Plant Systems Audit Report

Date of Audit: January 01, 2010

Facility Name: Blank Report
Plant Address:
City:
State: Zip: Country: USA
Telephone:
Fax:

Mailing Address:
Address: Same as Above
City:
State: Zip:

Contact Person for USDA:
Name:
Title:

Audit Category	Audit Report Section	Facility Score	Percentage of Available Point Score	Minimum Points Required 1/	Possible Points
Employee Practices	Section III - Personnel	125	100%	100	125
Food Defense	Section VIII - Food Defense	80	100%	64	80
Food Safety and Processing	Section I - Food Safety Section VII - Recall/Return	370	100%	326	370
Grounds/Equipment and Plant Sanitation	Section IV - GMPs/Sanitation	275	100%	220	275
Pest Control	Section V - Pest Control	50	100%	40	50
Quality	Section II - Quality Management Systems	80	100%	64	80
Receive, Storage, and Shipping	Section VI - Packaging/Labeling/Warehousing	100	100%	80	100

Scoring System	Audit Results Summary
98.5% to 100% = Superior 95.0% to 98.4% = Excellent 87.5% to 94.9% = Acceptable Less than 87.5% = Unacceptable 1/ Facility must meet the minimum points required for each section.	Facility Score (total points): 1080 Facility Score (percent): 100.0% Facility Rating : Superior
Comments/Corrective Action(s) Required: Comments	

Lead Auditor: **Area Office:** **Phone:**
Lead Trainee: **Auditor:** **Evaluator:** **Observer:**

Auditor's Signature: _____

U.S. Department of Agriculture, AMS, F&V, PPB
STOP 0247, 1400 Independence Ave., SW, Washington, DC 20250
Ph: (202)-720-5021 / Fax: (202)-690-1087

Supplier: **Blank Report, ,**
Audit Date: **01/01/2010**

Products packed:

Summary of Deficiencies:

Observations/Improvements:

I. Food Safety

A. Internal Quality Audit

1.*	**0**	Are there procedures in place for management/supervisors to conduct internal reviews of Quality Systems?
2.	**0**	Are Internal audit findings documented and reported to upper management?
3.*	**0**	Are Corrective Action Reports followed up and documented to determine effectiveness?

B. Purchasing

4.	**0**	Is there a system in place to evaluate and approve suppliers?
5.	**0**	Are suppliers evaluated for good agricultural practices? (i.e. Do they have process controls in place covering pesticide control, harvesting, and transportation practices?)
6.	**0**	Are purchasing documentation/records, including Certificates of Conformance (COC) and Certificates of Analysis (COA), maintained, current, and applicable?
7.*	**0**	Are receipt inspections performed and documented on incoming product (Product condition, accuracy of invoice, product identity, etc.)? Is there documentation of the disposition of rejected product?
8.*	**0**	Are acceptance criteria documented for incoming ingredients? Do these procedures include testing for quality, foreign material, pesticides, and/or microbial contamination?
9.	**0**	Is domestic origin compliance verified? (i.e., product can be traced to US origins) (where required by contract)

C. Process Control (see attached for appropriate commodity)

10.	**0**	Is there a system in place for the proper handling, segregation, and storage of raw materials?
11.*	**0**	Are raw materials washed or cleaned as necessary to remove soil or other contamination?
12.*	**0**	If water is part of the finished product, is there a drinking water quality analysis available? (chemical analysis)?
13.*	**0**	Is the processing/ingredient water potability certificate available? Date of certificate:
14.*	**0**	Is forced air that is used on product or food contact surfaces free from contaminations?
15.1/	**0**	Microbiological testing includes: 0 Tests required by specification or contract: 0 Routine analysis of food contact surfaces: 0 Environmental testing program (floors, walls, ceilings, etc.): 0 Testing of finished product:
16.	**0**	Is there a documented empty package integrity testing program? (e.g., can, mylar bags, paper sacks, etc.)
17.*	**0**	Are procedures in place to prevent shipment/use of non-conforming raw materials or finished product?
18.	**0**	Are ingredients properly weighed out and pre-blended according to the formula or specification?
19.*	**0**	Are sensitive ingredients maintained at the correct temperature during staging?
20.	**0**	Is product handled in manner designed to preclude contamination?
21.	**0**	Are in-process thermometers, timers, etc. properly calibrated according to a defined schedule and are results documented?

D. Foreign Material Contamination Prevention (Complete 1. and/or 2., as appropriate)

1. Metal Detection

22.*	**0**	Is calibration performed with ferrous, non-ferrous, and stainless steel standards? Verification?
23.*	**0**	Is there adequate documentation of metal detector's operation?
24.*	**0**	Is there an automatic rejection system in place and is it functioning properly?
25.*	**0**	Is there a written action plan in place for when test or metal detector fails?

2. In-line Magnet Traps, In-line Screen, Line filters, Blower or Rock Traps

26.*	**0**	Are there an adequate number/location of magnets/screens/filters? Is the frequency of inspection of the magnets/screens/filters adequate? Are the results of every magnet/screen/filter inspection documented?
27.*	**0**	Does a written action plan exist for when integrity of magnets/screens/filters has been compromised?

3. Extraneous Physical Hazard Prevention Program

28.*	**0**	Are light bulbs protected?
29.*	**0**	Is there a glass container accounting system in place?
30.*	**0**	Are can cleaners (steam, air or water) located on each line for glass, tin or semirigid containers?
31.	**0**	Is facility free from peeling paint, rust, loose nuts and bolts?

E. Allergen Controls

32.	**0**	Are there procedures in place for management to identify all allergenic materials (eight major allergens are peanuts, tree nuts, eggs or egg products, milk or dairy products, crustaceans, fin fish, soy and wheat; chemical sensitivities are sulfites and/or food colorings) present in the facility? What are the allergens that have been identified?
33.	**0**	Are raw material supplies organized in such a way to prevent cross-contamination of products? Are these procedures applied to product being processed and to stored finished product? (Physical segregation/labeling)
34.	**0**	Are production schedules planned to eliminate possible cross-contamination?
35.	**0**	Do sanitation procedures address the issue of possible cross-contamination between products? Is allergen cleaning verified? (All allergens cleaned from processing surfaces, etc.)
36.	**0**	Is allergen control a part of the company's training program with all employees (including new employees and on an annual basis)?
37.	**0**	Is the presence of an allergen clearly stated on finished product labels in terms understandable by the consumer? Does the firm include warning statements (for example, "May contain peanuts" or "Produced in a facility where peanuts are processed") on product labels when appropriate?
38.	**0**	Does the company's internal audit system include a review of their allergen control procedures?

Process Control: Canned Fruits and Vegetables — Addendum Sheet

A1.	**0**	Are processing schedules for thermal processed products on file and available for review?
A2.	**0**	Are processing parameters posted on cooker panel or in cook room?
A3.*	**0**	Does the process schedule include (as appropriate): Container dimensions Minimum product initial temperature (IT) Minimum process time and temperature Critical factors (fill weight, maximum pH, etc.) Minimum F-value delivered by the process
A4.	**0**	Are the critical factors measured and documented during processing?
A5.	**0**	Are retort records complete and accurate (retort operation/continuous cooker checklist, temperature record chart)?
A6.	**0**	Is the product cooled in accordance with specifications before packaging?
A7.*	**0**	If process deviations occur: Is the deviation satisfactorily addressed? Did the proper documentation take place? Is there a process deviation logbook for the last three years, previous to the current year?
A8.*	**0**	Is double seam tear down performed in accordance with Good Manufacturing Practices (at least every four hours)? Were results documented? Were the can manufacturer's guidelines met? Are visual double seam exams completed within current guidelines (1-container/closing machine/closing head/30 minutes)? Were results documented? Does the company recycle water?

		Are water chlorinating records accurate and complete? How often is the water checked for sanitizer levels?
A9.	**0**	Does each retort have at least one calibrated mercury-in-glass (MIG) thermometer, one temperature control device, and one temperature recording device? Are the MIG thermometers calibrated annually against a certified thermometer?
A10.	**0**	Are low acid or acidified products produced? If so, does the supervisor for each shift of operation hold a Better Process Control certification? Does a certified person sign the process records within a 24-hour time frame?
A11.	**0**	Are low acid products produced? If so, are process records routinely reviewed by any authority (i.e. State or FDA)? Date of last regulatory visit:
A12.	**0**	Do "hot fill and hold" products meet time and temperature parameters?

Process Control: Frozen Fruits and Vegetables **Addendum Sheet**

A1.*	**0**	If heat blanching is used, is the product held at the required temperature for an adequate time?
A2.	**0**	Is there a documented procedure in place for the periodic cleaning of the blancher?
A3.*	**0**	Do microbiological results show micro levels in control?
A4.*	**0**	Are the free chlorine levels in the cooling water in control?
A5.*	**0**	Do non-blanched products go through a sanitizing step?
A6.*	**0**	Is the finished product maintained at a suitable temperature?

Process Control: Dairy Products **Addendum Sheet**

A1.*	**0**	Are raw product storage temperatures adequate? Are temperatures recorded?
A2.	**0**	Are products pasteurized or heat treated and stored as per appropriate Standards of Identity?
A3.	**0**	Are pasteurization units properly timed and sealed? Documentation of State reports available?
A4.	**0**	Are pasteurization charts properly identified and marked?
A5.	**0**	Are finished product temperatures adequate? Are temperatures recorded?
A6.	**0**	Are raw and finished product processed properly segregated?
A7.	**0**	Are product streams properly protected?
A8.	**0**	Do any cross connections exist?

Process Control: Grain Milling **Addendum Sheet**

A1.*	**0**	Incoming grain inspected for aflatoxin, quality, and infestation?
A2.*	**0**	Granulation routinely tested to ensure proper milling?
A3.*	**0**	Proper handling and disposal of grain spills and leaks?
A4.	**0**	Plant operations conducted in manner designed to minimize potential for explosions,

		fires, or excessive dust accumulation?
A5.	**0**	Vitamin and mineral premix added according to specification?
A6.*	**0**	Process design precludes cross contamination of product streams (especially those designated as animal feed and human consumption).

Process Control: Dried Fruits & Vegetables Addendum Sheet

A1.*	**0**	Is the sulfuring or other preserving process with good commerical practice?
A2.*	**0**	Do microbiological results show micro levels in control?
A3.*	**0**	Are the moisture levels or water activity levels evaluated and recorded?
A4.*	**0**	Do the products go through a sanitizing step?
A5.*	**0**	Does the process address storage temperature of the finished product? Is it being followed?

Minimally Processed Fresh Fruits & Vegetables Addendum Sheet

A1.*	**0**	Are suppliers required to provide a written guarantee, or other documentation, stating that they have addressed good agricultural practices, such as: a. General condition and history of use of supplier's fields (and fields/areas adjacent to the supplier's fields) appropriate for present use; b. Type of water used for irrigation/pesticide application is appropriate; c. If manure is used as fertilizer, that it has been properly composted and applied; d. Sanitary facilities in field (toilets, handwashing facility), working conditions, and harvesting equipment promote proper handling of produce; e. Handling practices that minimize drift from adjacent fields, manure piles, or storage areas, and that prevent contamination from uncontrolled animal feces. Does the company visit any of the suppliers' fields to verify good agricultural practices?
A2.*	**0**	Are suppliers required to provide a written guarantee, or other documentation, stating that pesticide application and type of pesticide used is in accordance with all County, State, and Federal Laws and Regulations?
A3.*	**0**	If the water used in the facility is recirculated or reused, does the water flow counter to the movement of the produce through the facility? Is chlorine, or another antimicrobial agent, added to the wash water?
A4.*	**0**	During hydro-cooling, do procedures prevent microbial cross contamination between containers due to dripping water/coolant?
A5.*	**0**	Are bins/containers reused? If so, are there provisions in place to ensure that the food contact surfaces are maintained in clean and sanitary condition?
A6.*	**0**	Are all animals/birds excluded from the packing, storage, and processing facility?
A7.*	**0**	Are the storage conditions adequate to maintain product quality and product safety?
A8.*	**0**	Are the transportation vehicles cleaned and sanitized prior to loading? Are they free from moisture and materials that could contaminate product?
A9.*	**0**	Does the company have a HACCP/food safety plan in place for this facility? If so, how many critical control points does the plan have?

II. Quality Management Systems

A. Documentation/Control of Records

39.	**0**	Are quality systems records kept for required amount of time (minimum of three years)?
40.	**0**	Are procedures implemented to handle review of records?
41.	**0**	Are records legible, readily retrievable and protected from deterioration?
42.	**0**	Do company forms include revision date and form number?

B. Quality Assurance/Control Department

43.*	**0**	Is the Quality Assurance Department adequately staffed to perform product evaluations?
44.	**0**	Are finished product inspections performed and documented to ensure that the product conforms to specifications?
45.*	**0**	Are in-process quality checks performed throughout production?
46.	**0**	Are laboratory facilities sufficient to perform necessary analysis?
47.*	**0**	Are all records of product evaluations and analysis complete?
48.	**0**	Are product evaluation records kept throughout the shelf life of the product plus two years? (or three years, whichever is greater)
49.	**0**	Are reagents labeled and stored according to manufacturer's requirements and recommendations?
50.	**0**	Is there complete documentation of calibration on equipment? (schedule, procedures and results?)
51.	**0**	Is calibration certification of scales performed by a licensed agency? (minimum of annually)

III. Personnel

52.*	**0**	Do employees wear clean outer garments, gloves, and aprons that are readily washable as appropriate?
53.*	**0**	Do employees wear effective hair and beard restraints?
54.*	**0**	Are employees free from loose jewelry?
55.*	**0**	Are employees working in direct contact with food free from infected lesions or skin diseases? Do employees inform management if they are sick or have been infected with a food borne illness?
56.*	**0**	Do employees wash and sanitize hands when entering the processing area? (as applicable)
57.*	**0**	Do employees remove protective outer garments prior to leaving the processing area where necessary? (e.g., aprons, lab coats, gloves, etc.)
58.*	**0**	Are personal item storage and food consumption in a separate area away from production?
59.1/	**0**	Is there regularly scheduled training for new and continuing employees in the following areas? 0 Hygiene Sanitation: 0 Good Manufacturing Practices: 0 Food Safety: 0 Employee Safety: 0 Job/Task Performance: 0 Company Quality Policy and Practices:
60.	**0**	Are records kept of all training?
61.	**0**	Are signs posted indicating hazardous areas and where protective gear is required?
62.	**0**	Is there a Lock out/Tag out program for equipment (including training, instruction, and program implementation)?
63.	**0**	Is appropriate safety equipment worn by employees (as designated by the company)?
64.	**0**	Are material safety data sheets (MSDS) readily available and properly maintained?

IV. Good Manufacturing Practices

A. Facilities, Equipment and Outside Premises

65.	**0**	Are the outside premises properly surfaced to prevent dust and offensive odors and to promote drainage?
66.	**0**	Are the outside areas maintained in a manner which will prevent rodent and insect harborage?
67.	**0**	Are floors, doors, ceilings, walls and overheads in good repair and designed to facilitate proper sanitation and maintenance?
68.	**0**	Are there back flow prevention devices installed on all water and steam lines?
69.1/	**0**	Condition (Including proper temperatures) of: 0 Ingredient and raw material storage: 0 Cooler/Freezer: 0 Preparation areas: 0 Processing area: 0 Filling area: 0 Finished Product Storage:
70.	**0**	Is there a locked storage area for chemicals, cleaning compounds and similar materials separate from product ingredients and container storage? Are chemicals clearly and properly labeled?
71.	**0**	Is there sufficient lighting to permit efficient operations and cleaning?
72.	**0**	Are buildings reasonably free from excessive dust, heat, steam, condensation, vapors, smoke or fumes?
73.*	**0**	Are product contact surfaces of equipment, containers and utensils made of nonabsorbent corrosion resistant material?
74.	**0**	Is product contact equipment cleanable and in good repair?
75.*	**0**	Are containers and utensils used in handling the product cleaned, stored and utilized in such a manner as to preclude an unsanitary condition?
76.*	**0**	Are motors, conveyor belts and drive mechanisms located and protected so that oil or grease will not contaminate the product?
77.*	**0**	Are catwalks and stiles constructed and located to prevent product contamination?
78.	**0**	Is equipment constructed and located so that product contact surfaces are accessible for cleaning, maintenance and inspection?
79.*	**0**	Are production and preparation areas enclosed?
80.*	**0**	Are doors, windows and other gateways properly protected with screens, air screens or other protective devices?
81.	**0**	Is there a documented maintenance schedule for equipment and facilities?

B. Plant Sanitation

82.*	**0**	Is there a formal documented sanitation program?
83.	**0**	Name and Title of authorized personnel responsible for sanitation and pre-inspections:
84.	**0**	Is all major equipment disassembled for cleaning or can be cleaned-in-place (CIP)?
85.	**0**	Are all areas maintained in a clean orderly manner?
86.	**0**	Does the documented sanitation program include a master cleaning schedule for all production areas, equipment and facilities? Is it available and implemented?
87.*	**0**	Is sanitation of equipment maintained throughout the day to prevent product contamination?
88.	**0**	Are routine pre-operation sanitation inspections conducted and documented? Are follow-up procedures documented?
89.1/	**0**	Rest room facilities: 0 Are they clean, dry and of good general appearance? 0 Do they open directly into production area? 0 Do they have hot and cold water? 0 Do they have sanitizing or antimicrobial soap? 0 Do they have signs posted indicating the importance of hand washing (multilingual if appropriate)? 0 Do they have independent outside ventilation? 0 Do they have clean and accessible waste receptacles? 0 Are the restrooms equipped with self-closing doors? 0 Are they well lighted?
90.	**0**	Is the capacity of the waste storage sufficient?
91.	**0**	Is there timely removal of waste?
92.	**0**	Is idle equipment stored in an orderly fashion?
93.1/	**0**	Do the hand wash and/or hand dip stations have: 0 Posted signs (bilingual/multilingual)? 0 Sanitizing or antimicrobial soap (Type)? 0 Waste receptacles? 0 Cold and hot water? 0 Controls other than hand operated? 0 Appropriate locations? 0 Acceptable conditions?

GMP Violations: List all violations not previously identified in the report and deduct 5 points for each:

V. Pest Control

94.*	**0**	Is facility free from pest infestation? (insect, bird, rodent, etc.)?
95.	**0**	Is pest control station map properly maintained and available?
96.	**0**	Are pest control devices properly installed and monitored?
97.*	**0**	Is routine maintenance and inspection of pest control devices documented?
98.	**0**	Are the number and placement of pest control/deterrent devices adequate to prevent infestation?
99.	**0**	Are pest control records maintained for at least three years?
100.	**0**	Are all pest control chemicals properly identified and separated from potentially hazardous cross-contamination?
101.	**0**	Is the application of restricted use pesticides conducted or supervised by a licensed pest control operator?

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VI. Packaging/Labeling/Warehousing

102.*	**0**	Are packaging materials clean and stored in dry, clean location?
103.	**0**	Are visual examinations of packaging completed and documented after closure? (This includes sealing, labeling and coding)
104.	**0**	Are the packages coded and labeled correctly and legibly? (e.g., does what is in package match the label?)
105.1/	**0**	Package fill/net weights: 0 Have guidelines been established and is a procedure in place to verify compliance? 0 Are corrective actions taken as needed documented?
106.	**0**	Are miscoded or mislabeled packages documented and discarded or corrected as appropriate?
107.*	**0**	Are empty containers protected from contamination?
108.	**0**	Are there sufficient facilities for handling raw materials and appropriate rotation of materials (first-in, first-out)?
109.*	**0**	Does raw material storage and handling practices preclude contamination by environmental hazards such as rodents, birds and insects?
110.*	**0**	Are there temperature-recording devices or a high temperature alarm located in the refrigeration or freezer facilities?
111.	**0**	Is there a shelf-life sample retention program in place?
112.*	**0**	Is there appropriate rotation of finished products (first-in, first-out)?
113.	**0**	Is finished product stored in designated area and separated from raw ingredients?
114.*	**0**	Is trailer/railcar cleaning and inspection performed and documented prior to loading?

VII. Recall/Return Program

115	**0**	Is retained product identified and stored in a clearly designated area?
116.*	**0**	Is a log of Hold product maintained? Are records kept documenting the disposition of Hold product?
117.	**0**	Is there a person authorized to release product? (Name/Title)
118.*	**0**	Is there a recall procedure written and tested according to a defined schedule not less than annually?
119.	**0**	Are returned goods received in a clearly designated area?
120.*	**0**	Are raw ingredients traceable throughout the process?
121.	**0**	Is reworked product documented and traceable?
122.*	**0**	Is there product tracking capability to the customer?
123.	**0**	Does product tracking system include container code?
124.	**0**	Is there a system in place and documented to handle customer complaints?

VIII. Food Defense

FDA Food Facility Registration Number Verified: **Yes** **Verified Number**

(When a PSA is conducted in lieu of a Plant Survey for USDA Contracts, and if any points are deducted in this section, corrective action is required, and the deficiency shall be listed in Section IX.)

125.*	**0**	Management - A Food Defense Plan is established, implemented, and reassessed by management to assure it remains relevant to the operation. No
126.*	**0**	Management - The Food Defense Plan addresses preventative measures relative to product tampering and deliberate contamination at the processing facility and during transport in commerce.
127.	**0**	Management - Written security practices list management contacts and procedures for notifying appropriate authorities in the case of an emergency or security issue.
128.*	**0**	Human Element - Staff - Company personnel hiring practices include screening all potential employees. Photo identification or other measures are employed to restrict access to the facility.
129.*	**0**	Human Element - Staff - Facility employees have received training in Food Defense. The Food Defense training is documented.
130.*	**0**	Human Element - Public - Supplier delivery personnel, contract workers, and visitors are restricted access to vulnerable product areas of the processing and storage facility when not accompanied by a company representative.
131.*	**0**	Facility - The outside premises are secure with limited access to vulnerable areas. The grounds and facility are monitored for suspicious activity and unauthorized entry. "No Trespassing" signs are visible along the perimeter of the faciltiy, or other measures are being taken to secure and limit access to vulnerable areas.
132.*	**0**	Operations - Assurances are provided by suppliers of direct or indirect ingredients, product and equipment cleaning and sanitizing compounds, and packaging materials concerning security practices. This may include the use of tamper evident packaging for raw materials, sealing of trailers, and locking of bulk ingredient receiving ports.
133.	**0**	Operations - The security of water and utilities within the company's control are addressed in the company's plan and define limited access by designated company representatives.

IX. Contract Review: (Complete only if plant packs for Government Contracts)

No points assigned. Answer Yes or No with explanation		
134.		Are procedures documented and implemented to ensure contract terms can and will be met?
135.		Are defined procedures documented and implemented for handling amendments?
136.		Are records of contract reviews and amendments kept?
137.		Is this PSA conducted in lieu of the Plant Survey requirement for USDA Contracts? **No** If "YES", and if critical and major GMP deficiencies or Food Defense deficiencies are found, the following corrective action table must be completed. A follow up audit may be required to ensure corrective action has been completed.

GMP Violations and Food Defense Deficiencies that Require Corrective Action	Scheduled Completion Date	Date Corrected

Question Scoring:

* = 10 point question
1/ = each part of the question is worth 5 points
All other questions are worth 5 points each

In addition to receiving an unacceptable rating for not meeting the minimum percentage required in each section, an unacceptable rating may be given for the following reasons, but not inclusive:
(1) procedures or practices that could render a product unsafe or unfit for human consumption,
(2) unsafe employee practices that could cause product contamination,
(3) evidence of product contaminated with foreign material or filth (paint, rust, glass, wood, metal, jewelry,
lubricants, chemicals, etc.),
(4) use of non-approved sanitizers or cleaning agents,
(5) improper use of pesticides,
(6) infestation by rodents, insects, or other pests in food product processing or storage areas,
(7) products stored at improper temperatures, or
(8) failure to implement a sanitation program.

An unacceptable rating may require corrective action and/or a follow-up audit.

	10 Point Questions	5 Point Questions
Satisfactory = no points deducted	0	0
Need Improvement = points deducted as follows	5	3
Unsatisfactory = all points are deducted	10	5