FOOD SAFETY AUDIT REPORT

By
Food Safety Auditor

Food Safety International Inc.
www.FoodSafetyINTL.com
4180 Larchpoint Cove, Lakeland, TN 38002
(901-496-8036)
JRWilliams@FoodSafetyINTL.com

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RATING

A food safety and security audit was conducted at this facility on **Error! Reference source not found.**. This report contains what Food Safety International Inc. considers to be the most useful and appropriate standards for evaluating and improving the quality of the food product safety programs and practices on a plant level for a wide variety of food processors. The food safety/security auditor was accompanied throughout the audit by Mr. **(AUDITOR FILL IN)**.

Excellent cooperation was received by the food safety/security auditor. On some occasions, many of the items were immediately corrected.

At the conclusion of the audit, a meeting was held to discuss the observations, recommendations, and rating to evaluate the food safety/security risks. The standards used included: the U.S. Federal Food Drug and Cosmetics Act 1938, the Good Manufacturing Practices (GMP's), DFR Title 21, Part 110(1986), Global Food Safety Initiative Standards, Codex Principles for HACCP, the U.S. Military Sanitary Standards, and the U.S. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The laws that govern and require HACCP in the United States are: (1) 9 CFR 417: "Hazard analysis and Critical Control Point (HACCP) Systems" for meat and poultry products. (2) 21 CFR 123: "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products". (3) 21 CFR 120: "Procedures for the Safe and Sanitary Processing and Importing of Juice".

Based on the observations made, the information obtained, and the criteria set forth in the *FDA & USDA Code of Federal Regulations and Compliance Policy Guidelines & Standards for Food Contact Packaging ,*the overall food safety level of this facility was considered to be:

UNSATISFACTORY
(0)

The "serious" or "unsatisfactory" items are shaded, boxed, and bolded in the text of the report. Refer to the definitions in the above Standards.

The "opportunities for improvement" items are designated in bold type and require prompt attention.

Food Safety International Inc. (FSII) states that the report as given herein is to be construed as its findings and recommendations as of the date of this report. Food Safety International Inc. (FSII) accepts no responsibility and does not assume any responsibility for the food safety program in effect with (customer). That further Food Safety International Inc. (FSII) is only making report of the food safety conditions of (customer) as of the date of this report and assumes no responsibility or liability as to whether (customer) carries out the recommendations as contained in this report or does not carry out the recommendations as contained in this report. All information obtained by Food Safety International Inc. (FSII) in the course of its established survey is treated as confidential matters between Food Safety International Inc. (FSII) and the surveyed client.

As stated in our food safety/security program, Food Safety International Inc. (FSII) provides each establishment with a Certificate of Achievement where applicable. A Certificate of Achievement will be awarded following each survey that results in an "Excellent", or "Superior" rating using the following format.

Superior	950 – 1025
Excellent	875 – 950
Satisfactory	795 – 875
Unsatisfactory	795 or Below

A certificate of Participation will be awarded annually to all plants attaining a Satisfactory rating.

Very minor observations are deducted at 5 points, Opportunities For Improvement are deducted at 25 points, Serious or Unsatisfactory conditions are deducted at 45 points but if an unsatisfactory condition is found, the total score classification will be "Unsatisfactory" regardless of the total score.

Facility Information:

Size (Sq. Ft.) Production: Warehouse:

Construction of Building (Metal, wood, brick, etc.):

Number of employees:

Number of operation days/shifts:

RATING ANALYSIS

DATE OF AUDIT: **Error! Reference source not found.**

TYPE OF AUDIT: **FOOD CONTACT PACKAGING**

OVERALL RATING: **UNSATISFACTORY**

ADEQUACY & SECURITY OF **Error! Reference source not found.** SAFETY PROGRAM	-
INTEGRATED PEST MANAGEMENT	-
OPERATIONAL METHODS AND PERSONNEL PRACTICES	-
MAINTENANCE FOR FOOD CONTACT PACKAGING SAFETY	-
CLEANING PRACTICES	-
TOTAL:	**0**

FACTUAL OBSERVATIONS AND SPECIFIC RECOMMENDATIONS

ADEQUACY & SECURITY OF FOOD CONTACT PACKAGING SAFETY PROGRAM

1. A written Quality Management program including a quality/mission statement and organizational chart was available for review. The program included: A. A corporate policy that was displayed for all employees to see. B. Organizational chart. C. Independent quality unit/ Q.A. Manager/ Sanitarian D. Responsibilities listed E. Documents signed and up to date SOP F. Job descriptions. G. Designated Food Safety responsibility. A complete review of the food safety and security effort was accomplished on a periodic and scheduled basis with a committee inspection. The organization's commitment to supply safe packaging was evident by the findings of this audit. Adequate resources were available to ensure fundamental food safety packaging practices and objectives were achieved. The responsibility over the safety of the materials used in the packaging at this facility was documented in the form of an organizational chart with the Plant Manager responsible for the food safety and security program. Good manufacturing practices regulations were documented in the quality manual. A mission statement was on file. The manual required that packaging be processed under conditions that comply with good manufacturing practices and that it be packaged and labeled with truthful information presented in a way that it was not misleading. The Plant Manager and staff did oversee the development, implementation, review, and maintenance of the food packaging safety program.

2. The facility performed yearly audits of quality programs and documentation. The program included: A. Specific activities and areas to be audited. B. Qualifications of personnel carrying out the audits. C. The basis for carrying out the audits (organizational changes, reported deficiencies, routine checks, and surveys). D. Procedures for reporting audit findings, conclusions and recommendations. E. Self audits should be performed at least once per year. F. Written record retention programs.

3. There is evidence that the food safety manual has been implemented. Employees were aware of the food safety manual. Evidence was noted by observing their personal and production practices. Adequate resources were available to support the organization's food safety and quality objectives.

4. The plant is performing daily pre-operational inspections for product packing areas. The program must include: A. Time of check and person

responsible. B. Examination of equipment to verify cleanliness. C. Checking that the production line is ready to start. D. Checking that all personnel meet GMP requirements. E. Corrective action in case of non-compliance records on file.

5. Written cleaning procedures were developed and published for a daily, a weekly, and a monthly food safety program. A Master Cleaning Schedule (MCS) was in use and was current. The MCS specified frequency and responsibility.

6. The facility has a documented, established, Personal Practices Program. The program was compliant with the provisions of 21 CFR 110.

7. Proper use of chemicals and sanitizing agent was documented in the clean-up procedures. Training was documented in order to exchange information relative to effective procedural methods and cleaning techniques. Training was structured to provide background pertaining to the relationship of microorganisms and good plant sanitation. Appropriate tools and materials were on hand to support the cleaning of the facility. The program included cleaning procedures and Master Cleaning Schedules for: A. Storage areas, receiving, shipping areas. B. Maintenance areas. C. Offices, break room, rest rooms. D. Environmental cleaning in storage areas (floor, drain, walls, and ceiling) E. MSDS available for all cleaning chemicals. F. Procedures should include identification of all cleaning tools, equipment, implements, chemicals, dilution instructions and personal protective equipment/procedures and sequential steps of cleaning operations.

8. A documented chemical control program was in place. The facility must have a chemical control program if chemicals are in use for purposes such as sanitation. Program should outline procedures including a list of approved chemicals, purchasing of chemical and inventory records, storage and labeling.

9. The facility had a documented procedure for conducting monthly GMP self inspections/ audits. The program included: A. Time of check and person responsible. B. Inspection criteria C. Inspection includes inside and outside grounds. D. Records of inspections. E. Corrective actions. F. Records of inspections (12/year).

10. Records of results of examination and/or copies of supplier guarantees or certification that verify compliance with FDA regulations, guidelines, or action levels of raw materials, food- packaging materials, and finished goods were maintained and reviewed. Specifications were on file for the raw materials, packaging supplies, finished products, and semi-processed products. The program must describe: A. Frequency (guarantees/COA/testing) B. Testing procedures and specifications. C. Form used to keep the records. D. Rejection logbook. E. Records of

testing results. The records required for supplier guarantees or certification, processing records, and distribution records were being retained for a period of time that exceeds the shelf life of the finished product. Verification and validation records were on file for product releases and all pre-requisite programs. A register was on file with schedule frequency checks for the food safety program in detail. Signatures and dates are on file.

11. The plant has an approved supplier program. The program included:A. An approval process. B. Criteria used to approve any supplier. C. Supplier list. D. Contact information. E. Complaint and corrective action. F. Records on file.

12. Distribution records were being maintained to identify the initial distribution of the finished product to facilitate, when necessary, the segregation and recall of specific lots that may have become contaminated or otherwise unfit for their intended use. The shipping records must include: A. Date of Shipping. B. Item number. C. Name of products. D. Amount shipped. E. Final destination F. Lot numbers. A documented incoming and outgoing trailer and material/product inspection program was in place. The program included: A. Frequency. B. Inspection criteria C. Inspection form. E. Rejection logbook. F. Records of trailer inspections were on file.

13. From a security standpoint, a crisis management team was established to handle a recall. A list of key regulatory contacts was on file in the event of food security issues. A food defense plan has been developed

14. The facility has a program to ensure the safety of the water supply. The program should include: A. Definition of water sources (City, Well) B. If city water is used, is the city potable water report available. C. If well water is used, a sampling program and analysis (chemical and micro) with frequency of sampling program must be available. Backflow prevention documentation and observations of hose connections were in place.

15. Product is clearly identified through all stages of the process. Responsibility is assigned for product identification and methods were on file for identifying product. Raw materials, work in process, and packaging are traceable to the finished product. The program should include: A. All measures to assure traceability of all ingredients, packaging, and rework. B. Step by step procedure on how to conduct a traceability exercise. C. Traceability test policy, with a minimum of two exercises completed each calendar year. D. Records of traceability test (previous 12 months). E. Standard form to summarize results and corrective action.

16. The recall program was on file and was being tested on at least a semi-annual basis. The last mock recall was conducted on ( ). All products were coded and a lot or batch number was being maintained. A mock recall must be performed at the time of the inspection. Reworked product was clearly identified and traceable. Each batch of reworked product was inspected or analyzed before release. All records of reworking operations are maintained to maintain traceability. Responsibility for the release of product was assigned. The staff was aware of the product hold and release policy. The recall program included: A. Recall team (name, phone numbers – office/after hours). B. Recall Coordinator/ responsibilities. C. Regulatory and customer contacts (facility and head office). D. Spokesperson (responsible individual or agency for public relations). E. Step by step procedure on how to conduct a recall. F. Recall classification based on USDA/FDA guidelines. G. Standard form to summarize results, contact information and corrective action. H. Records of mock recall/actual recall are on file.

17. The plant has specifications for all products manufactured at the facility. These specifications included: A. Formulation. B. Processing instructions. C. Sensory characteristics/ testing procedures. D. Applicable standards and regulations. E. Packaging, labeling, transportation, handling and storage. F. Labeling approval program and verification if required by regulations. Specifications were on file for the raw materials, packaging materials, finished products, and intermediate/semi-processed products. These specifications were detailed to ensure compliance with relevant food safety and legislative requirements.

18. Sensory analysis was conducted and was completed by trained personnel. The sensory attributes were specified by the customer and the sensory analysis was conducted after shelf life trials. Records were on file for the tests and for the actions resulting from the sensory analysis.

19. A Hazard Analysis Critical Control Point (HACCP) program has been implemented for all processes and process lines. Records of all changes and reviews were maintained in the HACCP program. The program was verified and validated on a set frequency to insure the development, implementation, maintenance, and control of the program was in place and working. The program included the following components:

    a. Description of the products manufactured and hazards inherent to them

    b. Identification of critical control points (CCP) and critical limits

    c. Procedures to control the CCPs

    d. Determination of the monitoring frequency for the CCPs and designation of the person(s) responsible for testing

e. Documented deviation procedures

f. Verification program, with proper documentation

g. Documentation of procedures, records of conformance, and corrective actions. Records of the corrective actions and disposition of the product on file and up to date.

20. Food safety training for all personnel was on file for new hires. Refresher training for experienced employees was also on file and was being completed on a yearly basis. Employee polices had been established for the company in the form of GMP training for permanent and temporary employees as well as contractors. Training should include: A. Refresher training responsibilities B. Experience /qualification of the trainer. C. Training Policy (bilingual) D. Refresher Frequency (yearly or when otherwise required) E. Material used for training/records of training should cover GMP, sanitation, HACCP, allergen awareness, recall, traceability, rework, receiving, shipping, storage, glass and brittle plastics control, and security. Annual refresher training will be conducted in GMP, HACCP, and allergen awareness (if applicable). Instructions should be available for establishing how all tasks critical to meeting customer specifications, the maintenance of the food safety program, quality and process efficiency are to be performed. Contractors and guests had been provided with a copy of company visitor rules. Guest badges should be considered after reviewing picture identification. Restrictions on entry to the facility were present. Security cameras should be installed at critical control points. Background checks should be considered on a periodic basis for all employees.

21. A program for evaluating consumer complaints had been established. The information collected from these complaints was being used to track trends and to avoid recurrences. Follow-up to the seriousness of the complaint in reference to food adulteration was documented and corrective actions did include investigations. The program should include: A. Person responsible for handling complaints. B. Procedure on how complaints are investigated. C. Records D. Answer to customers. E. Corrective actions. F. Measures to prevent recurrence of the issue and verification that such measures have been implemented.

22. Records of a business continuity plan were being maintained to help prepare for possible future food safety emergencies. Records of a test for an emergency business continuity plan were on file and were tested on an annual basis.

23. A register of all the pre-requisite programs was on file. They were verified and validated on a pre-determined basis with documentation on file. Documentation was legible, signed and dated appropriately. Initials

were backed up with a signature register to verify signatures on documents. Records were maintained per regulatory requirements.

24. Selection of suppliers for goods and services was accomplished by a written set of guidelines. Certificates of Analysis (COA's) and or third party audits were used to further enhance the program. A list of approved suppliers was maintained. Letters of continuing guarantee were on file for all incoming goods. In house sampling was also being used as a check of supplier's goods. Monitoring of approved suppliers is on file.

25. A brittle plastics and glass policy was on file. It stated that no glass or brittle plastic was to be used in the facility, except where absolutely necessary. An inspection was set up on at least a yearly basis to find and correct any breakage that was found. Protective covers were acceptable for use in areas where brittle plastic or glass had to be used. The program should include: A. Control policy in warehouse areas or over exposed products: lights/utensils. B. Inspection program. C. Corrective actions. D. Procedures for changing ceiling lights. E. Procedure to handle any breakage and disposition of lights/hard plastics.

26. The maintenance program consisted of a written work order system. A priority schedule was used when repairs could affect product adulteration. The maintenance program also consisted of a preventative maintenance program in order to keep the equipment well maintained and in good repair. . It included: A. A list of all production equipment, refrigeration equipment, internal vehicles, receiving/shipping trucks, building/facilities, dock plates, safety and security devices, etc. B. Master maintenance schedule and responsibility. C. Records of all maintenance activities. D. Sanitation inspection of production equipment. E. Reconciliation of parts and tools used for maintenance activities F. Records of maintenance tasks.

27. Calibration records were undertaken in line with regulatory requirements or the equipment manufacturers recommended schedule. The program must outline: A. List of equipment subject to calibration. B. Frequencies/responsibilities C. Calibration instructions/standards used D. What actions are taken if critical equipment is found out of calibration. E. Records are available for review.

28. Laboratory testing of the manufactured product was conducted by an independent accredited lab on a periodic basis. This testing consisted of laboratory testing for bacteria, yeast, and mold. The records of this testing were on file in the (Quality Assurance Office). Shelf life trials were also being maintained. A register of raw material specifications was on file. Packaging specifications were also on file. A register of finished product specifications was on file. The program must clearly define: A.

Testing procedures. B. Sampling schedule. C. Form used to keep records. E. Validation of results. F. Good laboratory practices and records of training for employees. G. Calibration of lab equipment. F. Records on file.

29. Contract services were listed in a register that was current. Service specifications were documented for the contract services.

30. The Food Package Safety Plan and the Food Package Quality Plan had been validated and verified for each program by the Quality Manager on at least a yearly basis. This included packaging, specifications, contract services, prerequisite programs, HACCP, critical control points, traceability, recall, food defense, etc.

31. Methods and responsibility for identification and processing of products requiring the preservation of their identity preserved status was documented and implemented for such items that are Kosher, allergen, etc. Methods to control allergens were developed and were sufficient. A risk assessment of all ingredients was on file with the controls documented in the food safety plan. Specific procedures for the storage of allergen containing ingredients were on file.

32. The plant has a program to handle retained (non-conformance) and returned products. The program should include personnel responsible and procedures for hold/release and disposition of: A. Raw materials. B. Work in progress materials C. Finished products D. Returned products. E. Inventory policy. F. Records showing hold/release or disposition and inventory.

33. A risk assessment had been conducted for alternative storage and handling of goods in the event of an emergency.

INTEGRATED PEST MANAGEMENT

34. A written and well-documented integrated pest management program was reviewed at the time of the audit for the past year. It was found to be in compliance with the regulatory requirements. This included recording of pesticide product name, amount used, method of application, rate of application or dosage, date of application, applicator's signature, and where each pesticide was used for at least a 2-year period. The pest control services were conducted in house under the supervision of a currently licensed or trained Pest Control Applicator.

35. Pest control services were contracted to ( ) company which provided weekly/monthly service to the facility. An integrated pest management approach was being used to manage pests by combining biological, cultural, physical, and chemical tools in a way that

minimizes economics, health, and environmental risks. Pest control operators should be accompanied during spraying for security reasons.

36. The pesticides/herbicides and equipment used for application were stored in a locked and well-ventilated room. Labels were present on the application equipment for the material used.

37. Material Safety Data Sheets (MSDS) were checked against the pesticides being used. Sample labels and MSDS were on file and were accessible. The EPA # matched the records being maintained on the pesticide usage log. This log contained: materials applied, a specific target pest, amount applied, a specific area where pesticides were applied, method of application, rate of application, date and time treated, and the signature of the certified applicator. A copy of the applicator's license and an insurance certificate was on file and was current.

38. Pest monitoring devices, such as glue boards and pheremone traps, were maintained and were identified on the schematic. The schematic also included the other interior and exterior pest control devices that were being used.

39. Inside rodent monitoring devices consisted of ketchall traps and/or tin cat traps and glue boards. The traps were positioned properly along the inside of the exterior walls and on both sides (interior) of every outside door. The traps were checked and cleaned on a weekly basis, with documentation in the trap to verify this. The traps were checked randomly and appeared to be properly maintained. A rodent activity log sheet was used to track activity to help improve the integrated pest management program. The traps were properly positioned between 20 –40 feet apart.

40. Outside bait stations were also used at this facility. They were properly positioned at 50 – 100 feet apart. The outside stations were anchored in place, properly positioned, tamper-resistant, locked, and properly labeled in compliance with regulatory requirements. The stations were randomly inspected for fresh bait and proper locking devices. An activity log sheet was used to track activity to help improve the integrated pest management program.

41. Insect light traps were being used in this facility as part of the integrated pest management program. These traps were positioned at least 10 feet away from the exposed product and could not be seen from the outside of the building. The traps were listed on the schematic and were being monitored and cleaned on a routine basis. The light bulbs were being changed out on at least a yearly basis. Documentation was reviewed in the traps that were randomly checked.

42. No pest activity was noted in an around the facility. The integrated pest management (IPM) program was in place and was properly maintained.

OPERATIONAL METHODS AND PERSONNEL PRACTICES

43. Receipts and storage of materials were appropriate for the ingredients and were stored off the floor and away from the walls and ceiling. Raw materials were inspected to assure cleanliness and fitness for food. It was stored in a manner that protected it from contamination and minimized deterioration. Carriers of raw materials were inspected and documentation of seals was compared to be bill of lading. Proper identification should be required for all drivers. Wash certificates and/or documentation of previous loads should be required.

44. Proper rotation of all ingredients, packaging supplies, and other materials were undertaken on a first in, first out (FIFO) basis.

45. Stored materials were visually inspected externally for insect and rodent activity at the time of receipt. Insect susceptible material over three weeks old were inspected internally utilizing a random sample method.

46. Employees were practicing good personal hygiene habits during the audit. Hand washing was being performed at a frequency that was appropriate. Clean uniforms or outer garments were being worn. Employees were wearing effective hair restraints. Ball caps and hair spray are not acceptable hair restraint methods. Hairy arms are also a potential problem which can be addressed with the use of shirts with sleeves. No contamination was observed from perspiration, hair, cosmetics, tobacco, chemicals, fingernail polish, or medicates. No employees were observed with signs of illness who were working with exposed products. Nobody should be working in the facility who has an infectious disease (hepatitis, flu, etc.) or is a disease carrier, or who has an open cut or sore or an infected sore or boil (this is because of the high probability of contamination of the product with a food borne illness pathogen.). Nobody should be working in the facility who has diarrhea. (This is because of the high probability of contamination with salmonella, shigella or other food borne illness pathogens.)

47. No personal effects were observed in or near the production areas. Personal objects such as pens, thermometers, watches, etc. were carried in pockets or pouches below the waist in production areas. Insecure jewelry was not observed such as earrings, watches, rings with stones, tongue jewelry, etc. Eating, drinking, or using tobacco products, where food is exposed or utensils are washed, was not observed. All employees working in production should wear clean clothes and be clean physically (absent of dirt and body odors). They should have clean hair, and if handling product directly, they should have preferably, short clean fingernails with no fingernail polish or false fingernails.

48. All dry ingredients were sifted at the supplier or on site. All bulk liquid ingredients were strained before use and the inline strainers were

accessible and cleanable. All unused material transfer hoses, conveyors, pipes, etc., were locked and secure. Limited access should be considered for bulk ingredient storage areas

49. Suitable and sufficient hand washing facilities were provided at entrances and other appropriate points in the production areas. Wash hand signs were properly displayed in all restrooms and lunchrooms.

50. Rubbish and product waste was handled, stored, and disposed of properly so as to minimize odors, avoid attracting vermin, prevent contamination of food, product surfaces, ground surfaces, and water supplies. All containers were covered.

51. Products were not shipped with toxic chemicals or other contaminants. When shipping products, it is advisable not to ship them with toxic materials (e.g. pesticides, cleaning chemicals, sanitizers, retail cleaners), as there is a chance that these products may spill and contaminate the products. As it is not practical to require this, then every effort should be made to keep product and toxic items apart. Sensitive items should not be shipped next to highly aromatic products like spices or perfumed household products, as they can absorb odors.

52. Storage and transportation of the finished product was being held under conditions, which will not transmit contamination.

MAINTENANCE FOR FOOD CONTACT PACKAGING SAFETY

53. Conditions in the immediate vicinity outside the plant and under the control of the management, did not contribute to contamination. Storage of equipment outside was at least 18 inches off the ground. Dust from roads, parking lots, and yards in the vicinity, was not in excess. All areas were well drained.

54. The dock door buffers/shelters/levelers were clean and well maintained. The dock levelers were rodent proof. When trucks are being unloaded, it is essential that buffers around the dock doors seal against the trucks to exclude pests, insects, dust, etc. Rodents can enter a warehouse by scaling the outside dock wall and climb up the inside of the dock leveler, thereby entering the warehouse. As mice only need a ¼ inch hole to gain access, it is essential that the gaskets around the dock levelers are kept in good repair and that they tightly fit around the leveler, leaving no gaps. These gaskets should seal tightly against the bottom of the dock door.

55. The facility had adequate space, construction, and design to facilitate maintenance and sanitary operations for food processing purposes. Floors, walls and ceilings were cleanable and kept in good repair. Fixtures, ducts, and pipes that were suspended overhead did not drip condensate onto

food, raw materials, or food contact surfaces. An 18 - inch space between walls and equipment and between pieces of equipment was observed.

56. No cracks or flaking paint was observed. Smooth floors impervious to the substances contacting them, as free of crevices and imperfections, which could lead to unsanitary conditions. Floors were of concrete or equally impervious materials.

57. Adequate lighting was observed in all areas containing employee facilities and all areas where food or food ingredients are examined, processed, or stored, and in equipment cleaning areas. Light bulbs, fixtures, skylights, and glass suspended over exposed food being repaired, was of the safety type or was protected to prevent contamination of food in case of breakage.

58. Adequate ventilation was present to minimize odors, fumes, or vapors, which may contaminate foods. Vent systems did not move air from raw material or preparation areas into the processing or packaging areas.

59. Equipment and utensils were suitable for their intended use, adequately cleanable and properly maintained. Such equipment was designed to prevent adulteration of foods from lubricants, metal fragments, or other contaminants. Product zone surfaces were smooth, non-toxic, corrosion-resistant and odorless materials, free of cracks, pits, or imperfections. No raw wood was observed in the processing area. Wood cannot be kept smooth, free of cracks, clean and sanitary. If used for food storage shelving, it should be sealed so that it can be kept clean and sanitary.

60. No rust was observed on the outside of equipment or surrounding areas. Rust on the outside of equipment or in areas of the facility that are not directly over a food product or food-contact surface, although not as serious as directly over a food product, this should not be allowed as the rust can possibly be blown onto or carried into the food product.

61. It was understood that only food grade lubricants were used on food processing equipment. The food grade lubricants were stored separate from the non-food grade lubricants.

62. No rust was observed on the outside of equipment or surrounding areas. Rust on the outside of equipment or in areas of the facility that are not directly over a food product or food-contact surface, although not as serious as directly over a food product, this should not be allowed as the rust can possibly be blown onto or carried into the food product.

63. Methods were developed for the detection of foreign materials. The prevention controls were defined and communicated to staff. The methods developed for foreign material detection did adequately detect all foreign material.

64. An adequate sewerage system was present. Floor drains were properly trapped and plumbing fixtures were designed to prevent back siphonage. Toilet facilities and hand washing facilities were sufficient within the plant. Self- closing doors were present. Such doors did not open directly into areas where food is exposed to airborne contamination except where preventative measures were taken, such as use of double doors, exhaust fan in toilet room, etc. Blower type dryers are permitted only in addition to the single service towels. Lockers are provided for each employee.

CLEANING PRACTICES

65. Cleaning operations were being performed in a manner to prevent contamination of materials and products. All cleaners were being used at the proper concentration according to the documentation and interviews that were conducted. The facility should have the ability to test the strength of any sanitizer used on a product-contact surface. This can be done using either a chemical test kit or sanitizer test papers. It is essential that the facility have either one or the other as they need to know at all times whether their sanitizer is within the legal range or not.

66. Only USDA or EPA approved detergents and sanitizers were being used for cleaning of food product zones. The microbiological load on the equipment should be monitored. It is essential to be monitoring the bacterial load on the equipment on a regular basis to determine if a piece of equipment is clean and sanitary rather than just clean. Although not required by law, it is reflective of a plant's total effort to ensure that it is manufacturing its products under the most ideal conditions.

67. Garbage and waste removal was removed frequently. Garbage cans in the warehouse should always be emptied frequently so they are not overflowing. These garbage cans also should be on a regular cleaning schedule so they do not develop odors, fruit flies, high bacterial growth, etc. Documentation was on file for monitoring trash removal efficiently.

SECURITY

68. The facility has registered with the government where required.

69. The facility has a designated food security team or designated coordinator.

70. The facility has an emergency contact list that includes government contacts for use in case of an incident of an intentional product tampering or food security threat.

71. The facility has a food package security plan in place for emergencies.

72. The facility has controlled entry into it by requiring visitors to sign-in and sign-out and provides identification.

73. The facility has controlled access into it. Example: Swipe cards, key code pads, etc.

74. The facility has a procedure for handling visitors, contractors and inspectors, including escorting them in the facility.

75. The facility performs periodic food security self-inspections.

The facility has security guards or cameras monitoring it.

76. The facility has security guards or cameras monitoring it.

77. The facility has well maintained fenced perimeters.

78. The facility monitors all incoming shipper trailers for seals or locks.

79. The facility seals all outgoing trailers and records seal numbers.

80. The facility controls access to their main power source, phone line and computer systems.

81. The facility controls access to their refrigeration system (if applicable).

82. The facility emergency exits are locked and secured from the inside and are not blocked.

ALLERGEN CONTROL

83. The facility had records of the presence of any of the eight (8) allergen foods or food systems that are received or stored here. The 8 main allergens are: peanuts or peanut products, soybean or soy products, milk or mild products, egg or egg products, fish, crustacean (shrimp, crab, lobster), tree nuts (almonds, walnuts, pecans, coconut) and wheat.

84. The facility has written standard operating procedures for proper handling and control of allergens. They were developed by a committee of qualified personnel.

85. The procedures included a method for segregation for known allergens during storage.

86. The facility keeps records of which allergen foods are packed in sealed, air tight, moisture vapor barrier containers.

87. The facility keeps records of which allergen foods present are packed in non-air tight, non-moisture vapor barrier packaging. This is very important.

88. Written procedures indicate methods for prevention of cross-contamination.

89. All allergen stored in original containers or clearly labeled containers. Signs or other markings indicate allergen storage areas.

90. There are no mixed pallets of allergen products in storage.

91. The facility has written procedures for cleanup of allergen food that escapes from their packaging due to damage.

92. The facility has written procedures for cleanup for disposal of spills from damaged packaging of allergen foods.

93. The facility has written procedures to assure adequate cleaning of pallets that have been exposed to or contaminated with spilled allergens.

94. Training records of allergen awareness indicate that all personnel have received instruction.

95. The facility provides for designated storage sites for major allergen foods packed in non-air tight containers.

96. The facility has a written associate training program including instruction on allergen awareness, and which foods are stored that are major food allergens and which ones are in non-air tight containers.

97. Annual refresher classes are given to reinforce policies on allergen awareness.

APPENDIX A

MOCK RECALLS/TRACEABILITY EXERCISE REQUIRED DURING FSI AUDIT

The FSI Auditor should verify that Mock Recalls/Traceability have been conducted on at least a six-month basis to assess the effectiveness of the program. The latest Mock Recall/Traceability shall be on file, available for an account for 100% of the product, ingredients, or primary packaging used in this exercise.

A Mock Recall/Traceability exercise shall be performed at the time of the inspection.

This program should include:

Recall Team Name:

Recall Team # Office:

Recall Team Phone # After Hours:

Recall Coordinator Responsibilities:

Regulatory Contact Plant:

Customer Contact Plant:

Regulatory Contact Office:

Customer Contact Office:

Step-by-Step Procedure on how to conduct the Mock Recall:

Records of Mock Recalls:

Standard Form to Summarize Results, Including:

Material to be traced:

Production Date:

Lot Numbers:

Quantities produced in Lots per production day:

Quantities in House:

Location and quantities of remaining stock:

Percent of materials located (no recovery necessary)

Length of time needed to complete Mock Recall:

Issues Noted During Mock Recall:

Corrective Action for any Issues Noted:

HACCP GUIDELINES

HACCP is a systematic approach to food safety that emphasizes prevention within a facility rather than detection through end-product inspection or analysis. Food Safety International requires that all HACCP programs follow and use the approach proposed by the U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) or its equivalent from the UN/FAO Codex Alimentarus as a guide to developing a HACCP system. The HACCP program for each product should have the following key components; 1. Appointment of the HACCP Team. 2. Description of the product and its distribution. 3.Identification of the intended use and consumers of the product. 4. Development of a process flow diagram. 5. On-Site verification of the Process Flow Diagram.

98. The process flow diagram includes the sequence and interaction of all steps in the operation from receiving to final shipping. The introduction of ingredients and intermediate products into the process flow. The introduction of product for reworking if appropriate (ie. Water, labels, packaging material. (Principle 1)

99. All potential biological, chemical or physical hazards associated with the processing steps are indicated in the process flow diagram and area fully described on the Hazard Analysis Worksheet. (Principle 1)

100. An on-site verification was conducted to confirm that the process flow is completed. It indicates all pertinent steps and it is accurate in relation to hazard identification. (Principle 1)

101. All hazards are identified on the CCP determination form. All hazards are controlled either by CCP, or prerequisite programs or outside the facility. (Principle 2)

102. Hazards that cannot be controlled by the operator are identified. The plan must indicate how these hazards would be addressed outside the facility. (Principle 2)

103. Critical limits are present. Measurable critical limits are established to define acceptable parameters for all hazards controlled by the CCP. (Principle 3)

104. Monitoring procedures are complete as per the program and are implemented as described. (Principle 4)

105. Corrective actions are implemented when critical limits are not met. (Principle 5)

106. Verification frequency for record review, on site, review, and other activities specified in the CCP is adhered to. (Principle 6)

107. Monitoring, deviation, and verification records are designed to provide all information required and are up to date.

108. The establishment of effective recordkeeping procedures monitoring the CCPs and assigning documentation review responsibilities is in place. (Principle 7)