

Industry Handbook for the Safe Shelling of Peanuts

*Addendum I to Industry Handbook for the Safe
Processing of Nuts*

9/21/2009

[This is a guidance document for the peanut shelling industry and provides examples of prerequisite programs that can be used in ensuring the safe shelling of peanuts. The handbook is part of a broader nut industry initiative to provide food safety guidance for the supply chain. This is an interim first edition and it is in the process of finalization.]

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CHAPTER 1 - PREREQUISITE PROGRAMS FOR PEANUT SHELLERS

Introduction

Peanut shellers recognize that there are a number of programs that must be in place and fully functioning for a food safety system such as HACCP to perform effectively in assuring the production of safe foods. These “prerequisite programs” (PPs) are the foundation and will provide operating conditions conducive to the implementation of HACCP. 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.

Prerequisite programs should be documented and will be audited as part of food safety audits and include Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Sanitation Standard Operating Procedures (SSOPs). GMPs are a series of general principles that must be observed during manufacturing and their guidelines outline the aspects of production that would affect the quality of a product. Encompassed within GMPs are Good Handling Practices, Good Laboratory Practices and other best practice principles.

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 8, Cleaning and Sanitation, and an example of an SOP and its format can be found in Appendix AA.

This guidance material is not intended to be an all inclusive reference on PPs. Included are a number of key PPs that will provide a strong basic foundation for the shelling of safe nut products.

This document is a compilation of information from the *Industry Handbook for Safe Processing of Nuts* (interim first edition), GMA, 2009, and *Good Manufacturing Practices for Shelling Plant Operations*, M. Spooner, J. Trice, S. Calhoun, APC, 2008, as well as from referenced material listed at the end of the Guidelines. The *Industry Handbook for the Safe Shelling of Peanuts* was drafted by M. Arline, JLA Global; R. Starling, Golden Peanut Company; D. Cowart, Ph.D., JLA USA, now with Birdsong Peanuts; and, E. Plowden, Jr., WatsonSpence LLP, and endorsed by the American Peanut Shellers Association in October 2009

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

Facilities - The facility should be located, constructed and maintained according to sanitary design principles. There should be linear product flow and traffic control to minimize cross-contamination from raw incoming to cleaned and shelled peanuts. Facilities should be well-ventilated and designed to prevent moisture and extraneous matter contamination in shelled peanuts.

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

Receiving, Storage and Distribution – 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.

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

- Sanitation and pest control (e.g., spacing equipment or material storage away from walls, guideline 18 inches for multiple pallet applications; 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 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.).
- 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, strapped, or net wrapped 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.
- For 2200 pound boxes, the box should be poly taped (tamper evident) around the entire box 4 times, and the Federal-State Tag poly taped to the top of the box.
- 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 should be conducted to assure that the sheller's requirements are met.

Pest Control – 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 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 or alternative methods and tools for controlling pests are preferred over pesticide use and should be employed wherever feasible and practical, e.g., strategies for exclusion and trapping of pests.

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
- Product pipes should be capped when not in use
- Areas around farmer stock storage facilities should be free of 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, pipe, drums, etc., should not be accumulated on the grounds or parking lot.
- Metal refuse containers should have tight-fitting covers and be stored on racks.
- 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.

Rodent traps are set 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. Secondly, 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. 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. Rodenticides used should be in block form only (rodenticidal granulates, pellets or powders should not be used).

Light bulbs from the insect light traps should be replaced regularly (as per manufacturer requirement) for the maximum efficiency of these type 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.

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 Material Safety Data Sheets (MSDS), 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, MSDS sheets and check lists of activity with any corrective action, plus all training.

Chemical Control – 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.

Production Equipment – All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented.

All testing, recording and monitoring devices should be checked at specified intervals to assure accuracy. 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.

Supplier Control - Each facility should assure that its suppliers have in place effective GMP and food safety programs. Shellers who receive shelled peanuts from a seed sheller, toll sheller or other contract sheller should assure that their supplier's food safety programs are also in compliance with these guidelines.

Cleaning and Sanitation – All procedures for cleaning and sanitation of the equipment and facility should be documented and followed. The sanitation procedures should be written using the following information: Description of the area to be cleaned; equipment needed for cleaning including tools, chemicals, etc.; work instructions or procedures to be followed; person responsible for cleaning the assigned area; and, frequency of cleaning the area. Documentation using a master sanitation schedule should be in place.

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

SHELLER/GRAVITY AREA

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 for cleaning: broom, dust pan, trash can, air hose, shovel.

Procedure: Keep area around the shellers clean. Do not store parts, tools, or chemicals on the equipment and keep all items in a locked storage cabinet. On an as needed basis, keep all spills swept up and keep area neat and well-maintained. On a daily basis, blow down all equipment. On a weekly basis, clean out all peanuts from the elevators. Spray elevators as needed and required by label. Sweep up the entire area after blowing down.

Frequency of Cleaning: Weekly – Equipment, Elevators
Daily – Floors, Spills

Person Responsible: Operator

Documentation: Master Sanitation Schedule must be signed by the person completing the sanitation procedure.

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 should be given to maintenance pieces of equipment that may impact food safety and employee safety.

Appropriate measures should be in place to protect products in the event that repair or maintenance activities occur during production. A documented program should be in place to isolate maintenance work areas from active production lines and for line/area release to production after completion of maintenance work (equipment and area to be cleaned and sanitized as applicable prior to release for food production).

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 shall be adjusted in accordance with the outcome of the last intervention and equipment history.

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, 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 tool box 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.

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:

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 has assigned to the managers of food operations the responsibility for assuring compliance by all personnel with this part of the GMPs. To accomplish this, management has been given the 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.

There are several personnel practices with which peanut shellers should be diligent:

- Disease Control - Personnel with contagious illnesses, open lesions, boils, sores or infected wounds which could contaminate foods or food contact surfaces with microorganisms should be excluded from areas where contamination may occur. Personnel should be instructed to report such conditions to their supervisor until the condition is corrected. Personnel should also be instructed to report any exposure outside of the workplace that would pose a risk to the work environment. A comprehensive health policy outlining employee restrictions should be developed by each organization.
- Cleanliness - (a) Employees need to wear clean garments which are suitable for their activities, (b) clean footwear should be appropriate for the work environment and available for use in production areas, (c) uniforms, where provided, should be maintained and cleaned on a regular schedule, (d) it should be assured that any outside clothing be clean and sanitary if allowed in production areas, (e) personal cleanliness needs to be maintained by washing hands prior to work, when they are soiled, after eating, and after using restrooms.

- No jewelry should be worn or otherwise allowed in the plant.
- Effective hair covering and beard covering should be worn where products, food contact surfaces, and packaging materials are exposed.
- Foods, chewing gum, beverages, tobacco products, medicine, coins and like products need to be confined to areas such as break rooms, offices, or other designated areas of the facility so as to prevent product contamination. Lockers or other isolated storage areas should be provided for workers to store personal items.
- Precautions should be taken to prevent contamination from foreign substances including, but not limited to, perspiration, cosmetics, chemicals, fingernail polish, and medicines applied to the skin.
- Education and training - Personnel responsible for identifying sanitary failures or food contamination should have training, education 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 responsibility and accountability as to job expectations 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.
- 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 and be kept clean and sanitary during use or disposed of after use.

Educate workers on the importance of proper hand washing techniques

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

1. Wet hands with clean warm water
2. Apply soap
3. Scrub hands and fingernails (for 30 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 alcohol-based sanitizer
8. Dry hands before or after sanitizer use, as per sanitizer supplier directions.

Training – All employees should receive documented training in personal hygiene, GMPs, cleaning and sanitation procedures, personal safety and their role in HACCP 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, HACCP, 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 which 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.
 - e. Specific training to meet the requirements of this document should be provided as required.

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 labels should accurately describe the material. It should clearly exhibit the name and address of the sheller, lot number, net quantity, storage conditions, and/or other information, as specified.

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

Extraneous Matter 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 risk assessment 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 assessments should consider all types of extraneous matter. Periodic reassessments should be conducted, particularly following changes to the plant environment and instances of non-conformances (e.g., customer or consumer complaints, CCP failures, etc.).

Based on the assessment, 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., GMP, equipment design, preventive maintenance, covers on tanks 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).

Detection and Removal Devices

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; centrifuge is operating at required rpm's; 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 risks identified in the risk evaluation. These include the type of device and established detection limit.

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 equal to or less than:

- 1.5mm for ferrous
- 2.0mm for non-ferrous (brass)
- 2.5mm for stainless steel (316 grade)
- At no time should they be larger than 7mm (0.28 in) for all metals

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 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 rejection of the test piece(s). At the start of production each day and at each package or product 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. Consideration should be given to using a combination of leading edge and trailing edge passes where possible. The verification test pieces/packages 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 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 packages 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.

Use of Outside Laboratories

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 ≤ 15 ppb

*1AB ≤ 8 ppb, If >8 ppb and <45 ppb

then run the 2AB

*1AB + 2AB avg. ≤ 12 ppb, If >12 ppb and <23 ppb,

then run 3AB

*1AB + 2AB + 3AB avg. ≤ 15 ppb

Accept the lot

Product Hold and Release

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 which 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.

Complaint Investigations – Shellers should have procedures in place to receive, document, investigate, respond to and correct, if necessary, customer and consumer complaints.

Traceability and Recall – 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. 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.

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.

Appendix AA

EXAMPLE**Magnet Check – Packaging Standard Operating Procedure**

Purpose

To remove ferrous metal from the inshell product flow after the shelling and sorting process prior to packaging and document findings.

Scope

This procedure covers the last magnet in the process prior to packing raw inshell edible peanuts.

Responsibility

1. The Packout Team 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 Team Leader is trained to follow this procedure.

Procedure

1. The Magnet will be cleaned by the Packout Team Lead Person after each cut on shelled good are packed
2. The Lock Out Procedure for locking out equipment will be followed, if the Lead Person is working near moving parts or electrical connections.
3. The Lead Person will ensure that there are no safety hazards which will prevent the task from being performed safely. If there are questions about the safety aspect of the task, contact your Supervisor before proceeding with the magnet check.
4. The Packout Team 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, Packout Lead Person will inform the Supervisor who will evaluate and determine corrective action.

Confidential

Inshell Control Point #1
Packing Line Magnet
Revised 8/19/09

CHAPTER 2 – FOOD SAFETY PLAN

Introduction

A commonly used framework for a food safety plan is the Hazard Analysis and Critical Control Point (HACCP) system. The HACCP system is a preventive approach to control food safety. Philosophically, HACCP involves a proactive, preventive approach to control potential 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 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.

It is recommended that all products and/or processes have an approved HACCP plan. Approval is determined by an internal or external reviewer trained in a HACCP course endorsed by the International HACCP Alliance. 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 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 HACCP plan development.

It is helpful for each facility to have a HACCP 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 HACCP, 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 HACCP plan (Critical Control Points or CCPs) are identified by completing a risk evaluation.

The following steps are taken in determining whether a hazard needs to be controlled within a HACCP plan:

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

1.2 Conduct a Hazard Analysis

During the hazard analysis, the HACCP 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. It is the foundation upon which the food safety system is built.

1.2.1 Hazard Identification

To identify the potential hazards, the following assessments should be completed and documented. The following information should be available to all developers, approvers, and reviewers of HACCP plans.

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 HACCP 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

In the hazard identification process, the HACCP team should review the potential for undeclared allergens due to contamination (most likely pecan) 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 could include:

Biological: *Salmonella* from incoming raw nuts¹
Salmonella due to environmental contamination (e.g., roof leaks, dust from bird-infested staging areas)
Enteric pathogens from handling

¹ *Salmonella* is not eliminated at the sheller, but through heat or other approved processing methods at the manufacturer. The sheller should focus on prerequisite programs that do not increase the microbiological load.

Chemical: Allergen(s) due to incoming pecan contamination
Aflatoxin

Physical: Metal due to metal-to-metal wear of equipment (e.g., sorters, sizers, screens) or field metal
Field glass
Sticks, stones, nut grass, bone fragments
Plastic

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

Diagram 1**APPENDIX C: 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; e.g., 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 of potential biological, chemical and physical hazards, the HACCP 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 prerequisite programs
- Frequency of association of potential hazard with the food (e.g., glass contamination in product, likely to be low)
- Method of cleaning and inspection/detection within the shelling facility
- Storage and transportation conditions
- Historical experience within the shelling facility
- Design of cleaning and shelling equipment
- How the likely occurrence is affected by normal adherence to GMPs

In the determination of whether a hazard is reasonably likely to occur, the HACCP team may consider the following: likelihood of presence at levels likely to cause illness or injury; whether 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 HACCP team may also review applicable prerequisite program(s) that may be used to manage potential hazards, and ensure that the prerequisite programs are documented and implemented. Examples of applicable prerequisite programs:

- Building Structure/Utility Systems (e.g., walls, barriers, airflow)
- Employee Hygiene/Practices (e.g., traffic patterns)

Further elaboration of using the two-stage risk evaluation approach to conduct a hazard analysis can be found in published technical papers (Bernard, et al., 2006; Bernard and Scott, 2007). 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. Therefore, after identifying a hazard, each hazard should be assessed for the feasibility of designing it out. 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 cut/moved 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 (e.g., metal fragments that pass through screening equipment). These hazards are best managed by a CCP. 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 (e.g., sticks, stones, nut grass, glass from shelling mill light fixtures or fork trucks).

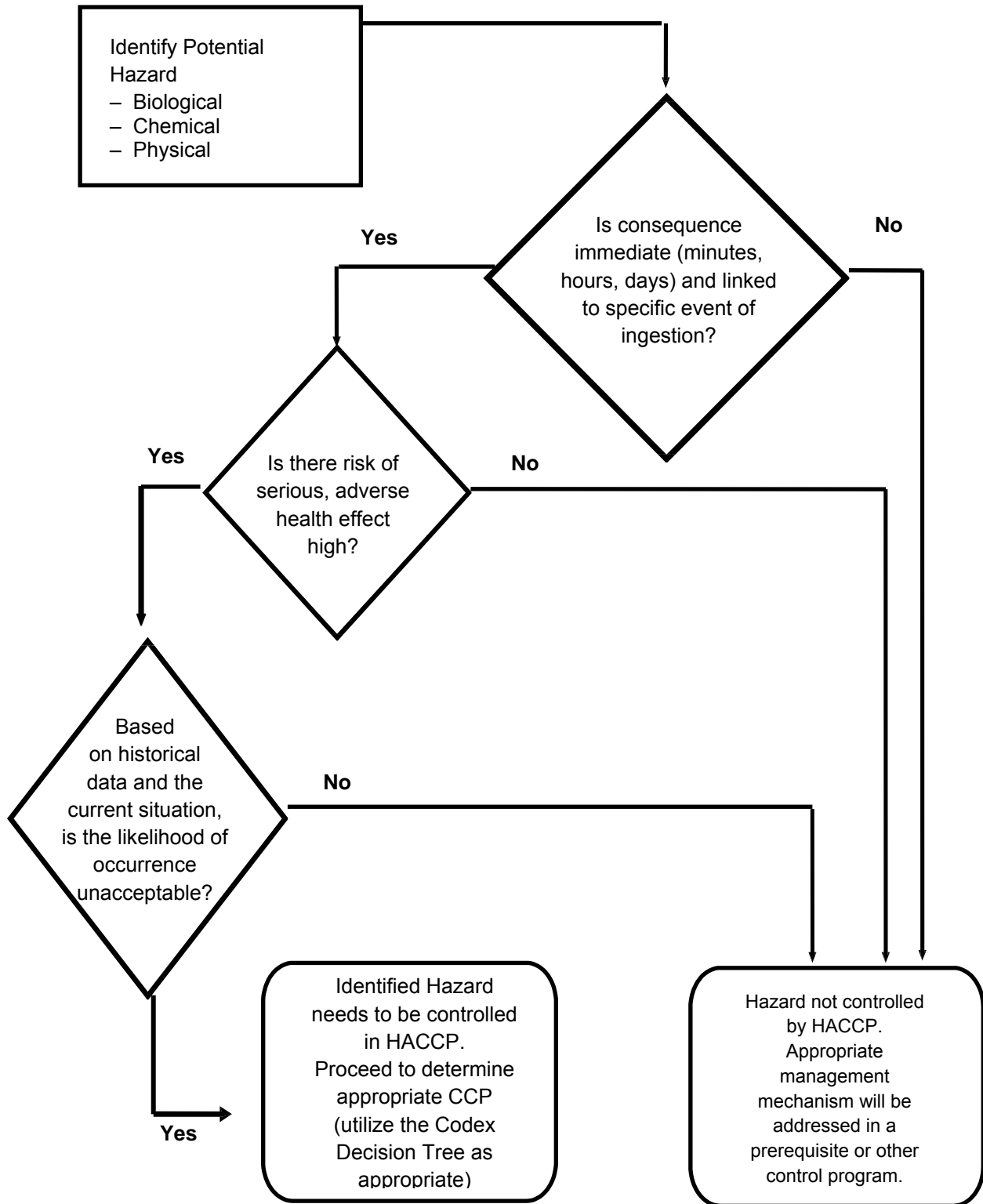
1.4 Hazard Evaluation Flow Chart

How to determine whether potential hazards are “significant hazards”:

After a list of potential hazards has been identified, the HACCP team may use the **Hazard Evaluation Flow Chart** (Diagram 2, below) to aid in the determination of significant hazards that need to be controlled in the HACCP plan by a Critical Control Point (CCP), or potential hazards that can be managed outside the HACCP plan by a Prerequisite Program (PP).

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

DIAGRAM 2. HAZARD EVALUATION FLOW CHART



2. 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 HACCP 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)

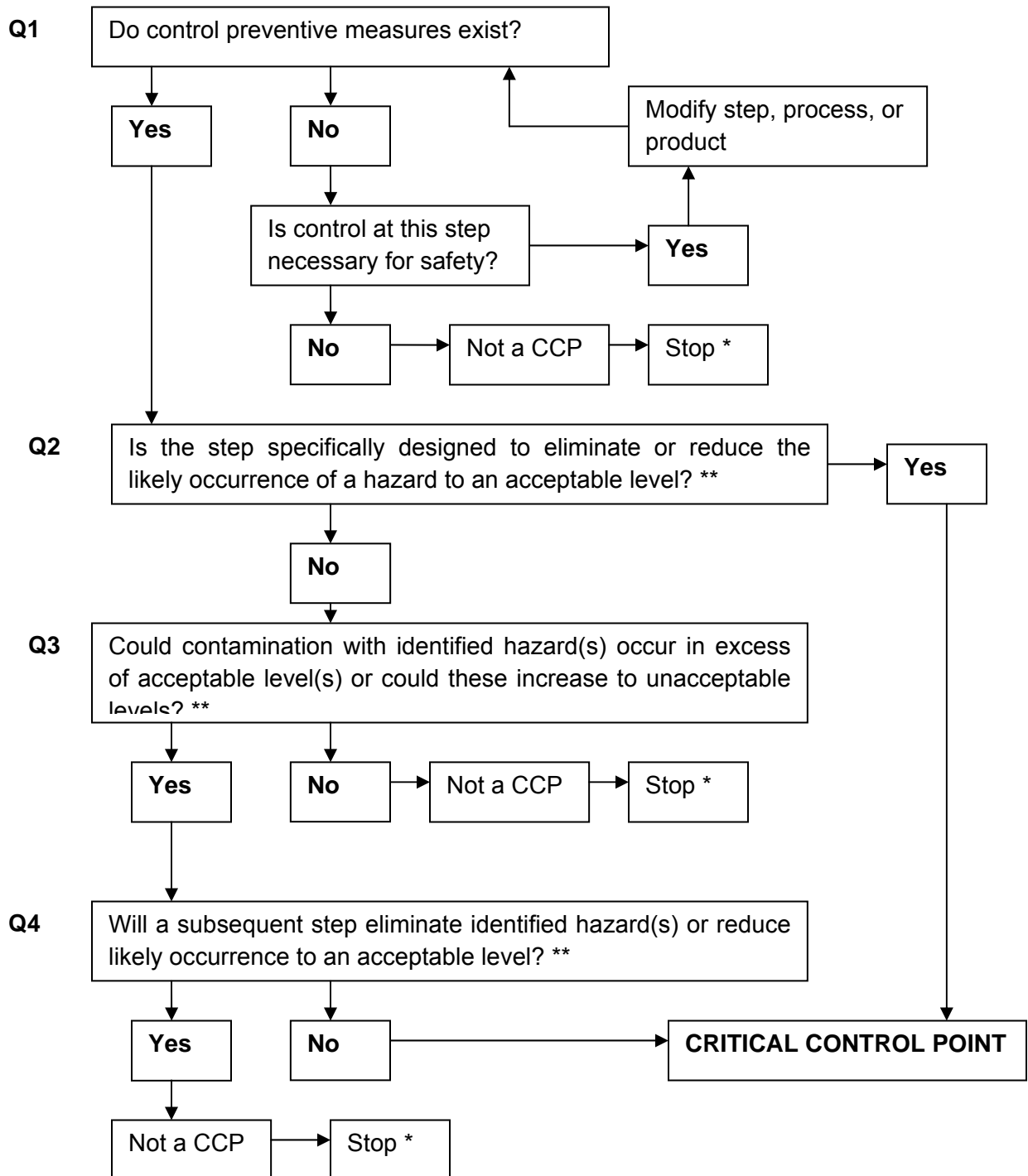
Potential hazards such as mycotoxins (e.g., aflatoxin), and under some circumstances pesticides, tend to be viewed as having the following characteristics:

- Occurrence of illness after long term, chronic exposure (perhaps years) to the causative material
- 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, 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 HACCP team may use a decision tree, such as the Codex Decision Tree (Diagram 3 below) to aid in the determination of whether a particular step on the process flow diagram is a CCP.

DIAGRAM 3. EXAMPLE OF DECISION TREE TO IDENTIFY CCPs (CODEX DECISION TREE) (Answer questions 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 HACCP plan.

2.3. Examples of Hazards Addressed by CCPs vs. PPs

Biological hazard(s)

For peanuts, the microorganism 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 in place to prevent *Salmonella* growth and minimize contamination.

The presence of *Salmonella* in peanuts **may be controlled at the manufacturer** during roasting (e.g., oil roasting, dry roasting), as well as by implementing a program to prevent post-roast recontamination prior to packaging (GMA, 2009).

Shellers who package raw peanuts for sale must include the following statement on the package:

“As with many raw agricultural food products, it is recommended that raw peanuts be cooked before consumption.”

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 (aflatoxin, pesticide residue). However, in certain instances a CCP may be the appropriate control for a food allergen.

An Allergen Control Program should be in place if pecan 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, employee practices.

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 CCP.

The HACCP 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 HACCP. The following criteria may be used to establish the CCP(s) or PP(s):

- An extraneous detection/removal device that is present on a line/process is a CCP 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.

Physical hazards removal/detection devices may include:

- *Density Detectors*
- *De-stoners*
- *Magnets*
- *Metal Detectors*
- *Filters*
- *Screens*
- *Sieves*
- *Strainers*
- *Vision Systems*
- *X-Rays*
- *Others*

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

3.0 Critical Control Points 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 are managed through prerequisite programs. This section focuses on CCP(s) designed to eliminate metal fragments (e.g., those that are not removed using PPs and are likely, unless controlled, to cause a significant injury).

3.2 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

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 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. Note book # 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 equal to or less than:

- 1.5mm for ferrous
- 2.0mm for non-ferrous (brass)
- 2.5mm for stainless steel (316 grade)
- At no time should they be larger than 7mm (0.28 in) for all metals

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 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

Examples of monitoring procedures for metal detection are provided below.

- Visual observation to ensure detector is working properly and product is passing through the detector should 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, above (refer to SOP# xx)
- Monitoring is generally performed by an equipment/line operator or QA technician

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 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 metal detector or repair or replacement of 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 or controlled disposal or crushing (for peanut oil) of rejected peanuts.

3.6 CCP Verification Activities

Verification activities should be performed for each CCP to verify that the CCP 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. 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 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)

Functionality verification method should assure 100% detection and rejection of the test piece(s). At the start of production each day and at each package or product change, each test piece (ferrous, non-ferrous and 316 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. Consideration should be given to using a combination of leading edge and trailing edge passes where possible. 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 316 nonmagnetic stainless steel test pieces through the geometric center of the aperture once/shift
- Management reviews and signs metal detector records daily
- HACCP team performs HACCP system audit annually, reviewing procedures and paperwork for compliance and effectiveness
- Annual metal detector calibration per manufacturer's recommendation

3.7 Monitoring, Corrective Action and Verification Responsibility

Trained employees should be designated for monitoring and initiating corrective actions, and for CCP verification. It may be beneficial to involve members of the HACCP 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. HACCP Plan Administration

A completed HACCP 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
- HACCP Plan Approval

Forms are acceptable if they follow NACMCF and/or Codex principles and guidelines. Example forms can be found in Appendix 3 (p. 98 above). Format of the forms is optional as long as the appropriate content is present. Retention time for HACCP 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. HACCP System Validation Procedures

HACCP plan validation ensures that all hazards have been identified, every hazard is being effectively controlled to the degree necessary, and only appropriate hazards are controlled within the HACCP system. HACCP system validation involves the collection and evaluation of scientific, historical and technical information to assess whether the HACCP plan, when properly implemented, efficiently identifies and controls all food safety hazards and emerging issues 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 HACCP 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 supplier that is no longer than two years or per regulatory requirement

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 microbiological, 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 1.1 – 3.5)

Review CCP documentation for each CCP to determine:

- Are all hazards that need to be addressed in HACCP addressed?
 - The Hazard Evaluation Flow Chart may be used (refer to Section 1.4)
- If addressed by CCP, is the CCP the right one?
 - The modified Codex Decision Tree may be used (refer to Section 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 HACCP team to determine if the HACCP plan needs to be changed.

- Documentation of the validation process can be done using a validation check list (see example below from NCIMS) to identify new food safety information.
- New information, if identified, should be evaluated by the HACCP team and documented.
- If needed, the plant HACCP coordinator should update the HACCP plan, as determined by the HACCP team.

NOTE: It should be noted that whenever there are changes to product, package or process, as appropriate, the HACCP team should be convened to review the effect on the existing HACCP 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 HACCP plan itself.

Example from the HACCP program developed by the NCIMS: HACCP Validation Checklist

SUBJECT HACCP Validation Checklist	ISSUE DATE	PRODUCT
PLANT NAME ADDRESS	SUPERSEDES	PAGE

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 HACCP plan including Hazard Analysis

Date Conducted:

Conducted By:

Topic	Yes	No	If "Yes", Describe	Food Safety Implication?	Are modifications to the HACCP system required?
1. Evaluate product & process					
Product description changed, e.g. intended use, consumer?	<input type="checkbox"/>	<input type="checkbox"/>			
Raw material / Packaging changed?	<input type="checkbox"/>	<input type="checkbox"/>			
Any new product consumption, manufacturing or storage methods?	<input type="checkbox"/>	<input type="checkbox"/>			
Any new suppliers?	<input type="checkbox"/>	<input type="checkbox"/>			
Process flow changed?	<input type="checkbox"/>	<input type="checkbox"/>			
Equipment / computer software changed?	<input type="checkbox"/>	<input type="checkbox"/>			
Shelled product distribution changed?	<input type="checkbox"/>	<input type="checkbox"/>			
Other, e.g. production volume increased	<input type="checkbox"/>	<input type="checkbox"/>			
2. Evaluate product / process history					
Repeat CCP deviations?	<input type="checkbox"/>	<input type="checkbox"/>			
Any recent industry recalls of similar product since the last annual validation?	<input type="checkbox"/>	<input type="checkbox"/>			

New or emerging hazards, e.g., recent CDC consumer health problems identified with product?	<input type="checkbox"/>	<input type="checkbox"/>			
Regulatory agency recommendations, e.g., guidance documents, regulations?	<input type="checkbox"/>	<input type="checkbox"/>			
Any confirmed food safety customer or consumer complaints?	<input type="checkbox"/>	<input type="checkbox"/>			
Other	<input type="checkbox"/>	<input type="checkbox"/>			
Topic	Yes	No	If “No”, Describe	Food Safety Implication?	Are modifications to the HACCP system required?
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?	<input type="checkbox"/>	<input type="checkbox"/>			
Are the CCP critical limits adequate?	<input type="checkbox"/>	<input type="checkbox"/>			
Do monitoring methods and frequency demonstrate control?	<input type="checkbox"/>	<input type="checkbox"/>			
Do corrective actions properly address affected product and correct deviations?	<input type="checkbox"/>	<input type="checkbox"/>			
Does validation include review of consumer complaints?	<input type="checkbox"/>	<input type="checkbox"/>			
Other, e.g. Prerequisite Programs or procedures may affect the hazard analysis	<input type="checkbox"/>	<input type="checkbox"/>			

6. References

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