rate or type of customer or consumer complaints.

☐ Annual Validation (Reassessment) of the FOOD SAFETY plan including Hazard Analysis

Date Conducted:

Conducted By:

Topic	**Yes**	**No**	**If "Yes", Describe**	**Food Safety Implication?**	**Are modifications to the FOOD SAFETY system required?**
1**. Evaluate product & process**					
Product description changed, e.g., intended use, consumer?	☐	☐			
Raw material / Packaging changed?	☐	☐			
Any new product consumption, manufacturing or storage methods?	☐	☐			
Any new suppliers?	☐	☐			
Process flow changed?	☐	☐			
Equipment / computer software changed?	☐	☐			
Shelled product distribution changed?	☐	☐			
Other, e.g., production volume increased	☐	☐			
2. Evaluate product / process history					
Repeat CCP deviations?	☐	☐			
Any recent industry recalls of similar product since the last annual validation?	☐	☐			
New or emerging hazards, e.g., recent CDC consumer health problems identified with product?	☐	☐			

Topic	Yes	No	If "No", Describe	Food Safety Implication?	Are modifications to the FOOD SAFETY system required?
Regulatory agency recommendations, e.g., guidance documents, regulations?	☐	☐			
Any confirmed food safety customer or consumer complaints?	☐	☐			
Other	☐	☐			
3. Evaluate adequacy of CCPs, critical limits, monitoring, corrective action, CCP verification, and record keeping procedures. Review current CCP documentation.					
Do the CCPs control the hazards?	☐	☐			
Are the CCP critical limits adequate?	☐	☐			
Do monitoring methods and frequency demonstrate control?	☐	☐			
Do corrective actions properly address affected product and correct deviations?	☐	☐			
Does validation include review of consumer complaints?	☐	☐			
Other, e.g., Prerequisite Programs or procedures may affect the hazard analysis	☐	☐			

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Appendix AA

EXAMPLE

Magnet Check – Packaging
Standard Operating Procedure

Purpose
To inspect and document metal removed from the product flow after the shelling and sorting processes, but prior to packaging.

Scope
This procedure covers the last magnet in the process prior to packing raw in-shell edible peanuts.

Responsibility
1. The Packout Lead Person will be responsible for cleaning, maintaining and documenting findings for the magnet located on the exit spout of the elevator supplying the bagging bin.

2. The appropriate Shift Supervisor will be responsible for ensuring the Packout Lead Person is trained to follow this procedure. The training shall be documented and refresher training provided on an annual basis.

Procedure
1. The Magnet will be cleaned by the Packout Team Lead Person after each cut on shelled good are packed.

2. The Packout Lead Person will follow all applicable lock-out procedures for the area and equipment in which he or she is working.

3. The Packout Lead Person will ensure that there are no safety hazards which will prevent the task from being performed safely. If there are questions or concerns about the safety aspect of the task, the Packout Lead Person should contact the Supervisor before proceeding with the magnet check.

4. The Packout Lead Person will stop the flow of the product going into the Elevator.

5. The Packout Lead Person will remove metal from the magnet, log findings on the magnet findings chart, and discard findings in the appropriate waste container, being careful to ensure that metal does not enter the finished product stream.

6. If metal exceeds action level, the Packout Lead Person will immediately inform the Supervisor. The Supervisor will evaluate the situation and determine the appropriate corrective action.