

NQS Level 1 - Food Safety Audit Report
Peanut Corporation of America, Plainview, Texas
January 5, 2006

There are emergency exit doors to the outside of the plant. These doors were found to be closed and not locked during the audit. The doors are equipped with handles on the exterior side and are self-closing.

The plant has a seals program, and there are seals utilized on all inbound and outbound loads of raw material or finished product. It was understood that the plant would reject any raw material received without an intact numbered seal that is matched to the shipping documentations.

A trailer inspection program is in place to document the conditions of each trailer and load of materials received, and empty trailers prior to loading for shipment. The incoming and outgoing forms contain sufficient information to insure trailers are being inspected adequately.

There are no liquid bulk ingredients or chemicals received or stored at this location.

HACCP (Hazard Analysis Critical Control Point)
Complying with Major Improvement Needed

A documented HACCP plan (dated December 29, 2005) based on the plan for the Blakely, Georgia plant has been developed. The plan was developed by the operations manager, quality manager, and technical director. The HACCP plan included process flow charts, CCPs, and corrective action plans. It was understood that a HACCP plan review is completed whenever there is a change to existing equipment, or when new equipment is added to the existing process line. The plant maintains a revisions history and log to track all changes to the HACCP plan. All paperwork that contains a CCP check is reviewed by plant and quality supervision.

Management has limited training in HACCP, but understands the basic principles of food safety related hazards. It is recommended that someone in management attend a certified HACCP training course to better understand food safety hazards that potentially occur through the entire product process flow from raw peanuts to finished roasted peanuts. Once complete, the HACCP program can be further reviewed and risk re-assessed. Risk assessment includes safety hazards related to microbiological, physical, and chemical (includes allergens) hazards. Currently the food safety concerns are centered on the physical presence of raw peanuts being handled in the peanut roasting area (microbiological).

The HACCP plan needs to include the following: risk assessment of processes and materials, process flow charts, CCPs, corrective action plans, meeting notes from HACCP discussions that might provide rationale for decisions (plan history), documentation of the process validation steps for CCPs, calibrations requirements, and documented outcomes of HACCP reviews.

A foreign material protection plan includes the following: a plant glass and brittle plastics policy is maintained, destoning equipment, in line screens / sifters, magnets, metal detectors, visual inspection of equipment prior to start up, and visual inspection of process of the operating condition and equipment during production.

The plant has 1 CCP for product that might be produced for Nestlé:

- CCP 1 – roaster conditions. The dry roaster is operated such that peanuts are roasted at ≥ 300 F for about 25 minutes.

The metal detection check was verified during this audit with no concerns noted. The system viewed was verified using 2.0 stainless steel, 2.0 non-ferrous, and 1.5 ferrous standards.

Metal detector monitoring procedures are established and include action in case of deviation. The systems are checked at least one time per hour by the quality control technician.

Comments / concerns related to HACCP and the current plant design / usage related to concerns for potential microbiological cross contamination with the raw and finished nuts. These items need to be reviewed by the plant / company HACCP authorities.

- The storage, dumping, and cleaning of raw nuts takes place in the pre-clean room. This room has a negative air pressure to the other areas of the plant. The room has a doorway entering into the roasting room, but no door is installed. What check is in place to be sure air pressure is maintained?

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- All peanut pieces are moved through the processing equipment via open top conveyors and bucket conveyors. All storage bins and conveyors are designed without any tops. The concern is for potential foreign material to easily enter the product flow.
- Employees wear their street clothes in all areas of the operation. At a minimum, a smock or outer garment should be provided by the plant to create a barrier between the employee clothes and the product being processed.
- There are informal traffic patterns and practices for moving vehicles and plant personnel, but no documented plant guidelines. A formal written control plan for the movement of personnel and equipment for the prevention of raw / further processed product contamination needs to be developed. This should include requirements for work assignments and personnel movement, uniform control / changes, hair net usage / changes, glove requirement, cleaning requirements, footwear treatments, etc.
- Raw and blanched peanuts are roasted and / or blanched on specific equipment that has been installed on a shared line. The roaster is used to transport peanuts to the blanchers when the plant is blanching, and the blanchers are by-passed when roasting. The conveyors after these are share pieces of equipment. No microbiological studies have been completed to show that no risk is present on these shared pieces of equipment.
- No environmental sampling program is in place or has been completed to provide information on the potential microbiological risks or concerns in the further processing areas.
- The plant is in the process of installing an oil roasting system in a corner of the finished product warehouse. The peanut dumping station for the oil roasting system is being installed in the corner of the roasting / blanching room about 30 feet from the pack-off station for roasted / blanched nuts. By design, blanched only raw nuts will have to be transported to, and then dumped, in the roasting / blanching room.

QMS (Quality Monitoring Scheme)

Complying

Although a program formally called "QMS" does not exist, procedures and policies, manufacturing parameters, quality-testing targets with ranges, specifications, corrective actions, and product/customer specific requirements are in place.

Results from quality testing are recorded throughout production on designated paperwork. Quality testing is completed throughout processing by quality control and production operators. The quality technicians are responsible to calibrate all equipment utilized for quality testing on a daily basis. Production and quality employees and supervisors are continually monitoring the quality of products through visual inspections.

Typically, routine product testing includes visual, odor, microbiological, and analytical before, during and after manufacturing. The results can be included on a Certificate of Analysis (COA) as requested by each customer. Testing of the products produced is based on customer requirements. Testing typically includes:

- Analytical – color, salt content, granulation or particulate sizing, odor, flavor may be informally tested
- Organoleptic - aroma, appearance, and occasionally, flavor may be informally tested
- Microbiological – aerobic plate count, yeast, mold, e. coli, salmonella, and coliforms – completed by an outside microbiological laboratory. Aflatoxin results are included on the COA, but these testing results are transferred from the information provided by the incoming results from the sheller.

All tasks and specifications are defined and completed for each lot produced. Additional customer specific testing requirements can be discussed and added if determined necessary.

The factory employees and management personnel I talked too were well aware of the product specifications, HACCP CCPs, and quality testing parameters.

Information is provided by the shellers for the incoming raw, shelled nuts. The results are from USDA parameters and testing for peanut grading. For testing purposes, a 75,000-gram samples is drawn across about 200, 000 pound lots.

- Slot screen sizing
- Percent other types of kernels
- Split or broken kernels
- Damaged or unshelled kernels
- Minor defects
- Foreign material based on 8, 012.60 grams.

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- Moisture
- Aflatoxin (typically by J. Leek & Associates)

Pathogen Monitoring of the Production Environment
Not Complying

There is currently no environmental pathogen-monitoring plan. There has been no pathogen-monitoring plan completed to provide historical information to justify the discontinuance of an environmental monitoring program for the operating areas of the facility.

A plan needs to be developed and implemented. If needed, Nestlé can provide recommendations for an appropriate sampling plan.

Formal Release / Status Control System
Complying with Major Improvement Needed

All product currently produced in the facility is subject to a release practice. If products are processed according to the designated parameters, including a review of the CCPs, and they meet the testing requirements, they are considered ready for shipping. There are no computer transactions or paperwork processed to let the shipping areas know that the product has been checked and is ready for release. There is no documented "formal" release system in place; however, practices appear to be in place to prevent any out of compliance materials from being shipped.

It is recommended that a formal release system be create with an appropriate procedures and a formal release checklist utilizing testing and monitoring that is currently performed. A finished product microbial test is a good test to use as a finished product release criteria.

It was understood that all finished product is tested for pathogens prior to distribution.

A certificate of analysis (COA) is generated for every lot of product shipped.

A written procedure is in place for the holding of non-conforming goods. The procedure reviewed was dated December 29, 2005. Non-conforming product would be tagged with a hold tag and moved to a designated area of the warehouse. The QA Manager has product disposition authority, but in some cases, may discuss these matters with the plant manager and company president.

Lot Traceability, Lot Identification, Coding / Recall & Crisis Management (Mock Recall)
Complying with Major Improvement Needed

A recall, mock recall, and crisis management procedure are documented and readily available. The recall procedure (dated December 29, 200) was reviewed during this audit. The procedure lists necessary steps in the event of a product recall and includes 24-hour emergency contact information.

It was understood that the plant conducted a mock recall during 2005, but no documentation was completed. No documentation is equal "did not happen". This does not meet Nestlé requirements.

PCA needs to develop and implement a workable protocol for conducting mock recalls and then it on a regular basis. The requirement is to be able to accurately locate and account for any lot of raw material or primary packaging material used from receipt through usage and finished product and on to the transfer of ownership of the finished goods. To be in compliance this must be completed within 2 hours. Further, a program must be in place to perform mock recalls and traces yearly and to analyze the results of the tests.

Based on paperwork reviewed, I believe that products and ingredients can be traced forward to orders and backward to incoming raw material.

The plant does not have a written rework procedure to describe how rework product (when and if used) should be handled and tracked during manufacturing.

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finished product label is printed in house and contains the following information:

Product name
Item number
Lot number T6005
 T – Texas,
 6 – year
 005 - Julian day of manufacturing
Manufacturing date 1/5/06 (month/day/year)
Net weight

Instrument Calibration (for CCPs) / Laboratories and Test Method
Complying with Major Improvement Needed

There is a quality control laboratory with equipment utilized for analytical product testing. No microbiological testing is completed at this site. All laboratory equipment is calibrated on a daily basis by the quality control technician. Calibration logs maintained for each piece of equipment were reviewed during the audit and found to be complete through today's date.

Plant scales are calibrated on an annual basis by Buffalo Gap Scale Company. The scales were last inspected on August 11, 2006. All scales are verified on a daily basis by the quality control and production operators.

The time/temperature recording devices and the thermocouples for the roasting line should be on a minimum annual calibration verification program by the vendor. These devices were originally calibrated by the manufacturer and have been operating for about 9 months. A written program needs to be established to be sure these devices are inspected / calibrated at least annually, or as needed.

The metal detection systems for the roasting / granulation lines should be on a minimum annual calibration verification program by the vendor. These devices were originally calibrated by the manufacturer and have been operating for about 9 months. A written program needs to be established to be sure these devices are inspected / calibrated at least annually, or as needed. The quality control technicians verify the operation of these units prior to start up each day and then on an hourly basis throughout operations.

The magnets for the roasting line should be inspected annually for pull strength. A written program needs to be established to be sure these devices are inspected / replaced annually, or as needed as indicated by test results.

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Key Issues

Training **Complying**

Although training practices are in place, there is no overall documented written training plan, which summarizes the training programs and plant training requirements. A formal written training plan containing plant / company training requirements should be written.

It is recommended that the plant implement a process by which learning effectiveness is measured. This can be completed by use of short tests following each training session.

Documentation **Complying**

The plant should create a written Change Management policy that defines steps to be followed for changes that might take place in manufacturing and documentation.

Pencils were being utilized in the quality control areas. The facility should put forth an effort to eliminate pencils and use blue or black pens in all areas.

GMPs – Housekeeping **Complying with Major Improvement Needed**

There were small amounts of peanut pieces along the south wall and behind electrical panels in the pre-clean room.

The exterior areas on the south and west sides of the plant had large amount of dirt and product debris (skins) scattered in depths for about ¼ inch to about 8 inches.

There is a remote building on the north side of the plant, which contains what appears to be excess equipment and items removed from the plant. There is a large amount of items stored in piles on the ground. This creates potential harborage areas for insects, rodents, and birds. The building on the southwest corner of the plant used to park the skins collection trailer has unacceptable amounts of product skins accumulated on the floor areas.

A number of brooms and shovels have wooden handles. Any tools with wooden handles in the manufacturing areas of the plant should be replaced with non-wooden handled items.

There was a designated perimeter painted white about 18 inches wide maintained around the warehouse areas. This perimeter was free and clear of product storage, equipment storage, and any other unwanted dirt or debris. Along the exterior southwest wall of the pre-clean room, the concrete at the floor / wall juncture is eroded to a depth of 1 to 2 inches. This area was collecting dirt and debris and is not readily cleanable.

GMPs – Sanitation **Complying**

The plant has established basic cleaning procedures and instructions for the pieces of equipment in the operation. These procedures are developed only for the major tasks. The cleaning standard operating procedures (SOPs) need to be developed throughout the plant to address all wet and dry cleaning. SOPs should be written to outline each task, the cleaning frequency, who is responsible for cleaning, chemicals to be used, chemical concentrations, personal protective equipment, tools needed to complete the task, and anything other information the plant personnel might need for these tasks.