Good Manufacturing Practices and Food Safety Systems Audit

for:

XXXXXXXXXXXX

Audit Date

Auditor Name
XXXXXXXXXXXXXXX

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Audit Summary:

Company: **Parent Company:**		**Audit date:** **Start/End Time:** **# of hrs in Plant/Records:**	
Plant address:		**Plant phone & fax numbers:**	
AsiaFoodInspection Auditor: **(name & contact info):**		**Company Associate(s) accompanying auditor: (name & contact info):**	
Products produced by plant:		**Audit Description:**	
USDA#:		**Bio-terrorism:**	
Audit Score:		**Rating:**	
Follow-up audit required:		**Reason for follow-up audit:**	
Company associate(s) with whom audit findings were reviewed:			

Auditor Signature:	

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Plant Description

Summary of Audit Findings

Critical or Major Areas (Questions scoring a 1 or 2)

Positive Observations/Comments

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Facility Management:

1. Are corrective actions from all audits completed and reviewed by Senior management?

2. Does the business actively maintain the facility and prioritize repairs to the facility and equipment based on food safety risk to product or process?

3. Does the demonstrated food safety culture comply with regulations, Current Good Manufacturing practices and result in the delivery of safe food products?

4. Has the business implemented a system to ensure that all personnel are adequately trained, Instructed and supervised in food safety principles and practices commensurate with their activity?

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Food Safety/GMP Rating Analysis

	Category	#Points Received	# Possible Points	Percentage (%)
I	FOOD SAFETY SYSTEMS		145	
II	QUALITY SYSTEMS		210	
III	GROUNDS, BUILDING, AND EQUIPMENT		95	
IV	PEST CONTROL		45	
V	EMPLOYEE PRACTICES		30	
VI	RECEIVING, STORAGE, AND SHIPPING		85	
VII	PLANT SANITATION		40	
VIII	PROCESSING		80	
IX	FOOD DEFENSE		55	
	OVERALL SCORE		**785**	

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I.Food Safety Systems

(Assessed by observation and review of records)

A.	HACCP	Rating
1.	A HACCP team, comprised of members from across the plant, has been established and meets on a routine basis. The team includes a person trained in a formal, external HACCP course. (2 Elements)	5
2.	Each product must be fully described in the HACCP plan. The descriptions must include raw materials and ingredients, finished products, how the products are to be distributed, intended use of the product and intended consumers. (2 Elements)	5
3.	A flow chart must exist for each product and for all variations of the process and sub process. The flow charts must be verified as being accurate, dated and signed. (3 Elements)	5
4.	The flow chart must identify and describe each step in the process, including all inputs and outputs and all interactions between process steps. The flow chart must include rework and recycled pathways, intermediate processes, hand operations, and outsourced or subcontracted work. (1 Element)	5
5.	A written hazard analysis must be available and identify the significant food safety hazards associated with the products and ingredients covered by the HACCP plan and reasonably likely to occur. The hazard analysis must be based on scientific and/or technical data and include the specific hazard relevant to the products and processes, including allergen cross contamination when appropriate. (1 Element)	5
6.	The critical control points are identified on the process flow chart as well as in the documented HACCP plan. (1 Element)	5
7.	Critical limits have been scientifically established, validated and documented. (1 Element)	5
8.	Critical Control Points are monitored at regularly scheduled intervals that ensure control of the process. Monitoring procedures are documented and monitoring records are maintained. The person monitoring the Critical Control Point understands the procedures. (2 Elements)	5
9.	Employees who are involved in the HACCP plan have been trained in the HACCP-related activities in their immediate work areas. This training is documented as to date(s) given and is a part of the employee's records. The training should be conducted annually. (2 Elements)	5
10.	Corrective action procedures have been identified and include all steps needed to identify, quantify and segregate affected product. Corrective action records are maintained and include documentation on applicable product disposition. (2 Elements)	5
11.	**CORRECTIVE ACTION PROCEDURES ARE TAKEN WHEN CRITICAL LIMITS ARE NOT MET (1 Element)**	**5**
12.	Appropriate verification procedures have been identified and are documented, including the frequency for each verification step. Calibration tasks are documented and records of the calibration are maintained. All verification activities are documented. (3 Elements)	5
13.	All records related to performing HACCP tasks and reviewing HACCP records are appropriately signed/initialed and dated. (1 Element)	5
14.	At least annually or whenever there have been process, product or ingredient changes, the HACCP plan must be re-verified. Verification includes all activities other than monitoring that determine the accuracy and validity of the HACCP plan and PRPs and ensure they are operating in accordance to plan and are	5

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	controlling the hazards. The reassessment team can be internal or external to the operation and include at least one person that has been trained in HACCP. Results of the reassessment must be documented by a report that is maintained in the HACCP plan's historical records. (3 Elements)	

B. Food Safety Practices

1.	Proper employee and equipment traffic flows are used to minimize contamination between raw products and finished products. Food processing areas are organized to minimize the risk of cross-contamination through adequate separation of raw materials, finished product, and storage and distribution areas. (1 Element)	5
2.	**EMPLOYEES WITH OBVIOUS SORES, INFECTED WOUNDS, OR OTHER INFECTIOUS ILLNESSES SHALL NOT BE ALLOWED TO HAVE DIRECT CONTACT WITH EXPOSED FOOD PRODUCTS OR PRODUCTION / STORAGE AREAS. (1 Element)**	**5**
3.	Employees are observed washing their hands after activities that may have contaminated them. Activities can include, but are not limited to: using the restrooms; after breaks; prior to entering production and product packaging areas; prior to handling product; prior to touching product contact and non-food contact surfaces or after handling garbage. When disposable gloves are being used they must be changed when they are damaged, after any absence from the workstation, or when potential contaminates are handled. Procedures for the proper handling and usage of gloves are established and implemented. Gloves must be worn when there is direct hand contact with ready-to-eat products. Non-disposable rubber gloves must be washed and sanitized frequently, after breaks, and/or after handling potential contaminates. (2 Elements)	5
4.	Only approved food-grade lubricants are used in product contact zones and they are appropriately stored and labeled. (1 Element)	5

C. Product Contamination

0

1.	**NO ACTUAL PRODUCT CONTAMINATION IS OBSERVED. (1 Element)**	**5**
2.	No condition or practice exists that may potentially contaminate product, or could lead to product contamination. (1 Element)	5
3.	A written glass control and brittle plastic program has been established. The program addresses all glass that is to be shielded within the facility, handling of glass and brittle plastic packaging, and clean-up procedures for glass and brittle plastic breakage. (1 Element)	5

D. Allergen/ Adverse Reaction Management

1.	**THE FACILITY HAS DEVELOPED AN ALLERGEN CONTROL PROGRAM TO PREVENT CROSS-CONTACT WITH ALLERGENS AND IF UNDER US FDA JURISDICTION** complies with US FDA Food Allergen Labeling and Protection Act of 2004. **(1 ELEMENT)**	**5**

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2.	A master listing of ingredients used by the plant that are food allergens has been developed and is documented. Ingredients that are allergens are identified as allergens on all formulation, batch, or raw material production records. (2 Elements)	5
3.	The allergen program includes documented control procedures for all areas of the facility: allergen separation in storage, clean up procedures for allergenic ingredient spills, controls for utensils and storage containers that come into contact with allergens which include proper allergen labeling when ingredients or products are not in original containers. (1 Element)	5
4.	Production scheduling is done to ensure allergens are run prior to change-over and that specific change-over procedures are developed for allergen removal. Verification of change-over activity is conducted. Records of change-over and verification activities are maintained. (2 Elements)	5
5.	Facility has a written label reconciliation program that includes regular review of product labels versus product being packaged, inspection of labels at receipt to ensure accuracy, and removal and destruction of obsolete labels. Records of allergenic containing label inspection at receipt and review of label vs. product are maintained. (3 Elements)	5
6.	Facility has a written procedure on handling the rework of allergens. It includes proper labeling of rework to identify the product and allergen present and control of rework back into process and/or product. (1 Element)	5
7.	Facility has validated the cleaning procedures that directly affect the cross contamination points of allergens. (1 Element)	Yes/No

E. Food Safety Training

0

1.	A program for conducting food safety, food defense, GMP, and allergen training for all employees, including new employees, has been established. Completion of this training is documented as to date(s) given, what topics were covered, who conducted the training and is a part of the employee's records. The training should be conducted annually. Provisions for temporary employees are included in the training program. (3 Elements)	5

F. Miscellaneous

0

1.	**FACILITY HAS COMPLETED THE REQUIRED REGISTRATION FOR THE BIO-TERRORISM REGULATION. THE AUDITOR CAN VERIFY THAT THE FACILITY HAS GONE THROUGH THE REGISTRATION PROCESS. (IF THE FACILITY IS NOT REGISTERED THIS IS AN AUTO-FAILURE.) Not required if facility is under USDA FSIS inspection.**	**5,1, N/A**
2.	Facility has completed corrective action from previous third party audits for designated audit defects. Auditor will randomly select 3 corrective actions listed from any previous audits and verify that designated audit non-conformities were not observed as being out of compliance in this audit. (1 Element)	Yes, No, N/A

Possible points	**145**
Actual points	

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Percentage

COMMENTS:

II.Quality Systems

(Assessed by review of records)

A.	QA/QC Program	Rating
1.	A written quality management program, which identifies and defines the policies and procedures for the operation and control of the site's food safety and quality programs, is established, organized, and current. The program includes a procedure for approval and communication of changes to policies and procedures. The program includes an organization chart and identifies an individual whose job description includes responsibility for managing the overall program. Records showing compliance to programs are easily located during the audit. (3 Elements)	5
2.	There are written standards and specifications for raw and finished food products and packaging materials that come in contact with food. How any rework is used in products must be defined. (2 Elements)	5
3.	Procedures and criteria have been established for all hold and release programs. Documentation and records are maintained. The procedures shall include a method of identification for held products, a log of holds with descriptions of the holds and reconciliation of open holds. (2 Elements)	5
4.	There is a written record retention program for all quality and food safety records, including electronic documents. The program describes what records are included, how long they are maintained and where the records will be kept. There are secure back-up procedures for electronically retained records. (2 Elements)	5
5.	Self-audits are performed at least monthly. Copies are maintained for at least 12 months. Self-audits must include physical inspections of all areas and equipment of the facility and grounds, evaluating maintenance, sanitation, food security, and GMP compliance. Personnel from all departments participate. Corrective actions include what is to be done, when, and by whom. (2 Elements)	5
6.	There is a defined program to review existing product labels and the development of new product labels for information accuracy and regulatory compliance. The program identifies the frequency of review, responsible function for completing it, and the approval process for new label development and label changes. The auditor will verify compliance to the process by reviewing a minimum of one label against specification and include the label name and compliance level in the comments. (2 Elements)	5

B.	Good Manufacturing Practices	
1.	**A DOCUMENTED GMP PROGRAM HAS BEEN ESTABLISHED. IT COMPLIES WITH ALL APPLICABLE REGULATIONS. (1 Element)**	**5**

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2.	Signage that identifies applicable employee hygiene requirements, in languages appropriate for employees to understand, is present at all entrances to GMP zones. GMPs are posted for employees and visitors and/or they are given a copy of the facility's GMPs. The GMPs or company policy should specify that lack of compliance with the standards might result in disciplinary action. Corrective action procedures must be established for deviations to employee hygiene practices, and records are maintained. (3 Elements)	5

C. Pest Control Systems

0

1.	**A WRITTEN PEST CONTROL PROGRAM HAS BEEN ESTABLISHED. IT MUST INCLUDE A DESIGNATED PEST CONTROL OPERATOR (INTERNAL OR AN OUTSIDE SERVICE, SCHEDULED FREQUENCY OF SERVICE A CURRENT MAP, UPDATED ANNUALLY SHOWING THE LOCATION AND TYPE OF ALL PEST CONTROL DEVICES (INTERNAL AND EXTERNAL. (1 Element)**	**5**
2.	The pest control files include documentation of all business licenses, proof of indemnity insurance and certification for all PCOs in accordance with state requirements. The files also include a current list of approved pesticides to be used in the facility. MSDS and sample labels for products used. All pesticides, chemicals and compounds used meet applicable regulations and approvals (EPA, USDA, OSHA, etc.). The files are accurate, up-to-date and complete. (3 Elements)	5
3.	Service reports, at the frequency described in the contract or in the program, must be up-to-date and available for review. They must show the service performed, types and amounts of chemicals used, EPA or other applicable regulatory registration numbers, the location treated, targeted pests, signs of activity and applicable follow-up actions. Trends in activity must be assessed by the PCO or plant to identify areas of improvement in the pest control program. (2 Elements)	5

D. Cleaning and Sanitation

1.	A written master cleaning/sanitation schedule lists all areas and equipment in the plant that require cleaning (including processing and non-processing areas and equipment) and provides the frequency of cleaning. Documentation of the person who completed the task and the verification that they were completed are available for review. (1 Element)	5
2.	Written sanitation SOPs are established and implemented for all cleaning tasks. They include all necessary and regulatory content, such as responsibility, task to be performed, chemicals and equipment to be used. The order of operations of the cleaning steps is established to prevent recontamination of already cleaned surfaces or overspray onto food contact areas of the equipment. Sanitation SOPs must address how equipment is to be cleaned after being out of service. (2 Elements)	5
3.	A program for conducting ongoing training on cleaning and sanitation procedures and safe chemical handling for sanitation employees, including new sanitation employees and employees who have emergency sanitation responsibility, has been established. Contract production cleaning and sanitizing companies must maintain SSOP and safe chemical training records at the facility. Completion of this sanitation training is documented as to date(s) given, what topics were covered, and who conducted the training and is a part of the employee's records. The training should be conducted annually. (2 Elements)	5

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4.	Verification activities that ensure proper cleaning and sanitizing procedures are followed are conducted by management on an established frequency. Criteria are defined and records of findings are maintained and reviewed with sanitation employees. (2 Elements)	5
5.	A pre-operational sanitation inspection program, with pass/fail criteria is established and includes all production related areas of the facility. Visual inspection is used to assess sanitation prior to the start of production. Corrective actions are written and implemented when results of visual inspection show failure. Records of all pre –operational sanitation checks and corrective actions are maintained. (3 Elements)	5
6.	An environmental monitoring program using rapid methods and /or microbiological swabbing for pathogens and indicator organisms unique to the product and production environment should be in place and used to verify sanitation on a pre-defined basis. Pass/fail criteria have been identified. Corrective action procedures are written and implemented and include investigations into cause of failure. Records are maintained and results are reviewed and trended on a routine basis to identify areas for continuous improvement. (3 Elements)	5
7.	**THE FACILITY WATER IS FROM A POTABLE SOURCE. (1 Element)**	**5**
8.	Water potability is tested annually by a certified laboratory. The sample should be taken from different locations in the facility, each year. Records are maintained. (1 Element)	5

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E. Systems for Controlling Inbound and Outbound Materials

1.	A documented program has been established for approving domestic and international suppliers of raw materials, ingredients and packaging. It must meet all applicable, current regulatory requirements. Facility should have a master list of approved suppliers. (1 Element)	5
2.	An inbound delivery inspection program is required for the ongoing monitoring of all ingredients and materials at receipt. Appropriate procedures or monitoring methods are used to document load conditions, including cleanliness of the delivery containers or trailers. They include the examination of incoming materials for evidence of contamination (pest, microbiological, chemical and physical), temperature abuse, damage, quality and condition. Inspection records are documented and filed, including disposition of any rejected product (2 Elements)	5
3.	A written, ongoing monitoring QA program is established to evaluate ingredients, raw materials, and packaging for compliance to specifications. Packaging includes product labels. When letters of guarantee are used to assure compliance, the plant has identified the frequency for their renewal and verification. Ingredients, raw materials and packaging that are monitored via a certificate of analysis upon receipt must be identified on a master list, and the site must have a predefined system for verifying the accuracy of the COA results against the specification. (3 Elements)	5
4.	A system for identifying and labeling all incoming packaged and bulk ingredients and packaging materials has been established for traceability. The system must include lot and date code identification. (2 Elements)	5
5.	A documented program has been established for verifying that finished products are ready for shipping and distribution. The procedures meet any applicable regulatory requirements and include trailer inspection and load condition. Outside storage facilities (company or independently owned) are identified, and there are defined procedures for verifying the condition and practices used at these facilities. (2 Elements)	5
6.	**FINISHED PRODUCTS CAN BE TRACED TO THE LOT NUMBERS OR CODE DATES OF ANY INGREDIENTS, RAW MATERIALS AND REWORK USED. (1 Element)**	**5**
7.	Finished products can be traced to the food contact/primary packaging materials used. (1 Elememt)	5
8.	Written procedures are established to determine the safety and security of returned goods. Procedures must define how returned products are to be segregated and evaluated for food safety and food security concerns when received. If there is a policy to use returned goods, there must be defined procedures on the controls to be used to insure safety. If the returned goods are to be destroyed, there must be procedures on what methods of disposal will be used. Code dates of all returned goods and all actions taken on the returned goods must be recorded and tracked from receipt to use or disposal. (2 Elements)	5
9.	Is the site aware of and putting controls in place in their supplier approval program to ensure foreign raw material suppliers will be in compliance with the Food safety Modernization Act? (1 Element)	Yes/No
10.	A documented program has been established for approving all co-manufacturers. It must meet all applicable and current regulatory requirements. Facility should have a master list of approved co-manufacturers. (1 Element)	5

F. Process Control Systems

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1.	Process control points and applicable limits have been identified for all production lines. There are written procedures for monitoring the control points and the corrective actions to be taken when deviations occur. Records of all process control point monitoring and corrective actions are kept. (2 Elements)	5
2.	All measurement equipment for monitoring process control points (e.g., thermometers, scales, pH meters, refractometers) is calibrated according to a defined schedule. The calibration results and any corrective actions are documented. (1 Element) • There is a set schedule for calibrating equipment and records of the calibration results and corrective actions are maintained.	5
3.	There are written procedures on how to calibrate and maintain all metal detectors or other automated foreign material detection equipment systems. There are written procedures on how to handle product rejected by the detection systems. Records of all calibration checks are maintained. Auditor is to list the type(s) of foreign material detection systems being used by the facility. (2 Elements)	5

G. Maintenance Food Safety Systems

1.	A written program exists for the proper preventive maintenance of all equipment and appropriate areas of the facility. There is an established schedule and a system for verifying that the PM tasks have been completed. (2 Elements)	5
2.	A documented program exists for employees to identify items in the facility needing maintenance. A system for reconciliation that maintenance has been completed is in place. (2 Elements)	5
3.	There is a written program to address the cleaning and sanitizing of equipment that has undergone repairs, maintenance or re-assembly before being used in processing. Responsibility for monitoring and verifying completion of this process is assigned. Documentation of this sanitation is required. (2 Elements)	5
4.	Written guidelines are in place to insure product is protected during all maintenance activities, including actions required to protect exposed and non-exposed product. Guidelines must be in place to ensure product disposition when product has been affected by maintenance activities. (2 Elements).	5
5.	Written guidelines are established to ensure tool and parts control when repairs are taking place during production. The guidelines should include proper placement of tools and parts and should address tools used in raw areas versus finished product areas. (1 Element) •	5

H. Good Laboratory Practices (If no internal lab exists rate this section as N/A. Only labs with microbiological or chemical analysis should be evaluated.)

1.	A documented GLP program has been established. It includes steps for the handling and storage of reagents and samples, the test methods to be used, and written SOPs for internal calibration and control procedures for all tests or analyses performed. Lab results are documented and initialed. There is a documented verification program for internal laboratory proficiency for chemical and microbiological testing, and records are available for review. (3 Elements)	5
2.	All appropriate laboratory equipment is calibrated as scheduled or as necessary and is functioning properly on a continuing basis. The calibration results are documented. (2 Elements)	5
3.	If the on site laboratory is testing for pathogens, There is a program in place for running positive controls. There are procedures in place for controlling cross contamination between laboratory and manufacturing area. Auditor will comment whether the laboratory is in a separte building or located under the same roof as the production facility. (1 Element)	Yes/No

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I. Product Recall Procedures and Customer Communications 0

1.	A documented product recovery program that can trace the distribution of specific production lots and the source of all primary packaging and ingredients used therein has been established and is maintained. The program must comply with FDA/USDA or equivalent guidelines for conducting a product recovery. The program must define procedures for contacting customers. Contact lists for responsible employees and customers are updated annually. Responsibility for managing the recovery program is assigned. (2 Elements)	5
2.	Mock recalls are conducted at least every 12 months to assess the effectiveness of the program. The results of the mock recall are on file, available for review, and must include a summary page and copies of all supporting documents. The mock recall should account for 100% of the ingredient, product, or primary packaging tested within 2 hours. Auditor will list the date of the last mock recall, the item tested, and the percentage of product recovered in the comments. (2 Elements)	5
3.	Auditor is to conduct a traceability exercise on one raw material or packaging item during the audit to verify that the facility can identify, track and locate 100% of raw materials or packaging to finished product and onto first external customer or first level of external distribution within 2 hours. Auditor will list the item tested and summarize results in the comments. (1 Element)	5
4.	A documented program on how to collect and evaluate customer complaints, especially those related to food safety and quality, has been established. There is a system for notifying food safety/QA personnel of applicable customer complaints and for investigation to identify a probable cause and resolution. Customer complaints are summarized on a routine basis to identify areas for continuous improvement. (3 Elements)	5

Possible points **210**

Actual points

Percentage

COMMENTS:

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III. Grounds, Building and Equipment

(Assessed by observation and review of records)

A.	Plant Grounds	Rating
1.	Roads, yards, grounds, and parking lots are maintained in neat and good condition, and free of trash and litter. Grass and weeds are cut to minimize harborage areas for pests and are not within 20 feet of the building. Ornamental landscaping must not provide harborage next to the building. (3 Elements)	5
2.	Plant grounds have adequate drainage to prevent pooling water that can serve as a source of contamination by seepage, foot-borne filth, or provide a breeding place for pests. There should be no evidence of pooled water and no standing water should be observed. (2 Elements)	5
3.	Equipment and pipes stored on plant grounds are at least 20 feet away from the buildings or at least 6 inches above the ground and in an organized manner to prevent breeding areas and harborage for pests. Any pipes within 20 feet of the building must have closed ends. (2 Elements)	5
4.	Litter and waste are properly stored in enclosed containers. All waste is removed from the premises at appropriate intervals and in such a manner to prevent spillage and litter. The dumpster is on a rigid, cleanable surface. The dumpster areas are cleaned on a regularly scheduled basis and/or are clear of debris and spilled product. (3 Elements)	5
5.	The loading dock areas are clear of debris and spilled products. Equipment or items stored on the dock should be clean and organized. All equipment or items stored on the dock should be clean and organized. All bumpers, levelers and shelters are in good repair and clean. (3 Elements)	5

B.	Plant Facilities	0
1.	Plant buildings and roofs are suitable in construction and designed to facilitate maintenance and sanitary operations. There are no roof leaks. (2 Elements)	5
2.	Interior floors, walls, and ceilings are constructed of materials that can be adequately cleaned and maintained in good repair. (3 Elements)	5
3.	Adequate screening or other protection is provided for defense against pests. Doors and windows should be closed or screened with no gaps greater than 0.25 inch. Cracks and crevices have been sealed to prevent entrance or harborage of pests. Drains protruding from outer building walls must be screened. (3 Elements)	5
4.	Aisles and workspaces between processing equipment and walls are unobstructed and of adequate width to permit employees to perform their duties and protect against contamination. There is adequate lighting in all areas of the facility, including processing, storage, receiving, shipping, locker rooms, restrooms and break areas. (2 Elements)	5
5.	All glass and brittle plastic in receiving, shipping, production, and storage areas of the facility are shielded or protected against breakage. (1 Element)	5
6.	Adequate ventilation or control equipment is in place to minimize odors and vapors. Fans and other air-blowing equipment are operated and maintained to minimize the potential for contaminating food, equipment or packaging materials. (2 Elements)	5

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7.	Water lines and hoses are protected against backflow or cross-connections between potable and waste water systems in areas where potential backflow conditions exist. (1 Element)	5
8.	Hand wash stations are appropriately located in the processing areas. Hand washing stations have hands-free water and towel operations and are provided with antibacterial soaps, warm water and single use towels or a suitable drying device at all times. Signs in the appropriate languages direct employees to wash and sanitize their hands before they start work, after each absence from their workstation and at any time their hands may become soiled or contaminated. (4 Elements)	5
9.	Break areas, locker rooms, and restrooms are maintained in a clean and sanitary condition. They are equipped with proper ventilation and self-closing doors. Drains function properly and are free of standing water. Break areas are separated from the food processing areas and are free of plant garments, aprons, etc. Employee lunches should not be stored in lockers. Ladies restrooms must have covered trash receptacles. Hand wash signage is posted in all of these areas. (3 Elements)	5
10.	Ladders and walkways over exposed product lines are protected to prevent potential contamination. Appropriate kick plates are installed as necessary. (1 Element)	5

C. Equipment

0

1.	All plant equipment and utensils are designed and constructed to prevent contamination of food products. Food contact surfaces and seams are smoothly bonded. Wooden equipment and / or wooden food surfaces are not used in food processing areas. (2 Elements)	5
2.	Equipment is maintained in good repair and is being used for the task for which it was intended. Contact surfaces are corrosion resistant and able to withstand the processing environment. No mold or rust is observed on equipment. Temporary repairs of equipment will not inhibit proper sanitation or be made with materials that contribute in any way to the contamination of the product or environment. (2 Elements)	5
3.	Soiled or broken pallets are not used. Empty pallets are not stored near raw material, in food processing, or food storage areas. (2 Elements)	5
4.	Vehicles and equipment used for moving raw materials, finished products and packaging throughout the facility are cleaned and maintained in good condition. Fork truck or hand truck battery storage or charging stations are located away from food products and packaging materials. (2 Elements)	5

Possible points	**95**
Actual points	
Percentage	

COMMENTS:

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IV. Pest Control

(Assessed by observation)

		Rating
1.	The plant has an adequate number of interior pest control devices. The spacing is at consistent intervals (typically 20-40ft.) around the interior perimeter of the building area and around interior perimeter of any walled in dry food storage, packaging or cooler areas. Inside of any exterior wall and cooler walls. Mechanical stations should be within 10 ft. of both sides of doors leading to the exterior, including dock doors. Pest control devices must also be used in dry storage areas, coolers, locker rooms, and break areas. All devices must be located so that they do not contaminate product, packaging or equipment. A number and/or color code must correspond with the master identification map. (2 Elements)	5
2.	The plant has an adequate number of tamper-resistant exterior pest control stations spaced at appropriate intervals (usually 25-50 ft.) around the building's exterior perimeter. (If the plant has conducted a risk study with its pest control service within the past 6 to 12 months using the National Pest Management Association standards and the study is available for review, spacing of the exterior stations can be adjusted based on the study results.) Stations are secured in place next to the building, closed, and a key or a tool (e.g., Allen wrench) is required to open. Bait must be anchored inside the stations to avoid being removed by a rodent or floating away during heavy rains. These devices must be located so that they do not contaminate product, packaging or equipment. The number and location code must correspond with the master identification map. (2 Elements)	5
3.	Live catch devices and glue boards are checked at least twice monthly. Exterior bait stations are checked at least monthly. The PCO must initial and date the labels and initial punch cards on all devices. These labels should be on the inside of the devices, unless they are mechanical devices with a clear window. (3 Elements)	5
4.	All pest control devices must be appropriately positioned and located so that they do not contaminate product, packaging or equipment. Bait must not be used in interior areas. All pest control devices are clean and functioning properly. Bait in the stations has a fresh appearance. (2 Elements)	5
5.	The site is controlling all internal and external pest activity, based on the pest control reports and observations during the audit. (2 Elements)	5
6.	**THERE IS NO EVIDENCE OF DECOMPOSED PESTS ANYWHERE IN THE INTERIOR OF THE FACILITY, INCLUDING IN PEST CONTROL DEVICES. THERE IS NO EVIDENCE OF INSECTS, SPIDERS, RODENTS OR BIRDS ON OR IN ANY FOOD INGREDIENTS, PRODUCTS OR PACKAGING MATERIALS. (1 Element)**	**5**
7.	Insect light traps (ILTs) (both low and high voltage) and flying insect traps may be used. Placement must be according to manufacturer instructions and comply with applicable regulations. If instructions are not available, ILTs must be between 2 and 5 feet off the ground. High voltage ILTs should be at least 10 ft. from covered/protected products or packaging and at least 30 ft. from exposed product, packaging, or equipment. Low voltage ILTs must not be above covered/protected or exposed product, packaging or equipment. Low voltage ILTs must also include sticky boards. They must be cleaned and maintained on a scheduled basis. Bulbs must be changed at least annually, and shatter protection must be in place. There must be a schedule for replacing the sticky boards in sticky-type ILTs. (4 Elements)	5
8.	Avicides are prohibited inside the facility. If used on the exterior, avicides must be used according to program and label requirements. (1 Element)	5
9.	All pesticides, chemicals and other compounds stored on site for pest control are properly labeled and kept in locked, secured areas away from any food storage or processing areas. (1 Element)	5
	Possible points	**45**

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Actual points _____

Percentage

COMMENTS:

V. Employee Practices

(Assessed by observation)

		Rating
1.	Employees follow written programs on employee hygiene practices, store personal items appropriately, maintain personal cleanliness, and use hygienic practices at all times. (2 Elements)	5
2.	Exposed jewelry, except for a plain wedding band, and other objects that might contaminate products like artificial nails and body piercings, are not worn. Objects such as pens, thermometers, etc. that could fall into food, equipment or containers, are not carried in above-the-waist pockets. (2 Elements)	5
3.	Hairnets or other appropriate restraints are properly worn in food processing areas and in other areas of the facility as designated by facility's employee hygiene practices. All employees with facial hair, working in production areas, must wear beard covers. The facility's employee hygiene policy must address all facial hair, including definition for acceptable appearance and when coverage of facial hair such as moustaches is required. (3 Elements)	5

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4.	Garments worn in the facility (uniforms, aprons, frocks, lab coats, etc.) are clean and appropriate for the operation and do not contribute to potential product contamination. All garments should have snaps not buttons. Outer garments like frocks and aprons are not worn in restrooms, break areas or outside of the facility. Employees adhere to traffic flows when moving through the facility by changing frocks, aprons or uniforms to minimize cross-contamination. (3 Elements)	5
5.	Gloves worn in the food processing areas are maintained intact, clean and in good condition. Gloves must be used where there is direct hand contact with ready-to-eat products. Procedures for the proper handling and usage of gloves have been developed, implemented, and verified where required. (3 Elements)	5
6.	Eating, chewing gum, drinking and use of tobacco are confined to designated areas outside of the processing and storage areas. (3 Elements)	5

Possible points	**30**
Actual points	
Percentage	

COMMENTS:

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VI. Receiving, Storage and Shipping

(Assessed by observation and review of records)

A.	Receiving and Shipping	Rating
1.	All ingredients and materials should be properly identified and labeled. They should include the date of receipt or a verifiable system for first in/first out (FIFO) or first expired/first out (FEFO) product rotation. Ingredients and primary packaging in storage must be traceable into the production system by the vendor's lot number or the processing facility's assigned system. (2 Elements)	5
2.	Products must be maintained in their appropriate temperature ranges. Products are not stored in the shipping and receiving areas, unless proper controls are used to prevent quality, food safety, and/or temperature degradation. Perishable product should not be stored on the cool dock. (2 Elements)	5
3.	Shipping and receiving areas are clean, organized, and free of debris and spilled products. Equipment stored on the dock (load bars, bulkheads, etc.) should be organized and in good repair. (2 Elements)	5
4.	Temperatures of refrigerated and frozen products are documented at the time of receipt. The temperature monitoring devices being used are available and in good repair. Auditor is to verify that devices cover the temperature ranges of the products being monitored and indicate this in the comment section. (2 Elements)	5
5.	Transport vehicles used (incoming or shipping) are clean and free of any pest contamination. They are in sound condition and capable of maintaining proper product temperatures and preventing any product contamination. Perishable product transport vehicles must be pre-cooled prior to loading, and documentation of the pre-cooling cycles must be maintained. (3 Elements)	5
6.	If ingredients are received in bulk (tanker, rail, etc.), transfer procedures must protect the product from contamination. Hoses must be clean, capped and stored off the ground, and connection ports into the building must be capped and locked when not in use. (3 Elements)	5

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B.	Storage	
1.	Sufficient space (typically 18 inches) is maintained along all walls to permit proper cleaning and inspection for pest activity. No materials are stored within this space. All materials are stored at an adequate height (6 inches or pallet height) above the floor. Easy access to all areas around the walls for cleaning and inspections is provided. (2 Elements)	5
2.	Stock rotation practices are used for all finished products. (1 Element)	5
3.	All stored ingredients and packaging materials are clean, dry, intact, in good condition, and free from contamination or spoilage. They are properly packaged or covered to prevent contamination of other products. . They are stored under appropriate conditions (e.g., dry, cooler and freezer). (3 Elements)	5
4.	Any damaged cases or packages are immediately segregated and repackaged or properly discarded. All materials rejected or on hold are properly identified, adequately segregated, and protected from contamination. Product on hold is clearly identified and held under appropriate conditions. (3 Elements)	5
5.	Ingredient containers are not reused, unless they are adequately sanitized or have protective liners. Single-use containers from microbiologically sensitive products must not be reused. (2 Elements)	5

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6.	Dry storage areas are maintained in a clean and sanitary manner. All spills are immediately cleaned up, and there is no evidence of spills, trash or other litter within the facility. (2 Elements)	5
7.	Restricted chemicals for use in processing or as an ingredient are stored in separate, locked areas away from food and packaging supplies. (1 Element)	5
8.	Racks, floors, walls and ceilings of coolers are in good repair and maintained in a clean, sanitary condition. There is no evidence of aged spills, trash or clutter. Floors are kept dry. (3 Elements)	5
9.	Coolers show no sign of condensation, and products stored in coolers should be free from condensation and ice. Cooler temperatures are maintained within the allowable ranges. Monitoring occurs either by checking temperatures manually at least twice a day or via continuous recording systems. (4 Elements)	5
10.	Racks, floors, walls and ceilings of freezers are in good repair and maintained in a clean, sanitary condition. There is no evidence of aged spills, trash or clutter. Floors are kept dry. (3 Elements)	5
11.	Freezers show no sign of aged frozen condensation or aged ice. Products stored in freezers are free from ice and show no signs of freeze/thaw conditions. Temperatures of freezers are maintained below the maximum allowable temperatures. Monitoring occurs either by checking temperatures manually twice a day or via continuous recording systems. (4 Elements)	5

Possible points	**85**
Actual points	
Percentage	

COMMENTS:
VI.B.9: Comment-Cooler temperatures
VI.B.11: Comment- Freezer temperatures

VII.Plant Sanitation

(Assessed by observation and review of records)

A.	**Cleaning Equipment and Chemicals**	**Rating**
1.	All chemicals used for cleaning, sanitizing, and processing must be approved for use in a food handling facility and are properly labeled. They are used for their intended purposes and they are stored in secure, locked areas away from any food processing or storage. Facility maintains current MSDS and labels for all cleaners and sanitizers being used in an organized, accessible and easy-to-use system. (3 Elements)	5
2.	There are testing procedures in place that routinely verify chemical concentrations used are in compliance with regulatory requirements and sanitation program requirements. Records are maintained. Auditor verification of sanitizing solutions in footbaths, hand dips, drop down stations are in compliance with the facility written programs. (2 Elements)	5

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3.	Containers, brushes and applicators used for cleaning and sanitizing are designed for use and color coded or labeled to properly identify them for their intended use. If a color-coding system is used, appropriate signage describing the system in languages appropriate for employees to understand is posted. Cleaning equipment is properly stored (when not in use) and is not stored in food processing areas. (3 Elements)	5

B. Cleaning, Sanitation and Housekeeping Procedures

1.	Cleanliness is maintained in all non-processing and non-food contact areas. The cleanup of spills and accumulation of materials is conducted on a continuing basis during production. (2 Elements)	5
2.	Cleanliness is maintained on all food contact surfaces. Significant accumulations of product build-up are not observed during production. (2 Elements)	5
3.	Excess moisture and pools of water are removed from equipment and the processing environment. (1 Element)	5
4.	Knives, saws, trimmers, and other tools used in processing and for opening ingredient bags and packaging are properly stored, cleaned and sanitized as necessary throughout the production shifts and at the end of the production period. (2 Elements)	5
5.	Proper cleaning and sanitizing procedures are followed and are accessible to employees needing them. Equipment is disassembled as necessary to insure thorough cleaning. Equipment in wet processing environments that has been out of service is cleaned and sanitized prior to use per written sanitation SOPs. Results are being documented to verify cleaning and sanitation was completed per procedure. (4 Elements)	5

Possible points	**40**
Actual points	
Percentage	

COMMENTS:

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VIII. Processing

(Assessed by observation and review of records)

A.	Raw Materials and Other Ingredients	Rating
1.	Water reused or recirculated for washing, rinsing, or conveying food must have documented procedures to insure the water is not increasing the level of contamination. These can include microbiological testing, ph and free chlorine levels or other validated processes. Monitoring should occur on a routine basis and records must be available for review. (2 Elements).	5
2.	Thawing or tempering of frozen materials is done under controlled conditions (e.g., under refrigeration) and is monitored to insure proper temperature controls are maintained. Thawing procedures have been developed that assure safety and quality are maintained, and verification checks of compliance must be documented. (3 Elements)	5

B.	Process Control	
1.	Appropriate process control points and limits are observed being monitored on a regular basis. The monitoring results are being recorded. Employees questioned during the audit are aware of and understand how to monitor their control points. Auditor will comment on what was asked and the worker's response. (2 Elements)	5
2.	Corrective actions are being taken as required and documented, whenever a process control point is outside of the established criteria or limits. Auditor will review random online monitoring and corrective action records and comment on compliance. (1 Element)	5
3.	No equipment or processing operations (such as washing, trimming, sorting and inspection, shredding, extruding forming etc.) used are observed to have the potential to contribute to the contamination and/or adulteration of product with physical, chemical or microbial contaminants that could be introduced into the product. (1 Element)	5
4.	No sanitation practices are observed, which could potentially cause product contamination. All food, food-contact surfaces and packaging are adequately protected during clean-ups. The use of hoses, including high-pressure hoses, during production or mid-shift clean-ups or where food or packaging materials are stored is done without causing contamination from water droplets and aerosols. (2 Elements)	5
5.	Breakdowns or line shutdowns are monitored to insure time delays, temperature fluctuations and other factors do not contribute to contamination, decomposition, or other safety and quality changes in either the ingredients or products being processed. There are procedures for actions to be taken, when product safety or quality is affected. (2 Elements)	5
6.	All perishable product-processing rooms are monitored with a calibrated thermometer. The temperatures of products being processed and/or ingredients being used in the process are observed being maintained in their appropriate temperature range. Auditor is to report the temperatures observed for temperature-sensitive products. (2 Elements)	5
7.	Ingredient containers are properly labeled and/or color coded and covered as appropriate. If a color-coding system is used for labeling ingredient containers, signage on use of the containers and equipment is posted in languages appropriate for employees to understand. (2 Elements)	5
8.	Glass and brittle plastic packaging must be controlled in processing areas. Controls are in place, when glass or brittle plastic containers are used for the storage of raw materials. (2 Elements)	5

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9.	Staged packaging materials and ingredients are kept clean, dry and free from contamination during processing. (2 Elements)	5
10.	When magnets, screens, sieves, etc. are used in the processing lines, they must be inspected on a scheduled basis to insure proper performance. Inspection records must be documented and maintained. (2 Elements)	5
11.	Metal detectors or other automated foreign material control systems are used as necessary, if the plant is highly automated, the potential for metal contamination exists, or customers require their use. These systems are online as close to final packaging as possible and must have automatic rejection or line stoppage mechanisms when metal or other foreign matter is detected. The systems are observed being calibrated on a specified frequency with ferrous, non-ferrous and stainless steel standards or as specified by the customer to insure proper functioning. (4 Elements)	5
12.	Any compressed air or other gases (e.g., carbon dioxide, nitrogen) used in processing, packaging or cleaning are treated in such a way to prevent contamination. (1 Element)	5
13	Floors are observed to be free of standing water. (1 Element)	5
14.	Maintenance tools, gloves, rags and other miscellaneous materials are not found on or near processing equipment. Tools used for equipment adjustment must be clean and in good repair (no rust, etc.). (2 Elements)	5

Possible points	**80**
Actual points	
Percentage	

Comments:

IX. Food Defense

A.	**Program**	0
1.	The facility must have a documented food defense plan that designates a multidisciplinary team, which meets at least annually. The team must initially assess all facility operations to determine potential deliberate contamination risks and appropriate strategies to reduce these identified risks. The team must reassess the risks and strategies on at least an annual basis. (4 Elements)	5
2.	The facility provides evidence that it meets all regulatory requirements for food defense (FDA's Bioterrorism Act of 2002). These elements include facility records that identify the previous source of ingredients and materials and the next customer (one up and one down the food chain.) Records verifying compliance are maintained for the appropriate time based on product shelf life). (3 Elements)	5
3.	The plan documents how access is controlled to all receiving/shipping, processing and storage areas within and around the facility. There must be a system for easy identification of employees, who belong in and around open food and who have access to open food sources, including food packaging materials and equipment that touches food. The ID system has procedures for supervising all non-employees in the facility, including contractors, visitors, outside drivers, etc. The access plan must identify how all critical departments and areas of the facility will be physically secured (4 Elements)	5

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4.	The plan identifies the systems and procedures for controlling the integrity of all incoming materials. There are procedures that describe how receiving of raw materials will take place including the matching of seal numbers, evaluation of product integrity and delivery driver identification verification. There must be procedures to address the securing of bulk ingredient ports and the securing of water handling facilities. There is a policy in place describing how unsecured inbound LTL loads are handled which would include 100% inspection for evidence of tampering and documentation of these inspections on receiving documents. (4 Elements)	5
5.	There are established procedures for how the manufacturing process and product are protected from deliberate contamination. They must include controlled authorized access for all formulas and all formulation software and tamper evident packaging on finished product. (3 Elements)	5
6.	There are established procedures on how the shipment of product is protected from deliberate contamination, including the sealing of outbound trailers, control of LTLs and documentation of drivers. (3 Elements)	5
7.	There are policies and procedures in the plan for screening employees. . At a minimum, they include a system to screen all employees prior to hiring, including reference checks for all employees and basic felony background checks for supervisors and above. Procedures have been set-up to educate and supervisee current employees on how to report suspicious activities. (3 Elements)	5

B. Food Defense Practices

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1.	The facility is complying with their program on restricting areas of the plant to authorized personnel only. The facility has systems in place on how to alert personnel about the restricted areas. All access points are secured or monitored according to the program. (3 Elements)	5
2.	All visitors must be in compliance with the facility's program. The visitor policy is posted or provided to all visitors and non-employees. (2 Elements)	5
3.	All inbound and outbound trailers are properly sealed or secured. Receiving records and shipping records document the matching of seals to receiving documents or outbound bills of lading. Delivery driver identification is verified. Records document that less than full loads are managed according to the facility policy. Bulk receiving ports and on-site water handling facilities are secured. (4 Elements)	5
4.	Formulas and all formulation software are protected by limited access. Tamper evident packaging is utilized. (2 Elements) •	5

Possible points	**55**
Actual points	
Percentage	

Comments:

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Food Safety and GMP Assessment Rating System

This rating system describes a food plant's level of compliance with recognized food safety and Good Manufacturing Practices. The point system and definitions are objective guidelines for evaluating the plant's compliance with the assessed standards and are intended to assure consistency in rating. ***Comments are provided for any standard rated lower than 5.***

Questions are scored per the matrix, with 5 being the highest rating possible and 1 being the lowest. If isolated issues for any element are found, an additional one point deduction will be applied to the question's rating *OR* if numerous issues for any element are found, an additional two point deduction will be applied to the question's rating.

Number of elements in question	>3 elements missed	3 elements missed	2 elements missed	1 element missed	All elements fulfilled	
>3	**1**	**1**	**3**	**4**	**5**	**Rating given To question**
3	N/A	**1**	**2**	**4**	**5**	
2	N/A	N/A	**1**	**3**	**5**	
1	N/A	N/A	N/A	**1**	**5**	

Definitions:

- Single issue - One observation, occurrence or instance of a specific/same issue or element
- Isolated issues - Two observations, occurrences or instances of a specific/same issue or element.
- Numerous issues – Three or more observations, occurrences or instances of a specific/same issue or element.

This rating system is an objective guideline. Auditors may use their discretion regarding scoring, considering the severity of food safety issues and numbers of observations of an issue noted.

Each plant will receive a total overall score based on the ratings of the individual standards in the audit form. The minimum acceptable numerical score may vary depending upon the company requiring the audit.

Numerical Score	Further Guidance
97% or higher	**Meets audit expectations**
93 – 96.9 %	**Generally meets audit expectations**
88 – 92.9 %	**Partially meets audit expectations**
< 88%	**Does not meet audit expectations**