Confidential Audit Report

for

Hi Tech Nutraceuticals, LLC
Reedsville, Pennsylvania
February 23, 2015
REVIEWED JC

ASI
Food Safety Consultants

800-477-0778 ★ www.asifood.com

FOOD PROCESSING

Quality Systems and Product Safety Inspection Report

for

Hi Tech Nutraceuticals, LLC

5135 Old US Highway 322

Reedsville, PA 17084

Grade   98.65%   **Rating**   Excellent

Audit Date:	2/23/2015	ASI Consultant:	Fred Catanzariti
Previous Grade/Rating:	96.63/Excellent	ASI Technical Director	Jeff Capell
Date of Previous Audit:	4/12/2013	Copies to:	Sherry Thompson

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Key Personnel

Name	Title
Sherry Thompson	Office Manager
Steve Swartz	Director of Quality
Nikeisha Walker	Lab Technician
Megan Frailey	Lab Technician
Stacey Alexander	Chief Scientific Officer

SUMMARY AND GENERAL CONDITIONS

This was a scheduled audit. The auditor was greeted by Sherry Thompson, Office Manager, and was given permission to tour the building and review the company records. The building is clean and well maintained. The records are in order and up to date. It was a pleasure to work with the staff at Hi Tech Nutraceuticals.

Facility Information

Size (sq. ft.):	Production	100,000 sq. ft.	Warehouse:		30,000 sq. ft.

Construction of building (metal frame, brick, etc.)   concrete and block

Number of operation days/shifts (i.e. days per week, shifts):   5 days/ 1 shift

Number of employees at this location: 25

Grading System

Section	Points Available	Points Applicable	%	Points Applicable Last Audit	%
1. Evaluation of Quality Systems	320	320	100.00%	0	0.00%
2. Pest Control	280	270	96.43%	0	0.00%
3. Evaluation of Operational Methods and Personnel Practices	310	310	100.00%	0	0.00%
4. Maintenance and Repair	310	300	96.77%	0	0.00%
5. Evaluation of Cleaning Program	280	280	100.00%	0	0.00%
6. Allergen Management	185	185	100.00%	0	0.00%
7. Security	145	140	96.55%	0	0.00%
8. HACCP	20	20	100.00%	0	0.00%
Total Points Available:	1850	1825	98.65%	0	0.00%

The score and comments listed in this evaluation are reflective for the day of the audit only.

Score	Rating
95%-100%	Excellent
90%-94.9%	Very Good
85%-89.9%	Good
80%-84.9%	Fair
70%-79.9%	Poor (Marginal)
Below 70%	Critical (Unsatisfactory)

EXAMPLES OF CRITICAL ITEMS IN FOOD PROCESSING
This list is not all-inclusive, and other situations may arise that lead to critical findings.

Pest control:
• A dead and/or decayed rodent on the floor or in a trap.
• Live rodents or rodent evidence (live rodent or freshly killed rodent in a trap is not critical).
• Live stored-product insects (i.e., cockroaches, grain weevils, etc.) in the processing area or storage areas (other live insects such as fruit flies or ants are not critical).
• Birds or bird evidence anywhere inside the facility.
• Rodenticide in use inside a food processing facility.

Improper handling and storage:
• Sanitizer concentrations used at improper strength on food contact surfaces: the concentration is below legal limit (less than 50 PPM chlorine, 12.5 PPM iodine or below minimum label directions for other sanitizers) or above the legal limit (greater than 200 PPM chlorine, 25 PPM iodine or above maximum label directions) and is not rinsed prior to product contact.
• Exposed packaging film is not critical unless it shows evidence of footprints or there is the direct potential for contamination of the film.

Facility maintenance:
• Unprotected lights: where exposed product is received, shipped, or stored. One end cap missing would be critical. A hole in a shield would be critical.
• A roof leak is critical only if it is dripping on food or food-contact items.
• Condensate in freezers or coolers dripping onto cases of food.
• Mold on equipment, walls, overhead fixtures, and ceiling.
• Rust, dripping condensation, chipping paint, flaking labels, etc. on surfaces above exposed food in a processing room or cooler.
• Sewage disposal problems (blocked drains, etc.).
• Lack of backflow prevention on hose bibbs.
• Restrooms improperly vented into production, processing, and/or packaging areas.

Critical Findings: **If Critical Finding Found Automatic Deduction of 100 points**

1.0 Evaluation of Quality Systems						
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
1.1	A written Quality Management program including corporate quality policy/mission statement and facility organizational chart is available for review. The program must include: 1. Corporate policy 2. Organization chart 3. Independent quality unit/QA Manager/Sanitarian 4. Responsibilities/authorities 5. Document signed and up-to-date SOP/WI 6. Job descriptions 7. Designated Food Safety responsibility	Y			15	0	
1.2	Facility performs yearly self-audits of Quality Programs and Documentation. The program must include: 1. Specific activities and areas to be audited 2. Qualifications of personnel carrying out the audits 3. The basis for carrying out the audits (organizational changes, reported deficiencies, routine checks, and surveys) 4. Procedures for reporting audit findings, conclusions and recommendations 5. Self-audits should be performed at least once a year 6. Written record retention program	Y			15	0	
1.3	Plant is performing daily pre-operational inspections for product repacking areas. Program must include: 1. Time of check and person responsible 2. Examination of equipment to verify cleanliness 3. Checking that the production line is ready to start 4. Checking that all personnel meet GMP requirements 5. Corrective action in case of non-compliance records on file			Y	0	0	
1.4	Facility has a documented, established, Personal Practices Program. The program must be compliant with the provisions of 21 CFR 110	Y			25	0	

1.0 Evaluation of Quality Systems						
Section	**QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."**	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
1.5	Does the Facility have a documented procedure for conducting monthly GMP self-inspections / audits? Program must include: 1. Time of check and person responsible 2. Inspection criteria 3. Inspection includes inside and outside grounds 4. Records of inspection 5. Corrective actions 6. Records of inspection (12/year)	Y			15	0	
1.6	Plant has an Approved Supplier program. Program must describe: 1. Approval process 2. Criteria used to approve any supplier 3. Supplier list 4. Contact information 5. Complaint and corrective action 6. Records on file.	Y			10	0	
1.7	Facility has a documented <u>incoming</u> trailer and material / product inspection program. Program must describe: 1. Frequency 2. Inspection criteria/use of light 3. Inspection form 4. Rejection logbook 5. Records of trailer inspections should be on file	Y			20	0	
1.8	Plant tests raw materials and it has written supplier guarantees or certificates of analyses (COAs) Program must describe: 1. Frequency (guarantees/COA/testing) 2. Testing procedures and specifications 3. Form used to keep the records 4. Rejection logbook 5. Records of testing results	Y			10	0	
1.9	Plant has specifications for all products manufactured at the facility. These specifications include: 1. Formulation 2. Processing instructions 3. Sensory characteristics/testing procedures 4. Applicable standards and regulations 5. Packaging, labeling, transportation, handling or storage 6. Labeling approval program and verification if required by regulations	Y			10	0	

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1.10	Facility has documented procedures for testing work-in-progress or finished products if appropriate. Program must clearly define: 1. Testing procedures 2. Sampling schedule 3. Form used to keep records 4. Validation of results 5. Good laboratory practices and records of training for employees 6. Calibration of lab equipment 7. Records on file	Y			10	0	
1.11	Facility has a program for calibration of equipment. Program must outline: 1. List of equipment amenable to calibration 2. Frequencies/responsibility 3. Calibration instructions/standards used 4. Training of employees in calibration of equipment 5. What actions are taken if critical equipment is found out of calibration. 6. Records are available for review.	Y			10	0	
1.12	Facility has a documented outgoing trailer and product inspection program with records on file. Program must describe: 1. Frequency 2. Inspection criteria 3. Inspection form 4. Rejection logbook 5. Records of inspections should be on file	Y			10	0	
1.13	Billing / shipping records are available for review. The Records must include: 1. Date of shipping 2. Item number 3. Name of products 4. Amount shipped 5. Final destination 6. Lot numbers	Y			10	0	

1.0 Evaluation of Quality Systems						
Section	**QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."**	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
1.14	Facility has written cleaning procedures with MSDS for all cleaning chemicals on file. The Program must include cleaning procedures and Master Cleaning Schedules for (if applicable): 1. Storage areas, receiving, shipping areas 2. Maintenance areas 3. Offices, break room and rest rooms 4. Environmental cleaning in storage areas (floor. drain, walls and ceiling) 5. MSDS available for all cleaning chemicals 6. Procedures should include identification of all cleaning tools, equipment, implements, chemicals, dilution instructions and personal protection equipment / procedures and sequential steps of cleaning operations	Y			10	0	
1.15	Plant has a cleaning schedule. Master cleaning schedule must include areas such as (if applicable): 1. Production equipment 2 Storage areas/receiving/shipping areas 3. Maintenance areas 4. Offices 5. Break room and rest rooms 6. Environmental cleaning (floor, drain, walls and ceiling) 7. Outside grounds 8. Laboratory 9. Equipment requiring Clean-In-Place (CIP) programs and systems	Y			10	0	
1.16	Does facility have a documented chemical control program? 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.	Y			10	0	

1.0 Evaluation of Quality Systems						
Section	**QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."**	Complies	Does Not Comply	Not Applicable Mark With **Y**	Total Points	Points Deducted	AUDITOR COMMENTS
1.17	Facility has a written preventive maintenance program in effect. Program must include: 1. List of: All production equipment Refrigeration equipment Internal vehicles Receiving/shipping trucks Building/facilities Fire devices (extinguisher/sprinklers) Dock plates Safety and security devices 2. Master maintenance schedule, responsibility 3. Records of all maintenance activities 4. Sanitation inspection of production equipment 5. Reconciliation of parts and tools used for maintenance activities 6. Records of maintenance task	Y			10	0	
1.18	Facility has a comprehensive, written recall program that must include: 1. Recall team (name, phone number: office/after-hours) 2. Recall coordinator/responsibilities 3. Regulatory and customer contacts (facility and head office) 4. Spokesperson (responsible individual or agency for public relations) 5. Step-by-step procedure on how to conduct a recall 6. Recall classification based on USDA/FDA & CFIA guidelines. 7. Standard form to summarize results, contact information and corrective action 8. Records of mock recall/actual recall are on file	Y			15	0	
1.19	Mock recalls are performed at least semi-annually to test the effectiveness of the recall program. A mock recall SHALL be performed at the time of the inspection. Deduct ALL points if facility cannot perform the mock recall in 2 hours or less. Mock Recall Form, *Appendix A,* must be filled out by the Consultant.	Y			10	0	

	1.0 Evaluation of Quality Systems						
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
1.20	Plant has a program to handle retained and returned products. The program should include personnel responsible and procedures for hold/release and disposition of: 1. Raw materials 2. Work in progress materials 3. Finished products 4. Returned products 5. Inventory policy 6. Records showing hold/release or disposition and inventory	Y			10	0	
1.21	Facility has a traceability program able to ascertain all inputs that comprised a specific lot of finished product. Program should include: 1. All measures to assure traceability of all ingredients, packaging, and rework 2. Step-by-step procedure on how to conduct a traceability exercise 3. Traceability test policy, with a minimum of two exercises completed each calendar year 4. Records of traceability test (previous 12 months) 5. Standard form to summarize results and corrective action	Y			15	0	
1.22	The Facility has a non-conformance procedure. The Program should include personnel responsible and procedures for hold/release and disposition of: 1. Raw materials 2. Work in progress materials 3. Finished products 4. Returned products 5. Inventory policy 6. Records showing hold/release or disposition and inventory	Y			10	0	
1.23	Facility has a written glass and hard plastic control policy. The Program should include: 1. Control policy in warehouse areas or over exposed products: lights/utensils 2. Inspection program 3. Corrective actions 4. Procedures for changing ceiling lights 5. Procedure to handle any breakage and disposition of lights/hard plastics	Y			15	0	
1.24	Facility has a written rework/reprocess policy, if the facility utilizes rework or conducts reprocessing. The Program should include: 1. Procedures for conducting rework operations, including labeling 2. Suitability of material for rework (product condition, like-into-like, etc.) 3. Documentation necessary to properly trace use of rework in a particular lot			Y	0	0	

1.0 Evaluation of Quality Systems						
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
1.25	Facility has a program to ensure the safety of the water supply . The Program should include: 1. Definition of water sources; City Well 2. If city water is used, is the city potable water report available? 3. If well water is used, Sampling program and analysis (chemical and micro) with frequency of sampling program must be available	Y			10	0	
1.26	The facility has a customer complaint program. Program should include: 1. Person responsible for handling complaint 2. Procedure on how complaints are investigated 3. Records 4. Answer to customers 5. Corrective actions 6. Measures to prevent recurrence of the issue and verification that such measures have been implemented	Y			10	0	
1.27	The facility has a training program for employees. The Program should include: 1. Refresher training responsibilities 2. Experience/qualification of the trainer 3. Training policy (bilingual) 4. Refresher Frequency (yearly or when otherwise required) 5. Material used for training/records of training should cover GMP, sanitation, HACCP, allergen awareness (if appropriate), recall, traceability, rework, receiving, shipping, storage, glass and brittle plastic control, and security. Annual refresher training will be conducted in GMP, HACCP, and allergen awareness (if appropriate).	Y			25	0	
1.28	Is there a policy in regards to personnel being sick in the facility and how would it be cleaned up? What happens to the product in the general area, i.e., vomiting?		Y				
	Total Points:				320	0	

2.0 Pest Control							
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
2.1	Are there insects, flies, rodents, or birds in the raw materials, packaging or finished products? The presence or evidence of insects, flies, rodents, or birds in or on the raw materials or finished products is extremely serious. This is adulteration of a product and could lead to a foodborne illness and definitely will bring regulatory criticism. A bird flying through the facility could cause adulteration of the product. This is CRITICAL	Y			100	0	
2.2	Are there insects, flies, rodents, or birds in storage areas or in areas outside the facility where they might gain easy entry to the facility? Is there evidence of insects, flies, rodents, or birds in the plant but not in the raw materials or finished products? Are there rodent burrows or birds nesting or roosting on the building? This is CRITICAL	Y			50	0	
2.3	The facility has a written integrated pest management (IPM) program. (IMP) should clearly indicate/require: 1. Name of the pest control company 2. Scope, frequency of the service, number of traps 3. Use of service reports 4. Map of the facility 5. Standards for location and placement of pest control devices 6. Use of numbers on wall / floor, bait station secured 7. Records of trap / bait inspection /insect lights 8. Use of pest sighting log 9. Use of Pesticide Usage Log 10. Use of punch cards/stickers/bar codes on pest control devices 11. License of technician 12. License of the company / branch 13. 18-inch perimeter in storage areas 14. Trimming of trees and weeds around the facility 15. Insurance liability	Y			25	0	

	2.0 Pest Control						

Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
2.4	Pesticides are applied by licensed personnel, where required. The following documents should be on file: 1. Certificate of insurance for the contracted pest control company 2. Business license for the contracted pest control company 3. Pesticide applicator's license. Check signature of the applicator for the last 12 months These documents must be current. Look for the expiration dates.	Y			10	0	
2.5	MSDS and sample labels are on file for all pesticides in use. Check for: 1. List of approved pesticides used 2. MSDS for all pesticides used in the past 12 months should be on file. All points deducted if unnecessary pesticides are found at the facility All points deducted if <u>any</u> **MSDS** or **sample label** are missing, or if EPA number on MSDS / label does not match Pesticide Usage Log.	Y			20	0	
2.6	Pest control map is on file and up-to-date. Check for: 1. Map 2. Legible and in good condition 3. Location of trap, bait station, light and any other pest control devices 4. Numbered / legend 5. Map signed and dated annually by the Pest Control Operator	Y			5	0	
2.7	Pesticides stored on site are in a locked, dedicated room, not adjoining or above product storage or product handling rooms. Access is limited to personnel certified by the state to handle pesticides.			Y	0	0	
2.8	Is there an adequate pest control program? Check for: 1. Location of traps/baits/Insect Electrocutors with map 2. Numbers on wall or floor 3. Punch cards/stickers/date/initials on glue board and Ketch-Alls 4. Location of inside traps on each side of door inside 5. Bait station secured to the ground and contain stickers/cards/for date /initial. 6. Insect Electrocutor lights protected/well maintained/installation date 7. No damaged traps or unwound traps	Y			20	0	

2.0 Pest Control

Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
2.9	Corrective Action Reports based upon Rodent activities noted in Service Reports are available for the last 12 months.	Y			20	0	
2.10	Facility conducts weekly evaluations of interior traps and Insect Electrocutors with documents on file.		Y		10	10	There are no weekly inspections being done.
2.11	Pesticide Usage Log is on file and up-to-date. 1. Date 2. Name of the chemical/EPA number (EPA number should be the same as the MSDS) 3. Location/amount used 4. Amount and concentration 5. Target pest 6. Initials of the applicator	y			20	0	
	Total Points				280	10	
Note:	Insects, rodents or other vermin in the product is an automatic critical rating regardless of the overall numerical score						

	3.0 Operational Methods						
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y"). Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
3.1	Inspection of trailers and incoming ingredients are being implemented (as per written program).	Y			10	0	
3.2	Are pallets of product examined for contamination / damage / improper shipping ?

On each truck , three pallets of product should be examined for any evidence of possible contamination and damage. These pallets should be taken form the back, middle, and front of the truck. This examination should be conducted using a strong flashlight, and the cases of product should be palletized and examined for any damage that could lead to contaminated product. This damage could be due to rodent activity, human tampering, transportation damage, etc. Depending on the extent of the damage, all or part of the trailer load may be rejected back to the supplier. If the evidence suggests rodent , insect or bird activity, then the entire load should be rejected. | Y | | | 10 | 0 | |
| 3.3 | Do receiving personnel have the authority to reject?
For a facility to have an effective incoming goods inspection program, it is necessary that a person in the receiving team have the right to reject product. | Y | | | 5 | 0 | |
| 3.4 | Are there effective measures to prevent cross-contamination / adulteration, and to prevent contact with foreign objects?
The facility should have in effect measures to prevent cross-contamination from one product to another.
 Look for cleaners and other toxic chemicals stored over food-contact items or soft-pack products.
Note: Remember to pay attention to salvage or repack areas as the potential in these areas is high. | Y | | | 25 | 0 | |
| 3.5 | Are all ingredients stored correctly?
1. No expired products, all product is in sound condition, free of spoilage, off the floor and away from the wall
2. All ingredients are properly covered, closed or sealed
3. All products stored at the correct temperatures
4. Coolers <48°F, Freezers< 3°F, Warehouse areas <70°F, unless mandated by customer or regulatory requirements
5. All rejected and damaged products properly quarantined and identified
6. Organic food properly segregated from non-organic food
7. All ingredients marked with the date of receiving/FIFO
8. Slip sheets are used when double stacking palletized ingredients. | Y | | | 10 | 0 | |
| 3.6 | Hold and Release Procedure, if used, is performed as documented. | Y | | | 10 | 0 | |
| 3.7 | Procedures for traceability of ingredients during formulation production, rework, and work-in-progress are implemented
All raw ingredients and food-contact packaging should have the lot number recorded for traceability. The plant should be keeping a record of lot numbers of raw materials, packaging, and into which product these ingredients went. | Y | | | 20 | 0 | |

	3.0 Operational Methods						
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y"). Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
3.8	Document including manufacturing procedures and directions are available in production areas at the time of production.	Y			5	0	
3.9	Are products and packaging correctly labeled, dated, and rotated (using the first-in, first-out rotation policy)? All product containers should be correctly identified as to contents. If in the original container, the name must be legible. If another container, this has to be clearly labeled with the common name of the ingredient. All non-labeled ingredients should be disposed. All packaging should be clearly identified as to its intended use.	Y			10	0	
3.10	Are all rejected materials stored separately and so identified?	Y			10	0	
3.11	Is the space adequate to perform operations and keep clean? The size of the area in the plant has to be large enough to perform the task at hand and to be able to clean up. If the area is too small and there is a possibility that the product may become contaminated, then this is a problem.	Y			5	0	
3.12	Are production areas segregated from storage and the outside? The product processing areas should be walled off from storage areas, and there should not be doors leading directly into the processing area from outside. This will, if complied with, reduce the chances of airborne contamination of the processing area.	Y			10	0	
3.13	Are all products manufactured legally and safely? Are organic foods handled correctly? Certain products have to be processed according to strict conditions to ensure a wholesome product that will not make the consumer sick. Check the process to see if the product is being manufactured legally. Dairy products should be pasteurized at a minimum of 175ºF for 25 seconds. Low-acid canned products should be processed under conditions that have been shown to kill botulism; the process should be kept on file with the FDA. Organic foods: all exposed (non-packaged) organic items must be segregated from non-organic items: they may be stored above, but not below non-organic foods, and cannot be stored in any container that has been treated with a synthetic fungicide, preservatives, or fumigants.	Y			35	0	
3.14	Is surplus / unused equipment stored in non-production areas? All equipment that is not being used in the normal day-to-day operation of the plant should be in storage and not in the production areas. This equipment should be stored clean and preferably covered.	Y			10	0	
3.15	Are raw material ingredients examined, sieved or strained before use (where appropriate)? All raw ingredients should be examined before use. This can be visual or by sieving, straining, etc., depending on the nature of the raw material and its past history of reliability. The plant should be looking for foreign materials.	Y			10	0	

	3.0 Operational Methods						
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y"). Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
3.16	Are metal detectors, magnets, etc., working properly? If magnets or metal detectors are part of the process, these need to be in good working order.			Y	0	0	
3.17	Is all rework / work-in-progress handled correctly ? Any rework or work-in-progress must be clearly labeled as such and kept segregated from the raw materials and the finished product. The rework and work-in-progress must be stored in clean, covered containers.	Y			15	0	
3.18	Is product coded in an appropriate fashion that supports recall/traceability? All product should be dated to indicate when it was produced. This can be by using the actual date or a code system that designates the date. It is advisable, but not mandatory, to also put the line, the shift, etc. This is essential for recall and traceability purposes.	Y			10	0	
3.19	Are all finished products stored correctly and in sound condition ? All products should be stored off the floor and away from walls. They should be undamaged and free from dust and debris.	Y			15	0	
3.20	Does the facility have an outer garment policy? Are clothing policies followed? Facility should establish an outer garment program for persons working in direct contact with food-contact surfaces or food packing materials. Employees must wear a clean outer garment that remains within the work area. Facility is responsible for providing clean uniforms to employees. Facility should document a glove policy that includes uses, material, procedure for control (during breaks) and exceptions.	Y			10	0	
3.21	Are products 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?	Y			10	0	
3.22	Are trailers for shipping inspected (as per the written program)? Are they clean and in good condition? Transportation vehicles should be clean and free of residual product, dirt, debris, and pest evidence. They should be routinely swept out and washed. They should be odor-free and in a good state of repair.	Y			10	0	

	3.0 Operational Methods						
Section	**QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y"). Explain in notes section if any items DO NOT COMPLY."**	**Complies**	**Does Not Comply**	Not Applicable Mark With **Y**	Total Points	Points Deducted	AUDITOR COMMENTS
3.23	Are employees with signs of illness 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 foodborne 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 foodborne illness pathogens.)	Y			10	0	
3.24	Are employees exhibiting good personal hygienic practices, including hand washing? Are employees exhibiting good personal hygienic practices? 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. Outer clothing should be light in color, and this clothing should preferably be worn only when in work.	Y			10	0	
3.25	Are employees wearing effective hair restraints where required? Hair is one of the leading adulterants of food-contact products, and is objectionable to the customer. It is essential that everybody working with exposed product wear an effective hair restraint. All hair has to be in the hair net for it to be effective. Ball caps and hair spray are not acceptable hair restraint methods. If a person has a beard, then a snood is needed to cover the beard. Hairy arms are also a potential problem which can be addressed with the use of shirts with sleeves.	Y			5	0	
3.26	Is jewelry confined to a plain wedding band ? Stones from jewelry and watches can fall into the exposed product. Only plain wedding bands should be allowed for employees handling exposed products.	Y			5	0	
3.27	Are eating, drinking, and the use of tobacco products restricted to designated areas? It is illegal to smoke, eat, drink or chew gum around exposed food-contact product or in warehousing areas where it may lead to adulteration of the product, except in a designated area.	Y			10	0	
3.28	Are all items removed from shirt / blouse top pockets where required? Items in top pockets can fall into the exposed items, leading to adulteration.	Y			5	0	
3.29	Are employees following all provisions of the facility's Good Manufacturing Practices policy other than those in previous elements?	Y			10	0	
	Total Points				310	0	

	4.0 Maintenance and Repair						
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
4.1	Light fixtures are appropriately sealed (sleeves, end caps, covers, etc.). Glass in products is a significant physical hazard. It is essential to do everything possible to protect product against possible glass contamination. All lights should be protected against accidental breakage. In dry storage areas, if the product is in hermetically-sealed containers or is sufficiently covered to keep out glass fragments, then protection is not required; but in this case, the facility shall be able to demonstrate how they will remove glass fragments from bags, etc., satisfactorily to ensure that they do not get into the product.	Y			15	0	
4.2	Do fan louvers close when the fans are turned off? All fans that are in the exterior wall should have louvers that automatically close tightly when the fan is turned off. This will exclude insect or bird entry.	Y			5	0	
4.3	Are all ladders and walkways over product lines protected? All walkways and ladders over or close to exposed product or packaging should be protected so that dirt from shoes does not drop onto the product. Open-grate walkways or ladders are not acceptable. The base should be solid with a minimum of a one-inch lip at the sides. These walkways and ladders should be kept clean and sanitary.	Y			10	0	
4.4	Are there catch pans under all motors in production or product storage areas? All motors, overhead conveyors, chains, etc., over product storage areas should be protected against oil, grease, dirt, etc., dropping into the product below. Catch pans should be installed below overhead equipment to provide protection to the food or food packaging below.	Y			10	0	
4.5	Is there visible condensation on ceilings and overhead structures that may pose a threat to exposed product or product stored in materials that water may penetrate?	Y			15	0	
4.6	Are overhead pipes protected against leaks or condensate drips? When storing under exposed overhead sewer pipes, it is necessary that these pipes be protected against possible leakage that would result in adulteration of the food product. When storing under exposed waterlines, these pipes should not be leaking or have condensate dripping from them. With the exception of sprinkler system piping, it is advisable to protect all waterlines against accidental leakage.	Y			10	0	

4.0 Maintenance and Repair							
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
4.7	Is there flaking paint, friable material, or temporary repairs (tape, cardboard, etc.) in production or product storage areas? Flaking paint, loose caulking, tape, etc., which are over food products or food repackaging areas cannot be tolerated, as this may result in adulterated food.	Y			15	0	
4.8	Is there any rust on 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.	Y			10	0	
4.9	Are the floors, walls, and ceilings in good repair and cleanable? To maintain a clean, sanitary environment free of rodents, insects and harmful bacteria, it is essential the facility be kept in good condition. All holes, broken tiles, missing ceiling panels, etc., should be repaired or replaced immediately so that the environment can be cleaned properly.	Y			10	0	
4.10	Are there cracks/crevices that allow insect harborage? Floor / wall junctures should be sealed and floor expansion joints should be sealed. Otherwise, these cracks make it difficult for housekeeping, and provide harborage for insects.	y			5	0	
4.11	Are all doors to the outside pestproof? Mice can enter through holes as small as ¼ inch. It is therefore necessary to have gaps around all doors to the outside weather-stripped or sealed to prevent rodent entry. Flies and other flying insects will enter through open doors when receiving shipments, shipping out product or when employees are entering or leaving the facility. It is advisable to have air curtains on the outside of all personnel doors to the outside which will operate automatically every time the door is opened. These air curtains should be directed to blow out, provide an air curtain the full width of the door and give an air current velocity of at least 5 mph down to the floor. All dock doors should be kept closed when not in use or screened. Employees must close all doors and windows except when in use, unless they are adequately screened to prevent entry of foreign entities.	Y			20	0	
4.12	Are all dock door buffers / shelters/ levelers, etc. clean and well maintained? When trucks are being unloaded it is essential that buffers around the dock doors seal against the trucks to exclude pests, insects, dust, etc.	Y			10	0	

	4.0 Maintenance and Repair						
Section	**QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."**	**Complies**	**Does Not Comply**	Not Applicable Mark With **Y**	Total Points	Points Deducted	AUDITOR COMMENTS
4.13	Are the dock levelers rodent proof? Mice and rats can enter a warehouse by scaling the outside dock wall and climbing up the inside of the dock leveler, thereby entering the warehouse. As mice only need a 1/4 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 also should seal tightly against the bottom of the dock door.	Y			10	0	
4.14	Are the exterior walls hole-free to keep out pests? All exterior walls should be hole-free to deny insects, birds and rodents harborage and/or access into the building. All pipes that enter from the outside also should be sealed or screened to prevent rodent entry. All windows that can be opened should be screened to prevent entry of birds or insects. All sewer grids should be sealed or have a grating which is less than ¼ inch to prevent rodent entry.	Y			10	0	
4.15	Are there separate areas for raw materials and finished products? To minimize cross-contamination from raw ingredients to finished products, it is advisable to have separate storage areas. As this is not always possible, the facility should at least have sufficient space to have the capability of segregating raw materials from finished products.	Y			10	0	
4.16	Are there separate areas away from product and distribution areas for employees' personal items? Employees' personal belongings (e.g., outer clothing, handbags, etc.) should be stored in a locker room or designated areas where the possibility of contamination of food or food packaging is zero.	Y			10	0	
4.17	Is an 18-inch perimeter aisle maintained in production and the warehouse? To provide access for the pest control operator to be able to spray pesticides and service the rodent control devices, an 18-inch space around the perimeter of the production and storage areas is required.		Y		10	10	Perimeter is not being maintained.
4.18	Is the lawn maintained in a neat and trim fashion? Litter and trash on the ground outside the facility are attractants to rodents and insects. This provides them with food and water. Weeds provide coverage for rodents to approach the building, and should be trimmed to at least 100 ft. from the building.. There should be an 18 in. to 24 in. vegetation free zone surrounding the facility with no tree branches touching or overhanging the roof.	Y			5	0	

	4.0 Maintenance and Repair						
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
4.19	Does the outside area have proper drainage to prevent accumulation of standing water? Outside grounds and parking areas should be graded so water does not accumulate and stand. This water is a breeding place for mosquitoes and a source of water for insects, files and rodents. Once attracted to the outside of the facility, they may find their way into the facility.	Y			5	0	
4.20	Outside, are pallets and equipment stored correctly? All surplus equipment, tires and/or pallets should be stored at least 18 inches from the wall of the facility and off the ground. This will prevent this area from becoming a haven for rodents and insects that may then enter the facility.	Y			10	0	
4.21	Is the compactor/dumpster kept closed? To not attract flies, birds and rodents, it is essential that the garbage compactor/dumpster be kept closed when not in use. The ram should be kept in when not in use.	Y			10	0	
4.22	Are product contact surfaces corrosion-free? It is essential that exposed food items do not touch rusted surfaces, as this will cause adulteration of the product.	Y			15	0	
4.23	Is all equipment in good repair, have smooth product contact surfaces, and is easily cleanable? All equipment has to be totally cleanable to remove old product residues. Broken welds, cracked shields, etc., must be repaired. Old product residues attract rodents and insects, allow for growth of microorganisms and will contaminate the next product.	Y			15	0	
4.24	Is all equipment made of food-grade material? All food processing equipment, food utensils and food-contact surfaces have to be made from materials that are approved for use with food. These materials have to be cleanable, able to be sanitized and they cannot impart any toxic materials or pieces into the food product. Avoid toxic metals (galvanized metal, brass), concrete, etc.	Y			10	0	
4.25	Is all compressed air filtered? It is essential to filter all compressed air to remove oil droplets, water droplets and any harmful microorganisms, especially if the air is used to agitate the product, to open up a packet for filling, to clean up the equipment after use, etc. This air can be a source of contaminants that are then introduced into the food product. A 5 micron filter is suggested.	Y			10	0	
4.26	Are there floor drains for processing and cleanup (where needed?) Each plant should have sufficient drains to convey away all processing water, waste water, condensate water and cleanup water.	Y			10	0	

Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
	4.0 Maintenance and Repair						
4.27	Is wooden shelving used? 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. Pallets are acceptable, provided they are kept clean and in good repair. Wood should not be used as shelving in a cooler or freezer.			Y	0	0	
4.28	Are accurate, calibrated, thermometers present in all the freezers and coolers? Every freezer and refrigerated storage area, whether walk-in or reach-in, has to have an accurate and readily visible thermometer. This should be located in the warmest spot of the storage area.			Y	0	0	
4.29	Are temperature recorders on all equipment, where required? Certain processes by law require that certain temperatures be attained during processing and that a temperature recorded be operational at all times that the product is being processed (i.e., low acid canning, dairy products, etc.).			Y	0	0	
4.30	Are temperature logs kept on the freezers and coolers? To be able to determine if the coolers and freezers are working correctly and consistently, it is necessary to be taking temperature reading on all equipment daily. These temperature readings should be kept as a permanent log showing time of day, piece of equipment and temperature on the external and internal gauges. The time of day for taking the readings should be varied, and they should not be taken during a defrost cycle or 30 minutes after one. Readings should be taken a minimum of 1 time per shift. If the facility is a one shift operation, electronic monitoring must be in place.			Y	0	0	
4.31	Are all water lines protected against backflow/backsiphonage? Does the facility have documented proof that the building is back-flow prevented? All waterlines should have backflow preventers installed in the lines or screwed onto the hose bibbs. These will prevent contaminated water or sewage from being sucked into the potable water system, if the water pressure should drop. This is CRITICAL if the warehouse makes its own ice for use on produce. All facilities should have documented proof that building is back-flow prevented. This proof should be updated annually.	Y			10	0	

4.0 Maintenance and Repair							
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
4.32	Are there hand-wash, and if needed, hand-sanitize stations? All employees working in and around exposed food products need to be washing their hands regularly. There needs to be available to all employees hand-wash sinks supplied with soap, tempered water, hand towels and a waste receptacle. These need to be accessible and convenient to the employees and the number should be reflective of the number of employees at the facility. In the produce and repackaging areas it may be advisable to have, in addition, hand-sanitizing stations where the employees can sanitize their hands, therefore further reducing the chances of a food borne illness.	Y			10	0	
4.33	Are there hand-wash signs over hand-wash sinks in appropriate languages? All hand-wash sinks need to be marked as such with a sign reminding employees to wash hands before returning to work.	Y			5	0	
4.34	Are garbage and waste removed frequently? Garbage cans in the warehouse should 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 files, high bacterial growth, etc.	Y			10	0	
4.35	Examine the roof (if possible) for pooling of water, open vents, birds nesting, debris and obsolete equipment.			Y			
	Total Points				310	10	

	5.0 Cleaning Programs						
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With **Y**	Total Points	Points Deducted	AUDITOR COMMENTS
5.1	Are all dock areas clean including dock pits? All food spills and cobwebs need to be removed on a frequent basis to reduce the possibility of contamination and adulteration to the product.	Y			10	0	
5.2	Are areas under shelves, pallets, and / or racks clean? Housekeeping is an essential part of maintaining a clean and sanitary environment. It is important that the floors under all storage shelves and racks be swept on a daily basis to remove all items that have fallen on the floor and general dust and dirt. The warehouse also should be cleaned under pallets on a regular basis.	Y			10	0	
5.3	Are the processing areas clean? As part of a good housekeeping program, all dead insects and old spider webs should be removed on a regular basis. This includes floors, walls, ceilings, vents, etc. Areas under and behind the equipment and storage shelves must be kept clean.	Y			20	0	
5.4	Are all spills cleaned up immediately? To prevent microbial growth and to stop providing food for insects and rodents, all food spills in storage, produce and food repackaging areas should be picked up and/or mopped as soon as they occur.	Y			10	0	
5.5	Are ingredients, work-in-progress and finished products dust-free? All raw materials, work-in-progress, and finished products should be kept free of dust by good rotation and good housekeeping.	Y			10	0	
5.6	Are the repacking operations done under sanitary conditions? The food repacking areas should be walled off from storage areas, and there should not be doors leading directly into the food repacking areas from outside. This will, if complied with, reduce the chances of airborne contamination of the food. Damaged food should be repackaged and put back into the distribution system quickly or disposed of. If this does not occur, product can become insect-infested or otherwise contaminated and unfit for human consumption.			Y	0	0	
5.7	Are all coolers free of mold? All cooler areas should be kept clean to prevent mold growth, bacteria growth, and to keep from providing a potential food source for insects and rodents. The warehouse should be cleaning up all spills immediately and have a regularly scheduled program of cleaning and sanitizing to remove all dust and dirt. The surfaces need to be cleanable.			Y	0	0	

5.0 Cleaning Programs							
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
5.8	Are all freezers free of excess ice build-up? All freezer floors, walls and ceilings need to be examined on a regular basis for vapor barrier leaks that will allow for ice formation. This ice is composed of dirty water, and can lead to contamination of the product.			Y	0	0	
5.9	Are cooling units in the freezers and coolers clean? It is essential to keep cooling coils, drip pans and condensate piping clean as harmful bacteria (i.e., Listeria) has been found in these places. This bacteria can grow in refrigerated temperatures and if introduced into the food supply, can lead to death in persons who consume the food. Check if the facility has an environmental cleaning and sanitizing program to cover these units.			Y	0	0	
5.10	Is the ice machine clean? Water used for ice for product cooling has to be potable, free of harmful bacteria and other substances. If the facility is using ice for product contact, then the ice machine has to be clean and in good repair.			Y	0	0	
5.11	Equipment used in conveying, storing, repacking, etc., is in good condition and is clean and sanitary? All vehicles used for transporting food products around the warehouse should be kept clean. These vehicles can become infested with insects and / or mold which can then be transferred to the food product.	Y			5	0	
5.12	Are rest rooms and break rooms clean and sanitary? Are they properly supplied?

Toilet fixtures should be kept clean and in good repair. A supply of toilet tissue should be provided at each toilet at all times. Easily cleanable receptacles should be provided for waste materials. Women's rest rooms shall have a covered waste receptacle. Each hand-washing sink should have a supply of liquid hand soap, tempered water that runs for a minimum of 20 seconds when activated, and either disposable towels or an air dryer to dry hands.

If a hand sanitizer is made available to employees, it has to be used in addition to hand-washing and not in place of hand-washing. | Y | | | 10 | 0 | |
| 5.13 | Is there evidence that the garbage cans are cleaned on a regular basis? All garbage cans need to be kept clean so they do not become a source of odor or contamination. | Y | | | 5 | 0 | |

Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
5.14	Are floor drains clean and unblocked? Drains and sewer lines are a prime location for the growth of microorganisms that can cause foodborne illnesses. These must be kept in good working order. Are floor drains highlighted on plant schematic?	Y			5	0	
5.15	Are overhead fixtures clean? Cobwebs, residue, and dust can become an adulterant if the overhead fixtures are not cleaned on a regular basis.	Y			10	0	
5.16	Is equipment available to perform general housekeeping? Each facility should have (where applicable) mops, buckets, brooms, wash cloths, cleaners and sanitizers, etc., available to clean the warehouse. The equipment should be dedicated to cleaning and not used for any other purpose. This equipment should be kept in a sanitary condition and a good state of repair.	Y			10	0	
5.17	Is cleaning equipment stored in a separate area or cupboard? To not become a potential source of contamination or a breeding ground for cockroaches, all cleaning equipment should be stored in a separate room, closet or cabinet. Mops should be hung up to dry; mop buckets should be emptied and inverted ,when not in use, etc.	Y			10	0	
5.18	Is the facility using only cleaning chemicals approved for purpose? All chemicals need to be approved for use as per the written cleaning program. If food-contact surfaces are cleaned, then food-grade chemicals must be in use on these surfaces.	Y			10	0	
5.19	Are all cleaners used at the proper concentration? All cleaners must be used as per the instructions included in the written program.	Y			10	0	
5.20	Does the facility have sanitizer strength test strips / test kit, where applicable? The facility has to 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.			Y	0	0	
5.21	During cleaning, are all products and packaging protected? When cleaning the equipment or warehouse (walls, floors, etc.,) all cases of products, packaging, and food items should be removed from the immediate area or protected from splash.	Y			20	0	
5.22	Are all cleaning chemicals properly stored? All chemicals and sanitizers must be segregated from the storage areas to protect the products from adulteration. Ideally, all chemicals will be stored in locked rooms or cages.	Y			15	0	

	5.0 Cleaning Programs						
Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
5.23	Are all cleaners and sanitizers properly labeled? All cleaner and sanitizers have to be clearly and correctly identified as to type. If the original label is missing or illegible, then a new label should be placed on the container. This will help to prevent misuse of a cleaner or sanitizer or a possible employee accident.	Y			10	0	
5.24	Is the processing equipment clean? Examine all processing equipment that is not in use for cleanliness and lack of rust: open up tanks, take apart valves and piping, dismantle pumps and look for old products residues. Old product residues are an adulterant to new product and could result in a possible foodborne illness. This should include all equipment used to hold, store or convey product.	Y			20	0	
5.25	Are filters, screens and sieves clean? The plant should have a regularly scheduled program for cleaning all filters, screens, sieves, metal detectors, etc. This should also include examining these pieces of equipment for their condition and ability to perform the task they are supposed to perform.	Y			10	0	
5.26	Are non-product-contact surfaces clean? The outside of equipment, underneath tables and conveyors, on top of shelves and storage shelving should be kept clean. These areas can, if not kept clean, become growth sites for mold and other harmful microorganisms.	Y			10	0	
5.27	Is disused equipment clean and stored with food-contact surfaces protected? All equipment that is not in use should be stored with the food-contact surfaces protected. If small, the equipment can be stored inverted. If large, then the equipment can be stored with a lid on it, covered with plastic or otherwise protected from airborne contamination.	Y			10	0	
5.28	Is there sufficient hot water to clean the plant? To clean any plant and its equipment, it is essential that there is sufficient hot water to do all cleaning. To properly dissolve soil and grease, water should reach at least 120°F. Cleaning with cold or only warm water will not accomplish the task at hand.	Y			10	0	
5.29	Is the microbiological load on the equipment monitored (where appropriate)? 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.	Y			10	0	
5.30	Is Environmental swabbing done to test the present of Listeria?			Y	0	0	

5.0 Cleaning Programs

Section	QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y") Explain in notes section if any items DO NOT COMPLY."	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
5.31	Is sanitation equipment color-coded to prevent cross-contamination (where appropriate)? Brushes should be color-coded as to the surface on which they are used: one color for equipment handling raw foods, another color for cooked, etc. Sanitation brushes used on the floor must be a different color.			Y	0	0	
5.32	Are excess lubricants and grease removed from equipment, or are there instances of dripping lubricant? Maintenance, when greasing and lubricating equipment, should not use excess material and should wipe off any excess that is used.	Y			10	0	
5.33	Are all sprinkler risers, guard rails, fire extinguishers, etc., clean and unblocked? It is important that these items be kept clean so that dirt does not contaminate the associates or equipment.	Y			5	0	
5.34	Is the area around the compactor / dumpster kept clean? The area around the compactor / dumpster should be swept and washed down daily to limit food and nutrients for birds, flies, and insects. The compactor / dumpster should not have any holes that will let liquids leak out on the floor. The pad under the compactor / dumpster should be smooth, in good repair and sloped to drain to the sanitary sewer. The area around the compactor / dumpster should be kept clean and odor-free.	Y			15	0	
	Total Points				280	0	

	6.0 ALLERGENS/SENSITIZING INGREDIENTS						
Section	**QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y"). Explain in notes section if any items DO NOT COMPLY."**	Complies	Does Not Comply	Not Applicable Mark With Y	Total Points	Points Deducted	AUDITOR COMMENTS
6.1	The facility keeps records on the presence of any of the legally-defined allergen foods and food systems that are received and/or stored at the facility, along with storage methods (air-tight, moisture-vapor-barrier packaging or permeable packaging that represents a greater threat for cross-adulteration).	Y			25	0	
6.2	The program contains a list of the major allergens appropriate to its geographic locale and its customer base (eight major allergens in the United States, eleven major allergens in Canada, and appropriate additions for other markets).	Y			5	0	
6.3	The facility has a written Standard Operating Procedure for the proper handling and control of allergens.	Y			30	0	
6.4	The procedure includes a method of segregation and other methods for prevention of cross-adulteration for known allergens during storage.	Y			20	0	
6.5	The facility provides designated storage sites, where possible, for major allergen foods packaged in non-air tight containers so that cross-contamination of non-allergens can be eliminated or minimized.	Y			15	0	
6.6	All allergens are stored in original containers or clearly labeled containers.	Y			10	0	
6.7	Signs or other markings indicate allergen storage areas.	Y			10	0	
6.8	There is no mixed pallet of allergen products in the storage area.	Y			10	0	
6.9	The facility has written procedures for clean-up and disposal of allergen foods that escape from their packaging due to accidental damage, along with items such as pallets and racking that may have been adulterated with allergen-containing materials.	Y			20	0	
6.10	The facility has written procedures for prevention of cross-adulteration during manufacture of products (both for production of finished products with and without allergens and of finished products with different allergen profiles).	Y			25	0	
6.11	The facility has a written procedure in place to validate sanitation methods of production equipment that demonstrates that removal of allergens is adequate. Results of this validation method will be available.	Y			15	0	
	Total Points				185	0	

7.0 SECURITY							
Section	**QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y"). Explain in notes section if any items DO NOT COMPLY."**	**Complies**	**Does Not Comply**	Not Applicable Mark With **Y**	Total Points	Points Deducted	AUDITOR COMMENTS
7.1	Has the facility registered with the FDA per the provisions of the Bioterrorism Act of 2002? Note: facilities under the inspection of USDA, FSIS are not required to register with FDA. Facility must have documentation.	Y			20	0	
7.2	Does the facility have a designated and trained Food Security Team or designated coordinator, with emergency contact information? Facility must have documentation.	Y			20	0	
7.3	Does the facility have an emergency contact list that includes government contacts for use in case of an incident of intentional product tampering or food security threats? Facility should have documentation.	Y			5	0	
7.4	Does the facility have a food security plan in place and maintained, for emergencies? Facility must have documentation.	Y			10	0	
7.5	Has the facility conducted an assessment on which the food security plan is based? Facility must have documentation.	Y			5	0	
7.6	Does the facility have controlled entry into it, with a clear method of identifying visitors and a record of visitors? The facility must document the method by which visitors are allowed into the facility and identified.	Y			10	0	
7.7	Does the facility have controlled access into it? Example: Swipe cards, key code pads, etc.	Y			5	0	
7.8	Does the facility have a procedure for handling visitors, contractors and inspectors, including escorting them in the facility? Facility must provide documented procedure.	Y			5	0	
7.9	Does the facility perform periodic food security self-inspections? Records must be on file.		Y		5	5	No inspections being done at this time
7.10	Does the facility monitor all incoming shipper trailers for seals or locks where appropriate? Records must be on file.	Y			5	0	
7.11	Does the facility seal all outgoing full trailers and record seal numbers on bill of lading? Records must be on file. LTL loads generally do not require seals.	Y			5	0	
7.12	Does the facility control access to their main power source? Where is the main panel and how is it access controlled?	Y			5	0	
7.13	Does the facility control access to their phone line? Where is the main phone line and how is it access controlled?	Y			5	0	

7.0 SECURITY							
Section	**QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y"). Explain in notes section if any items DO NOT COMPLY."**	Complies	Does Not Comply	Not Applicable Mark With **Y**	Total Points	Points Deducted	AUDITOR COMMENTS
7.14	Does the facility control access to their computer systems? Computer systems should be password protected or have an equivalent method of control.	Y			5	0	
7.15	Does the facility control access to their refrigeration system? Where is the main refrigeration system and how is it access controlled?			Y	0	0	
7.16	Does the facility ensure that new employee do not pose a clear risk prior to starting employment? This can be accomplished using background checks, verifying references, or other systems.	Y			5	0	
7.17	If trailers are used to store raw materials, packaging, or finished goods while at the facility, are they secured?			Y	0	0	
7.18	Are the facility emergency exits locked and secured from the inside and are not blocked? Observe emergency exits during visual inspection of the facility.	Y			5	0	
7.19	Are all employee and visitor entrances clearly marked and used?	Y			10	0	
7.20	Are permanent employees trained to raise their awareness of facility and food security issues?	Y			10	0	
7.21	Are the office areas secured and locked with only access to authorized personnel?	Y			5	0	
7.22	Are there security alarms and an alarm service if appropriate?			Y	0	0	
	Total Points				145	5	

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	8.0 HACCP						
Section	**QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y"). Explain in notes section if any items DO NOT COMPLY."**	**Complies**	**Does Not Comply**	Not Applicable Mark With **Y**	Total Points	Points Deducted	AUDITOR COMMENTS
8.1	The facility has a documented HACCP Program that is compliant with the requirements appropriate to the facility and types of products manufactured (such as Codex Alimentarius, NACMCF, Seafood HACCP).			Y	0	0	
8.2	A HACCP Team has been appointed, with a list of its membership, to include names and job titles, included as part of the HACCP Program.			Y	0	0	
8.3	A list of products manufactured by the facility is available, which includes the following: 1. Product name or names 2. Type of packaging 3. Shelf life as declared on the immediate package 4. Distribution and / or final point of sale 5. Special labeling instructions (e.g. ,"Keep Refrigerated Or Frozen") 6. Special distribution controls required (e.g., shipping at specific temperatures or humidity) 7. Whether or not the product is targeted to populations which may require additional or stricter food safety requirements (such as children, the elderly, and people with chronic medical conditions) 8. Special characteristics which may require added measures of manufacture or distribution (such as allergens, kosher, halal, and Certified Organic). Products can be grouped into categories if the same process is used to manufacture them.			Y	0	0	
8.4	The intended use for all products is included as part of the list of products.			Y	0	0	
8.5	A flow diagram of all processes the facility uses to manufacture product is available. The flow diagram should include only process steps, and include all steps from receiving to shipping. If all process steps are not included, the flow diagram is not compliant.	Y			20	0	
8.6	All flow diagrams include Critical Control Points if the process has them.			Y	0	0	
8.7	A Hazard Analysis has been performed on all inputs the facility uses, including raw materials, ingredients, and packaging.			Y	0	0	
8.8	A Hazard Analysis has been performed on each process the facility uses. The process steps in the Hazard Analysis must exactly match the steps included in the Flow Diagram for that particular process.			Y	0	0	
8.9	The Hazard Analyses must describe exact types of evaluated hazards based on the following criteria: 1. Hazards of a biological nature ("Contamination" is not sufficient; the type of microorganism must be cited) 2. Hazards of a chemical nature (at the least, the classification of chemical, such as cleaners, must be cited) 3. Hazards of a physical nature (if a physical control measure is used, the type of adulteration, such as metal, must be cited) 4. Hazards caused by allergenic materials; these can also be categorized under chemical hazards			Y	0	0	
8.10	Hazards designated by the Hazard Analyses must be appropriate to the processing step and must be possible to occur.			Y	0	0	

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	8.0 HACCP						
Section	**QUESTIONS & STATEMENTS ARE ALL OR NOTHING (Mark Comply or Does Not Comply with "Y"). Explain in notes section if any items DO NOT COMPLY."**	**Complies**	**Does Not Comply**	Not Applicable Mark With **Y**	Total Points	Points Deducted	AUDITOR COMMENTS
8.11	Critical Control Points must be listed on the Hazard Analysis (if appropriate; if the facility has no Critical Control Points in its processes, then all elements from this one, inclusive, are not applicable except for the final element)			Y	0	0	
8.12	Critical Limits for each Critical Control Point must be established.			Y	0	0	
8.13	Critical Limits must have the following characteristics: they must be quantifiable (it must have some numerical value, including zero), measurable (using an appropriate method; this can include visual observation), able to be documented, and justified scientifically or through appropriate regulations.			Y	0	0	
8.14	Critical Limits must be appropriate to control or mitigate the hazard it is intended to monitor.			Y	0	0	
8.15	Monitoring procedures for each Critical Control Point must be established. Monitoring procedures must be documented, and must contain the following: what is to be monitored (e.g., internal temperature of product, the temperature of a refrigerated room, etc.), the method of monitoring and equipment used in monitoring (e.g., a calibrated thermometer), the frequency of monitoring, and the party responsible for performing monitoring.			Y	0	0	
8.16	Monitoring documentation for all Critical Control Points must be available and complete, with all necessary information included and the ability to identify the person monitoring the Critical Control Point.			Y	0	0	
8.17	A procedure for applying corrective action in case of the Critical Limit being exceeded must be documented for each Critical Control Point.			Y	0	0	
8.18	The corrective action must be effective in being able to bring the Critical Limit back into compliance, isolate and identify all product manufactured during the period when the Critical Control Point may have been non-compliant, and identify methods of ensuring that such product either does not re-enter the process or verifies that such product is safe to re-enter the process.			Y	0	0	
8.19	Each Critical Control Point must have a method of being verified. This will include such methods as review of monitoring documentation, calibration of instruments used to measure the Critical Control Point, and/or a physical check of monitoring activities. The method of monitoring and all verification activities will be documented. Verification documentation will be available.			Y	0	0	
8.20	The method of recordkeeping at each Critical Control Point shall be documented, along with a list of all documentation used for monitoring and verification.			Y	0	0	
8.21	The HACCP program shall be reassessed for changes to processes or procedures at least once per calendar year. Records of any reassessments, or of changes to the HACCP program, shall be maintained and available.			Y	0	0	
	Total Points				20	0	

APPENDIX A

MOCK RECALLS/TRACEABILITY EXERCISE REQUIRED DURING ASI AUDITS

The ASI Auditor should verify that Mock Recalls / Traceabilities have been conducted on a six-month frequency to assess the effectiveness of the program. The latest Mock Recall / Traceability shall be on file, available for review, and account for 100%

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

The ASI Auditor must assure that this exercise includes the elements that apply:
- finished product
- raw materials
- ingredients
- packaging
- processing aids

The ASI Auditor must ensure that a comprehensive written (clear, concise and current) Mock Recall/Traceability program is available for review during the exercise. This program should include:

	YES	NO
Recall Team Name	Hi -Tech	
Recall Team # Office	717-667-2142	
Recall Team # After Hours	717-437-5797	
Regulatory Contact Plant	Sherry Thompson	
Customer Contact Plant	Sherry Thompson	
Regulatory Contact Office	Sherry Thompson	
Customer Contact Office	Sherry Thompson	

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

Records of Mock Recalls:
On file.

Standard Form To Summarize Results, Including	
Material to be traced:	Barley with chromium Tablets
Production Date:	8/19/14 to 8/25/14
Lot Numbers:	30099
Quantities produced on Production Day:	984,450 tablets
Quantities in House:	0
Quantities Shipped:	984,450 tablets
cent of materials located (no recovery necessary):	100%
Length of time needed to complete Mock Recall:	11 minutes

Issues Noted During Mock Recall:

Corrective Action for any issues noted:

MOCK RECALL SHALL BE PERFORMED SUCCESSFULLY IN 2 HOURS, AND ACCOUNT FOR 100% (+ - 5%) OF TEST PRODUCT. (SEE ITEM # 1.17 FOR SCORING ? RATING)

Please fax to 314.727.2563
Or mail to: 7625 Page Ave
St. Louis, MO 63133

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Food Safety Consultants

Customer Service Survey

FACILITY NAME: _____

ADDRESS: _____

CITY, STATE, ZIP: _____

AUDIT DATE: _____ SCORE: _____ ASI AUDITOR NAME: _____

ANNOUNCED: ☐ Yes   ☐ NO

    1.   WAS THE AUDITOR ON TIME?

    ☐ Yes   ☐ NO

    2.   WAS THE AUDITOR THOROUGH?

    ☐ Yes   ☐ NO

    3.   DID THE AUDITOR LEAVE A HARD COPY OF THE CORRECTIVE ACTIONS?

    ☐ Yes   ☐ NO

    4.   WAS YOUR CORRESPONDENCE WITH ASI CORPORATE PLEASANT?

    ☐ Yes   ☐ NO

    5.   DID YOU RECEIVE A LETTER CONFIRMING YOUR AUDIT?

    ☐ Yes   ☐ NO

    6.   DID YOU RECEIVE YOUR AUDIT REPORT AND CERTIFICATES IN A TIMELY MANNER?

    ☐ Yes   ☐ NO

    7.   DID THE AUDITOR CONDUCT A CONCLUDING CONFERENCE?

    ☐ Yes   ☐ NO

GRADE THE AUDITOR: ____A____B____C____D____F (A=Excellent: F=Poor)

GRADE ASI CORPORATE:____A____B____C____D____F (A=Excellent: F=Poor)
SEND ME INFORMATION ON ☐ SQF   ☐ BRC   ☐ ON-SITE TRAINING

ADDITIONAL COMMENTS:

┌──┐
│   │
│   │
│   │
│   │
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