

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
SECTION A: GOOD MANUFACTURING PRACTICES AND GOOD AGRICULTURAL PRACTICES									
1.0 MANAGEMENT RESPONSIBILITY									
1.1 Management Commitment and Review									
General	1.1.1	Is a Mission Statement and Product Safety Policy documented and communicated to all levels of the organization?	4						
General	1.1.2	Is an organizational chart in place that identifies positions responsible for Food Safety System compliance including descriptions of responsibilities?	4						
General	1.1.3	Is management following Current Good Manufacturing Practices (cGMPs) (21 CFR Part 110) and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables?	7						
General	1.1.4	Are first aid kits readily accessible to all employees and appropriately stocked?	4						
		Other Section Total Points	19		0	0	0	0	0
2.0 FUNDAMENTALS									
2.1 Employee Practices (Assessed by Observation and Documentation)									
General Expectation: Compliance with 21 CFR 110.10 (a) and (b), 110.37 (e)(5), and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section IV.A. and B.									
Employee Practices	2.1.1*	1. Are employees with: a. open and/or infected wounds or cuts on their hands or face, or with symptoms of infectious illness (e.g., diarrhea, vomiting), prohibited from having direct contact with exposed product or production and/or storage areas? b. signs of communicable disease evaluated? (e.g., observations) 2. Are corrective actions taken if a worker is found to be infected?	10						
Employee Practices	2.1.2	Are employees maintaining: a. clean clothing or uniforms including outer garments? (e.g., aprons, smocks, lab coats) b. adequate personal cleanliness?	7						
Employee Practices	2.1.3*	Are employees removing aprons, gloves, and other protective clothing (when in use) before leaving the product handling area?	10						
Employee Practices	2.1.4	Are employees wearing hair restraints (e.g., hair nets, caps, headbands) and/or beard covers in an effective manner in product handling areas?	7						
Employee Practices	2.1.5	Are employees prohibited from: a. wearing any jewelry other than a plain wedding band? b. wearing false eyelashes or finger nails and finger nail polish? c. carrying loose items, such as pens or thermometers, in above-the-waist pockets?	7						
Employee Practices	2.1.6*	Are employees washing and/or sanitizing hands and/or gloves prior to beginning or returning to work, or whenever the hands and/or gloves may have become soiled or contaminated?	10						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Employee Practices	2.1.7	Are employees maintaining gloves, if they are used in product handling, in an intact, clean, and sanitary condition? NOTE: The gloves should be of an impermeable material.	7						
Employee Practices	2.1.8*	Are employees prohibited from eating food, drinking beverages, spitting, chewing gum, and using tobacco and/or toothpicks in product handling areas? NOTE: Food consumption should also be prohibited in locker rooms.	10						
Employee Practices	2.1.9*	Are all mushrooms, materials, and packaging that come in contact with blood destroyed, and any equipment, tools, and/or product contact surfaces that come in contact with blood cleaned and sanitized before use?	10						
Employee Practices	2.1.10	Does the operation have a written policy, which addresses applicable worker health and hygiene issues?	7						
Employee Practices	2.1.11	Are readily understandable written signs and/or pictures in appropriate language(s) strategically located around the product handling areas? (e.g., reminding employees to wash and sanitize their hands, when necessary, cGMPs policy)	4						
Employee Practices	2.1.12	Are employees storing their clothing or personal belongings in appropriate designated areas away from the product handling areas? NOTE: Food storage should be prohibited in lockers.	7						
Employee Practices	2.1.13	Is movement of employees and visitors between mushroom growing areas and Composting production or staging areas controlled to prevent contamination?	7						
Employee Practices	2.1.14	Are identification badges or cards issued to all employees that clearly indicate current employment status with the company. IDs should be returned upon resignation or dismissal.	4						
		*Food Safety Section Total Points	50		0	0	0	0	0
		Other Section Total Points	57		0	0	0	0	0
2.2		Training and Education (Assessed by Observation, Interview, and Documentation)							
		General Expectation: Compliance with 21 CFR 110.10 (c) and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section IV.2.0							
Training & Educ.	2.2.1	Is there a documented employee training program, which includes initial and ongoing and/or refresher food safety training (e.g., cGMPs, personnel practices) for all employees, and training on cleaning and sanitation procedures for sanitation employees?	7						
Training & Educ.	2.2.2	Is there an assigned person or an outside agency responsible for conducting training on topics such as food safety, cGMPs, and sanitation and cleaning procedures?	4						
Training & Educ.	2.2.3*	1. Is there an initial and ongoing and/or refresher employee training program that addresses food safety related issues (e.g., cGMPs, personnel practices, sanitation procedures) to all employees, including new employees? 2. Is the general content of the training sessions included? (e.g., topics covered, who was trained, who provided the training, date of training)	10						
Training & Educ.	2.2.4	Is worker participation in respective training programs (initial and ongoing and/or refresher, addressed in 2.2.3) documented, including the employee's signature, and available for review?	4						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Training & Educ.	2.2.5	1. Do employees appear to have received and understood training and are they practicing proper product handling procedures? 2. Have employees been trained to dispose of any mushrooms, that come in contact with blood or other bodily fluids? 3. Have employees been trained that product that comes into contact with the ground is discarded?	7						
Training & Educ.	2.2.6*	Is there a supervisor with relevant educational background and/or experience, who oversees the food safety practices? (e.g., sanitation, cGMPs)	10						
		*Food Safety Section Total Points	20		0	0	0	0	0
		Other Section Total Points	22		0	0	0	0	0
2.3 Sanitary Facilities (Assessed by Observation and Documentation) General Expectation: Compliance with 21 CFR 110.37 (d) and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section V.									
(a) Toilet Facilities General Expectation: Each facility shall provide its employees with adequate, readily accessible toilet facilities.									
Toilet Facilities	2.3.1*	1. Is a minimum of one toilet facility provided for every 20 people? 2. Are separate toilet facilities provided if there are 5 or more employees of each gender? 3. Are toilet facilities located within a 5-minute walk or 1/4 mile for all workers?	10						
Toilet Facilities	2.3.2*	1. Are toilet facilities located and/or designed so as to reduce the possibility of contamination to water sources or product in the event of a malfunction? (e.g., adequate drainage). 2. Are doors to toilet facilities situated so they do not open into areas where product is exposed to air-borne contamination, except where alternate means have been taken to protect against such contamination? (e.g., double doors or positive air-flow systems)	10						
Toilet Facilities	2.3.3	Do toilet facilities have: a. self-closing doors? b. ventilation systems to eliminate odors? c. floors, walls, ceilings and toilets built in such a way that they can be cleaned and sanitized properly? d. floors, walls and ceilings in good repair? e. functional toilets and urinals? f. trash receptacles?	7						
Toilet Facilities	2.3.4	Are toilet facilities maintained in clean condition?	7						
Toilet Facilities	2.3.5	Are toilet supplies monitored and/or stocked throughout the day?	7						
Toilet Facilities	2.3.6	1. Are the cleaning procedures described in a document that details how and when to clean (at least daily)? 2. Is cleaning documented and are records legible?	7						
(b) Hand washing facilities General Expectation: Compliance with 21 CFR 110.37 (e) and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section V.									
Hand washing	2.3.7*	Are hand washing stations provided next to the toilet facilities to facilitate their use?	10						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Hand washing	2.3.8	Are additional hand washing stations and, where appropriate, hand sanitizer stations (e.g., hand dips, wall units) provided in the facility where good sanitary practices require employees to wash and/or sanitize their hands? (e.g., at entries to product washing, sorting, and/or packing areas)	4						
Hand washing	2.3.9*	Are hand washing stations located and/or designed: a. to prevent contamination of the product (e.g., water is not splashed near product or product contact surfaces) and to protect against recontamination of clean, sanitized hands? (e.g., installation of devices and/or fixtures such as water control valves) b. to facilitate hands-free operations?	10						
Hand washing	2.3.10	1. Are single-use paper towels or air drying devices used at hand washing stations? 2. Are hand washing stations functional (e.g., not leaking) and equipped with warm running water, bacteriostatic soap, and/or an appropriate hand sanitizer? 3. Are written signs and/or pictures in appropriate language(s) located next to the hand washing stations reminding employees to wash and sanitize their hands, when necessary?	7						
Hand washing	2.3.11	1. Are hand washing stations and/or hand sanitizing stations (e.g., hand-dips, wall units) monitored and/or stocked throughout the day? 2. Is the chemical concentration in hand-dips maintained at appropriate concentration at all times, documented, and available for review?	7						
Hand washing	2.3.12	1. Are hand washing and/or hand sanitizing stations maintained in clean condition? 2. Are hand washing and/or hand sanitizing stations cleaned on a scheduled basis and as needed?	7						
		*Food Safety Section Total Points	40		0	0	0	0	0
		Other Section Total Points	53		0	0	0	0	0
2.4		Water (Assessed by Observation and Documentation)							
		General Expectation: Compliance with 21 CFR 110.37 (a) and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section II.							
(a)		Water Source Testing							
Water Source Testing	2.4.1	1. Is water with adequate quality provided in sufficient quantities and locations in the facility? 2. Are analytical tests for water kept on file? 3. If results are out of specification, are corrective actions documented and legible?	4						
(b)		In-house Water Testing							
Water Test	2.4.2*	1. Is the water supply checked for microbial quality from several different locations in the facility on a periodic basis? 2. Are analytical tests for water kept on file? 3. If results are out of specification, are corrective actions documented and legible?	10						
Water Test	2.4.3	Are drinking water supply delivery points, fountains or containers maintained in a clean and sanitary manner, with single use paper cups provided where appropriate?	4						
Water Test	2.4.3	Are wells regularly inspected and maintained to prevent them from contamination?	4						
		*Food Safety Section Total Points	10		0	0	0	0	0
		Other Section Total Points	8		0	0	0	0	0

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
2.5 Grounds (Assessed by Observation and Documentation) General Expectation: Compliance with 21 CFR 110.20 (a) and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section VII.B.3.0									
Grounds	2.5.1*	1. Is there a written policy, which describes the required maintenance of grounds and is it being followed? 2. Are roads, yards, and parking lots maintained in a condition so that they do not constitute a source of contamination in areas where product is exposed? (e.g., keeping weeds or grass cut, no pot holes and adequate surface drainage to prevent foot-borne filth and breeding places for pests)	10						
Grounds	2.5.2	Is 16-18 inches of clearance maintained around the outside perimeter of the building?	7						
Grounds	2.5.3	Is equipment and/or materials, which is stored on the grounds, stored in a manner so as to prevent harborage of pests? (e.g., idle equipment and/or material is at least 20 feet away from any buildings and 6 inches off the ground (pallets are acceptable), pipes must have sealed ends)	7						
Grounds	2.5.4	Do all trash receptacles have closed lids?	4						
Grounds	2.5.5*	Is litter collected and waste stored and/or disposed of in a manner adequate to minimize the odor, prevent contamination of product and/or become an attractant to vermin?	10						
Grounds	2.5.6*	Are appropriate measures taken that seepage and runoff from composting area (phase I) is collected or diverted so that they cannot reach growing areas? DOWN SCORE IN THIS QUESTION IS AN AUTOMATIC FAILURE.	10						
		*Food Safety Section Total Points	30		0	0	0	0	0
		Other Section Total Points	18		0	0	0	0	0
2.6 Building Size, Construction and Design (Assessed by Observation and Documentation) General Expectation: Compliance with 21 CFR 110.20 (b), 21 CFR 110.37 (b), and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section VII.B.2.0									
(a) Building Size, Construction and Design									
Building Size, Construction and Design	2.6.1*	1. Are Phase I preparation and storage separate from Phase II substrate, casing materials and finished casing so that cross contamination cannot occur? 2. Is the facility constructed and/or arranged so to allow complete separation of ingredients, in-process, and finished products, to reduce potential for cross-contamination? 3. Are packaging material and product storage areas completely enclosed?	10						
Building Size, Construction and Design	2.6.2	Are working spaces provided between equipment and walls, and are they adequately unobstructed and of adequate width to allow employees to perform their duties and to protect against contaminating product or product contact surfaces with clothing or personal contact?	7						
Building Size, Construction and Design	2.6.3	Are employee break and/or locker areas separate from the product handling areas?	7						
Building Size, Construction and Design	2.6.4	1. Is adequate lighting available in all areas where the product is manufactured, examined, packaged, or stored, and in all employee areas? (e.g., to allow for product to be properly fabricated, stored, rotated) 2. Is adequate outside lighting provided to permit adequate inspection of the facilities?	7						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Building Size, Construction and Design	2.6.5*	Does the system for removing waste materials from product handling area work efficiently? (e.g., litter and waste stored and/or disposed of in a manner adequate to prevent contamination of product and/or become an attractant to vermin)	10						
(b) Building Structures/Fixtures									
Building Structures/Fixtures	2.6.6	Is the roof properly maintained? (e.g., no leaks)	7						
Building Structures/Fixtures	2.6.7	1. Is the facility and its structures, such as ceilings, walls, floors, windows, vents, drains, and overheads (e.g., pipes, air vents, and lights) designed and constructed of materials to be adequately cleaned and maintained in good repair, to protect product from cross-contamination? (e.g., using appropriate construction materials) 2. Are these areas kept in good repair? (e.g., no deep holes or cracks, exposed foam materials, and broken windows and lights)	7						
Building Structures/Fixtures	2.6.8*	Are overhead fixtures, ducts, and pipes located over product contact surfaces, packaging materials, and exposed products, maintained in clean and good condition? (e.g., no cracks, rust, breakage, missing parts, or drips)	10						
(c) Plumbing									
Plumbing	2.6.9	Is water used for cleaning of equipment, utensils, and for employee sanitary facilities maintained at a suitable pressure?	4						
Plumbing	2.6.10*	Are sewer pipes and water pipes placed to avoid possible contamination of product or equipment in the event of a leak or dripping from condensation, and are preventative measures in place?	10						
Plumbing	2.6.11*	Are the water lines for product handling and/or employee use protected against back-flow or cross-connections from the wastewater and sewage plumbing system? (e.g., there is a main water back-flow device as well as devices at points where there is potential for back-flow into potable water lines)	10						
Plumbing	2.6.12	Is there adequate floor drainage in areas where floors are subject to flood-type cleaning, or where normal operations release or discharge water or other liquid waste on the floor, and is there a procedure in place to remove discharge?	7						
Plumbing	2.6.13*	If potable and non-potable water is provided at the facility, is the water source and plumbing system identified potable vs. non-potable, and are they separate?	10						
(d) Environmental Control									
Env. Control	2.6.14	1. Is proper ventilation or control equipment in place to minimize odors? 2. If fans or other blowing equipment are used, are they operated in a manner that minimizes the potential for contaminating product, equipment, or packaging materials? 3. Are filters in air conditioning, ventilation and air filtration units regularly cleaned and replaced when necessary?	4						
Env. Control	2.6.15	1. Are disinfectant foot foamers, foot baths, or foot sprayers provided at entries to product handling areas if appropriate? 2. Are sanitizer concentrations monitored regularly, documented, and available for review?	7						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
		*Food Safety Section Total Points	60		0	0	0	0	0
		Other Section Total Points	57		0	0	0	0	0
2.7		Pest Control Program and Procedures (Assessed by Observation and Documentation)							
General Expectation: Compliance with 21 CFR 110.20 (b)(7), 21 CFR 110.35 (c) and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section VII.B.2.0									
Pest Control	2.7.1	Is there a written pest control program and is it available for review?	7						
Pest Control	2.7.2	1. Are pesticide applications performed by trained and licensed/certified personnel? 2. Are the service agreement, license and certificate of insurance (if service is provided by an outside company) current and available for review? 3. Does the facility have an assigned person responsible for overseeing the pest control program and is this responsibility documented?	4						
Pest Control	2.7.3*	1. Do pesticides, chemicals, or other pest control measures meet applicable regulations (e.g., USDA, EPA, OSHA)? 2. Are MSDSs and copies of labels for all chemicals and compounds used available for review?	10						
Pest Control	2.7.4	1. Are locations of all traps (e.g., glue boards, bait stations, light traps, pheromone traps or any other device in use) indicated on a facility map, which is cross-referenced to a list or a key on the map showing the descriptions and/or types of traps at each station? 2. Is the facility map signed and dated (verified as accurate) within last year?	4						
Pest Control	2.7.5	Are pest control stations properly coded (e.g. ID #, bar code) to correspond with the master identification map?	4						
Pest Control	2.7.6*	1. Is there an adequate number of interior pest control devices, spaced at intervals (typically 25-30 feet) along the interior perimeter of the facility, including on both interior sides of overhead doors? 2. Is there an adequate number of secured (to the ground, building or some type of block), tamper resistant (lid must be secured and require some type of "key" or other device to open) exterior pest control devices, spaced at intervals (typically 30-50 feet) around the building perimeter? 3. Are pest control stations set-up or constructed to avoid product, packaging, or equipment contamination?	10						
Pest Control	2.7.7	Are live catch devices and glue boards checked at least bi-weekly, insect traps checked at least monthly, and bait stations checked for fresh bait at least monthly?	7						
Pest Control	2.7.8	1. Are pest control devices functioning properly? 2. Are pest control exclusion devices (e.g., light traps, mechanical traps) cleaned and maintained on a scheduled basis?	4						
Pest Control	2.7.9*	Is there no evidence of decomposed rodents in the interior or exterior pest control devices?	10						
Pest Control	2.7.10*	Does the inside of the facility appear to be free from insects, rodents, birds, and domestic animals?	7						
Pest Control	2.7.11*	Is there no evidence of insect, rodent, or bird activity on or in product, packaging, and product-contact surfaces (e.g., excreta, feathers)?	10						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Pest Control	2.7.12	1. Are insect-exclusion devices used appropriately at exterior entrances (e.g., air curtains, light traps)? 2. Are insect exclusion devices cleaned and maintained on a scheduled basis?	7						
Pest Control	2.7.13	Are all light traps positioned so that they will not attract insects from outside, into the building?	4						
Pest Control	2.7.14	Are destructive type traps located at least 30 feet from exposed product or packaging and 5 feet away from covered product or packaging?	7						
Pest Control	2.7.15	Are birds controlled by netting, screens, traps, or other exclusion methods? (Application of avicides are prohibited in the facility.)	7						
Pest Control	2.7.16*	Is toxic bait used only in exterior bait stations?	10						
Pest Control	2.7.17	Are inspection records /inspection reports from the past twelve months available for review, including: dates of inspections, findings, corrective actions/steps taken to eliminate any problems, trap observations, trend reports, pesticide application, and equipment used.	7						
Pest Control	2.7.18*	1. Have cracks or crevices been sealed to prevent entrance or harborage of pests? 2. Are outside drains protruding from exterior building walls screened? 3. Are doors and windows sealed to prevent gaps greater than 1 inch? 4. Are windows and exterior doors, vents, fans, and other similar features screened, and rodent-proofed to protect against insect and rodent entry and infestation? 5. Do dock door levelers have intact seals?	10						
Pest Control	2.7.19	Are exterior doors and entrances closed when not in use?	4						
Pest Control	2.7.20	If pest control chemicals are stored on site for pest control, are they properly labeled and kept in secure, locked areas, away from any product handling and packaging material storage areas?	7						
Crop Protection	2.7.21*	Is a written procedure in place for use and handling (loading and/or mixing) of crop protection materials?	10						
Crop Protection	2.7.22	Are there documentations that show employees who handle crop protection materials are trained or are under the supervision of a trained person?	4						
Crop Protection	2.7.23*	Do all applied crop protection materials meet applicable regulations (e.g., USDA, EPA, OSHA) and are they registered in the country of use for the target crop where official registration is required?	10						
Crop Protection	2.7.24*	Are crop protection preparations and applications conducted according to the label instructions, manufacturer's recommendations, and/or by local and/or national standards and guidelines?	10						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Crop Protection	2.7.25*	1. Are records of crop protection material applications (spray histories) maintained and current? 2. Does the application records indicate information such as re-entry period, application dates, amount applied, type of equipment used and target pests?	10						
Crop Protection	2.7.26*	Are the required pre-harvest intervals indicated on the crop protection chemical product labels, manufacturer's recommendations, and/or by local and/or national standards and guidelines, adhered to by the grower when harvesting is restricted by pre-harvest intervals?	10						
Crop Protection	2.7.28*	Are workers restricted from entering the area based on the re-entry interval established?	10						
Crop Protection	2.7.29*	Are re-entry interval signs posted in the area(s) treated when crop protection applications occur? Is this in accordance with local and/or national standards and guidelines?	10						
Crop Protection	2.7.30*	If crop protection containers are kept on the property, even on a temporary basis, are they stored in a secure manner to prevent contamination?	10						
Crop Protection	2.7.31*	If empty crop protection containers are disposed of by the farm operation, are they disposed of according to the label and/or regulatory instructions?	10						
Crop Protection	2.7.32*	Is crop protection application equipment inspected and calibrated periodically?	10						
		*Food Safety Section Total Points	160		0	0	0	0	0
		Other Section Total Points	84		0	0	0	0	0
2.8		General Operational Practices and Procedures (Assessed by Observation and Documentation)							
		General Expectation: Compliance with 110.80 (a) and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section II, Section VII.B.2.0							
(i)		Product Washing and Cooling							
(i.a)		Ice							
Ice	2.8.1*	Is ice in direct contact with product or product contact surfaces periodically checked for adequate microbial quality, and are results available for review? (If ice is purchased from an outside source, is it checked for microbial quality, and are analytical results requested and available for review?)	10						
Ice	2.8.2*	In the event of adverse analytical findings, are corrective actions documented, legible, and available for review?	10						
Ice	2.8.3*	Is ice handled or stored in a manner that prevents or minimizes the possibility of contamination?	10						
(i.b)		Wash Water							
Wash Water	2.8.4	Is the wash water source: 1) municipal (city/town) 2) well(s) 3) an irrigation district 4) a pond or reservoir 5) from a source other than municipal, well, irrigation or pond/reservoir?							Unscored Question
Wash Water	2.8.4.a	Is the water re-circulated or uncirculated?							Unscored Question

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Wash Water	2.8.4.b*	Is water that is used for conveyance, rinsing, or washing of adequate quality, and/or is it subjected to a treatment process (e.g., chlorine, ozone, UV light or other means) adequate to ensure it is safe and of adequate sanitary quality? NOTE: Must be treated if water is recycled.	10						
Wash Water	2.8.4.c.	Is concentration of antimicrobial chemicals and are parameters of the treatment process such as pH, temperature, and oxidation reduction potential (ORP), specified in a written document, monitored adequately, documented, legible, and available for review?	7						
Wash Water	2.8.4.d*	1. If water is recirculated, is water changed as necessary to maintain sanitary conditions? 2. Is there a written procedure that includes water change schedules for all processes that use water?	10						
Wash Water	2.8.4.e*	Are adequate corrective actions taken when monitoring results indicate water supply and/or treatment parameters are out of specification, and are corrective actions documented, legible, and available for review?	10						
(i.c)		Product Type							
Product Type	2.8.5	Does the product type present a risk of absorbing water due to a temperature differential?		Unscored Question					
Product Type	2.8.5.a.	For product, which poses a risk of water absorption: 1. Is water temperature monitored to ensure that the pressure differential will not result in water being absorbed into the product? 2. Are water temperature records maintained/current and available for review?	7						
(ii)		Handling Practices: Incoming, In-Process and Finished Products, Packaging Materials, Containers							
<p>General Expectation: Compliance with 21 CFR 110.80: Raw materials shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into product and shall be stored under conditions that will protect against contamination and minimize deterioration.</p>									
(ii.a)		Handling Raw Materials							
Raw Materials	2.8.6*	1. Are raw materials and other ingredients pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels of microorganisms that would cause the product to be adulterated? 2. Are records available to ensure adequate pasteurization during Phase II composting? 3. Has documentation been received from raw material suppliers that materials are appropriate for mushroom production, including origin and date of purchase?	10						
Raw Materials	2.8.7	1. Are raw materials/ingredients stored or located in a place separate from in-process, rework and finished products, to prevent cross-contamination? 2. Are receiving docks for raw materials and /or composting located away from areas where harvest containers, packaging material, spawn, and other sanitary supplies are received or where mushrooms are shipped?	7						
Raw Materials	2.8.8*	1. Does the facility prohibit the reuse of ingredient containers for holding products or ingredients, unless they are adequately sanitized or have protective liners? 2. Are single-use containers for microbiologically sensitive products prohibited from reuse?	10						
(ii.b)		Incoming Products							

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Incoming Products	2.8.9	(Applicable to incoming washed products only.) Are incoming products stored or located in a place separate from in-process and finished products, to prevent cross-contamination?							
Incoming Products	2.8.10	Are products inspected for evidence of contamination prior to packaging?	7						
Incoming Products	2.8.11	Are first-in/first-out (FIFO) rotation practices used and documented for all stored products (raw incoming and finished)?	4						
Incoming Products	2.8.12	Are incoming or in-house product harvest baskets (e.g., totes, empty containers) kept in good repair, approved by FDA for food contact surfaces, and maintained so they are without splinters or shards?	7						
Incoming Products	2.8.13	(Applicable to incoming products transferred to in-house bins.) 1. Does the facility prohibit the reuse of in-house containers such as harvest baskets used for holding products, unless they are adequately sanitized or (if applicable) have protective liners? 2. Are containers properly labeled and/or color coded?	7						
<p>(ii.c) Hold and Release Program</p> <p>General Expectation: Products shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for packing and shall be stored under conditions that will protect against contamination and minimize deterioration.</p>									
Hold & Release Program	2.8.14	Is there a documented Hold and Release Program that includes: a. who is responsible for putting items on hold and releasing them? b. how products are marked and controlled? c. how "hold" product is monitored, how often it is reconciled and by whom?	7						
Hold & Release Program	2.8.15*	1. Are non-conforming products (incoming and outgoing), which are rejected or on hold, properly identified (e.g., clearly tagged), adequately segregated, and controlled against inadvertent shipment, and protected from contamination? 2. Are adulterated products disposed of in a manner that protects against the contamination of other products?	10						
<p>(ii.d) Packaging Materials</p> <p>General Expectation: Compliance with 21 CFR 110.80 and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section VII.B.1.0</p>									
Packaging Materials	2.8.16*	1. Are packaging material storage areas maintained under conditions that prevent or minimize the likelihood of contamination? 2. Are packaging material the areas monitored for pest activities and from a sanitation standpoint on a regular basis?	10						
Packaging Materials	2.8.17	1. Is documentation that packaging materials (baskets, lugs, trays, tills, and boxes) are approved by FDA for food contact surfaces on file? 2. Has documentation been received from suppliers of packaging that indicates materials are appropriate for mushroom production, including origin and date of purchase?	10						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Packaging Materials	2.8.18	Is FIFO (First In First Out) practiced (i.e., stock rotated on packaging materials)?	4						
Packaging Materials	2.8.19*	Are packaging materials inspected for evidence of contamination prior to use? (e.g., a. packaging materials, which are damaged, dirty, wet, or which have evidence of pest activity, foreign materials, and/or chemicals, must be prohibited from reuse, b. inspected and released into inventory)	10						
Packaging Materials	2.8.20	During production, are packaging materials handled in a manner that eliminates contamination from the ground or from inappropriate employee handling?	7						
Packaging Materials	2.8.21*	Are damaged cases or packages segregated immediately and products repacked or properly disposed of?	10						
Packaging Materials	2.8.22	Are packaging materials used only for their intended purpose and not used to store other things?	7						
(iii) Foreign Material Control/Indirect Product Additives General Expectation: Compliance with the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section VII.B.									
Foreign Material Control	2.8.23*	Are foreign material detectors used on the packing lines? If yes, are they inspected on a routine basis to ensure proper performance and are inspection records maintained and available for review?	10						
Foreign Material Control	2.8.24	1. Is there a documented glass and/or brittle plastic management policy? (e.g., no unprotected glass or brittle plastic will be allowed in the facility) 2. Does it include procedures for: a. line stoppage?, b. segregation of suspect materials? c. clean-up? d. re-inspection?	7						
Foreign Material Control	2.8.25*	Is exposed glass and/or brittle plastic prohibited, and is a highly audited "glass free zone" maintained in the product handling and storage areas? (e.g., a. shatter-proof light bulbs and/or light bulbs covered with protective covers, including insectocutors, dock lights; b. windows coated or made of tempered glass or of plastic; c. no exposed glass or mercury thermometers; d. no storage or use of food and drinks in glass containers in product handling areas)	10						
Foreign Material Control	2.8.26*	Is the packaging material made of glass? If so, are proper control measures in place to prevent breakage, and is there a written policy for handling glass packaging in product storage and handling areas?	10						
Foreign Material Control	2.8.27	Is compressed air used to clean product contact surfaces or equipment, handled in such a way as not to contaminate the products with unlawful indirect product additives?	7						
Foreign Material Control	2.8.28	1. Are food grade lubricants approved for use in appropriate areas and are they properly stored? 2. Are Material Safety Data Sheet(s) and label(s) maintained on file? 3. Are excess grease or lubricants removed from the equipment located over or close to product contact surfaces?	7						
(iv) Calibration									

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Calibration	2.8.29	1. Are temperature measuring devices (e.g., pulp thermometers, cooler thermometers and units) and other monitoring equipment (e.g., product weighing scales), including foreign material detectors, calibrated on a specified schedule and are records available for review? 2. Are temperature probes, supporting hardware and software used to monitor Phase I and II conditions maintained and calibrated on a regular basis?	4						
(v) Recall/Traceability Program General Expectation: A written recall procedure, which identifies the steps required to retrieve product.									
Recall/ Traceability	2.8.30	Is there a formal, written Product Recall Program that includes: a. a recall coordinator b. a 24 hour recall team contact list c. a description of categories (e.g., class 1, class II, class III) d. regulatory contacts and procedures to notify regulatory agency?	7						
Recall/ Traceability	2.8.31*	Is there a product coding system that can identify products and can the system track products back to their source? (e.g., date of receipt, lot and/or date codes for incoming products; identification, lot codes on outer case and/or inner packages for finished products such as MM DD YY, YDDD or YYDDD).	10						
Recall/ Traceability	2.8.32	Are mock recalls for lot code backwards and lot code forward performed at least annually and are results (e.g., % product recovery, elapsed time) documented and maintained on file?	7						
Recall/ Traceability	2.8.33	In the event of an actual recall, is the associated documentation available for review?	7						
Recall/ Traceability	2.8.34	1. Is a food-safety-related customer complaint program in place? 2. Are records of food-safety-related customer complaints and company responses kept on file and available for review? (e.g., tracking of customer feedback, including notification of QA of issues reported, assignment of responsibilities, and follow ups)	4						
(vi) Facility Inspection/Food Safety Program Review General Expectation: Periodic facility inspections will assist in assessing effectiveness of product safety practices and periodic reviews of written procedures will assure that product safety practices will continue to control hazards.									
Facility Inspection/Food Safety Program Review	2.8.35	Are good manufacturing practices or facility inspections conducted periodically, and are findings, corrective actions, and follow ups documented and available for review?	7						
Facility Inspection/Food Safety Program Review	2.8.36	Are regulatory inspection procedures documented and are inspection records available for review?	4						
Facility Inspection/Food Safety Program Review	2.8.37	Are reviews of the written product safety management plan and associated procedures conducted periodically and are periodic reviews documented and available for review?	7						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
(vii) Visitor and Contractor Access Control									
Visitor and Contractor Access Control	2.8.38	Are truck drivers restricted from production and warehouse areas?	4						
Visitor and Contractor Access Control	2.8.39	Is facility access limited to authorized personnel?	4						
Visitor and Contractor Access Control	2.8.40	1. Is there a policy requiring inspectors, visitors, and contractors to comply with good manufacturing practices? 2. Are they required to read or are they briefed on cGMPs policy upon entry to the facility?	7						
		*Food Safety Section Total Points	160		0	0	0	0	0
		Other Section Total Points	164		0	0	0	0	0
2.9 Cleaning Equipment and Chemicals									
General Expectation: Compliance with 21 CFR 110.35 (d)(e). Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of the use.									
Equip & Chemicals	2.9.1*	1. Are cleaning compounds and sanitizing agents appropriate (anti-microbial, food grade approved) for product and non-product contact surfaces? 2. Are MSDSs and copies of specimen labels maintained for cleaning and sanitizing chemicals?	10						
Equip & Chemicals	2.9.2	Are cleaning compounds and sanitizing agents used by the sanitation crew or for production clearly identified with chemical name, when in original container and when not in original container? (e.g., chemical barrels, spray bottles, spray containers, buckets)	7						
Equip & Chemicals	2.9.3	1. Are cleaning compounds and sanitizing agents stored in secure, locked areas away from any product handling or storage areas? 2. Do chemical storage areas have clean floors (no excessive or old spills)?	7						
Equip & Chemicals	2.9.4	Are first-in/first-out (FIFO) rotation practices used for all cleaning and sanitizing chemicals?	4						
Equip & Chemicals	2.9.5*	1. Are containers, brushes, and applicators, which are used for cleaning and/or sanitizing, color coded or labeled to properly identify them for their intended use? (e.g., cleaning items used in restrooms should not be used elsewhere) 2. If a color coding system is used, is appropriate signage posted regarding use of the containers and equipment?	10						
		*Food Safety Section Total Points	20		0	0	0	0	0
		Other Section Total Points	18		0	0	0	0	0
2.10 Cleaning, Sanitation, and Housekeeping Procedures									
General Expectation: Compliance with 21 CFR 110.35 and with the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section VII.B.1.0, VII.B.2.0									

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Sanitation	2.10.1	1. Is there a written sanitation program that describes how sanitation in and around the facility is managed, who is responsible for managing it, and policies related to sanitation? (Internal or external contract). 2. Are the cleaning procedures (for product contact and non-product contact equipment surfaces, including other product handling areas) described in a document that details frequency of cleaning, type(s) of cleaning chemicals used (with concentrations), cleaning items used, and how and when to clean?	7						
Sanitation	2.10.2*	1. Are non-product contact surfaces and areas throughout the facility, including dry and cold storage areas, cleaned on a scheduled basis and as needed? (e.g., daily and/or weekly housekeeping, master sanitation schedule) 2. Is cleaning documented (initialed by sanitation person and/or supervisor), reviewed (dated and initialed by reviewer), and are records legible and available for review?	10						
Sanitation	2.10.3*	1. Are product contact equipment, harvest equipment, and surfaces throughout the facility cleaned on a scheduled basis, or as needed? (e.g., master sanitation schedule, daily/weekly housekeeping) 2. Is cleaning documented (initialed by sanitation person and/or supervisor), reviewed (dated and initialed by reviewer), and are records legible and available for review?	10						
Sanitation	2.10.4	Are pre-operative inspections conducted and documented, and are records legible and available for review?	7						
Sanitation	2.10.5	Is environmental sampling performed on a periodic basis to monitor the effectiveness of cleaning and sanitizing procedures and are results maintained on file?	7						
Sanitation	2.10.5.a	Does the environmental testing program document corrective actions in response to isolated positive results (to eliminate harborage sites)?	7						
Sanitation	2.10.5.b	Have trends or recurring environmental positives been identified through periodic in-house record reviews and are corrective actions taken to eliminate recurring positive results?	7						
Sanitation	2.10.6	1. Are chemical preparations tested by trained personnel for concentration, via test kits or sanitizer strength strips, prior to use or on a periodic basis? 2. Is chemical concentration documented, and are records legible and available for review?	7						
Sanitation	2.10.7	Is safety equipment provided to sanitation crew?	4						
Sanitation	2.10.8	Are water hoses stored off the floor? (e.g., on wall-mounted hangers)	4						
Sanitation	2.10.9	Are adequate staffing and time allocated to ensure complete cleaning of all areas?	4						
Sanitation	2.10.10*	Are product and packaging materials protected during cleaning procedures?	10						
Sanitation	2.10.11*	Are cleaned and sanitized portable equipment and utensils protected from contamination during storage?	10						
Sanitation	2.10.12	Is there a written SOP to ensure that equipment is cleaned, sanitized and inspected after having been worked on and/or repaired? (This includes equipment that has stopped functioning during production and has been repaired on the line, or equipment that has been moved out of the production area and repaired in another area.)	7						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Sanitation	2.10.13*	1. Are equipment product contact surfaces, which have undergone repairs, maintenance or re-assembly, cleaned and sanitized prior to use? 2. Is this task documented and available for review?	10						
Sanitation	2.10.14	Are maintenance tools, gloves, rags, and other miscellaneous materials stored in secured areas away from product handling equipment to prevent contamination?	4						
Sanitation	2.10.15	Are floors kept free of standing water and/or ice? (e.g., floors sloped towards drains)	7						
Sanitation	2.10.16	Are product handling and storage areas maintained in clean condition?	7						
Sanitation	2.10.17	Is there a pallet inspection program?	4						
Sanitation	2.10.18	Is storage of wooden pallets in product handling or storage areas prohibited? (e.g., pallets are brought to these areas only as needed)	4						
Sanitation	2.10.19	Are employee break and/or locker rooms, and all other employee welfare areas maintained in sanitary conditions?	7						
Sanitation	2.10.20	1. Is sufficient aisle space (typically 12-18 inches) maintained along walls to permit cleaning and inspection for pest activity? 2. Are materials stored at an adequate height (typically the height of a pallet) above the floor?	7						
		*Food Safety Section Total Points	50		0	0	0	0	0
		Other Section Total Points	101		0	0	0	0	0
	2.11	Equipment Construction, Design, and Maintenance							
		General Expectation: Compliance with 21CFR 110.40: All facility equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained; 21 CFR 110.80 (7): Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or product shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination; the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section VII.B.2.0							
	(a)	Equipment/Containers/Utensils							
Equipment/ Containers/ Utensils	2.11.1*	Is equipment designed to: a. prevent adulteration of product with lubricants, oil, or other similar contaminants? (e.g., catch pans used under the motors and/or bearings on production lines located over food contact surfaces, where there is potential for leakage of oil or other lubricants, b. prevent water collection? (suggest cautious use of hollow structures, such as catwalk framework, table legs, conveyor rollers, and racks, because they may collect water and debris, and harbor pathogens)	10						
Equipment/ Containers/ Utensils	2.11.2*	Are product lines, which are underneath ladders and walkways protected to prevent potential contamination? (i.e., there are kick plates that are at least 4 inches wide, covers, or other shields installed where necessary)	10						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Equipment/ Containers/ Utensils	2.11.3*	1. Are equipment, containers, harvest equipment and utensils: a. in good repair? (e.g., no rust and/or peeling paint present) and being used for their intended purpose(s), b. able to be cleaned and sanitized? (i.e., wooden equipment, utensils and/or wooden product surfaces are prohibited) 2. Are product contact surfaces made of smooth, non-absorbent, sealed, durable, non-corrosive, nontoxic materials, easily cleanable food contact surfaces that are sloped to drain freely, and are they able to withstand the environment in which they are used? 3. Are seams on product contact equipment or surfaces smoothly bonded?	10						
Equipment/ Containers/ Utensils	2.11.4	Are materials such as string, tape, wire, and/or cardboard that might have potential to contaminate the product or that cannot be properly cleaned and sanitized, not being used for temporary repairs on product contact equipment?	7						
Equipment/ Containers/ Utensils	2.11.5	Are vehicles and/or equipment, which are used for moving raw materials, finished products, and packaging throughout the facility, cleaned and maintained in good condition?	4						
(b) Preventive Maintenance Program									
P.M. Program	2.11.6	Does the facility have a preventative maintenance program for its equipment and utensils, and are logs kept for ordered maintenance work or repairs, which are signed off when the work is completed? (e.g., wash tanks, hydrocoolers, packing line and/or table, chlorine injectors, water filtration systems, backflow devices, cutting knives)	7						
*Food Safety Section Total Points			30		0	0	0	0	0
Other Section Total Points			18		0	0	0	0	0
2.12 Receiving, Storage and Distribution									
General Expectation: Compliance with 21CFR 110.93 and the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, Section VIII.									
(a) Receiving: In-bound Inspection									
Receiving	2.12.1	Are temperatures of refrigerated and frozen products documented at the time of receiving?	7						
Receiving	2.12.2*	1. Does the company have practices for the inspections of incoming trucks and are inspections (e.g., cleanliness, temperature) documented, and available for review? 2. Do incoming trucks, trailers, or transport containers that are used for transporting product appear to be clean and in good condition?	10						
(b) Storage									
Storage	2.12.3	1. Are storage room temperatures maintained within a defined acceptable range? 2. Is storage room humidity maintained within a defined acceptable range? (Applicable only if humidity control is in place)	7						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Storage	2.12.4	1. Is temperature and/or humidity monitored regularly via continuous recording device or manually? 2. Are records and corrective actions available for review?	7						
(c) Transportation and Distribution									
Transp. & Distrib.	2.12.5	Does the facility use an outside carrier company for transportation? If yes, go to 2.12.5.a. If no, go to 2.12.6.		Unscored Question					
Transp. & Distrib.	2.12.5.a	Is protocol on safe transportation and proper product handling procedures provided to the carrier companies?	7						
Transp. & Distrib.	2.12.5.b	Is the protocol issued to the drivers when they enter the site as a reminder?	7						
Transp. & Distrib.	2.12.6	Is there a cleaning procedure on trucks that requires adequate cleaning and inspection (incoming and outgoing)?	4						
Transp. & Distrib.	2.12.6.a	1. Does the company have practices for the inspections of outgoing trucks? 2. Do outgoing trucks, trailers, or transport containers that are used for transporting product appear to be clean and in good condition? 3. Are inspections (e.g., cleanliness, temperature) documented, and are inspection records and corrective actions available for review?	10						
Transp. & Distrib.	2.12.7	Are perishable products maintained in their appropriate temperature range if staged and/or stored in shipping areas (outside the coolers) to prevent temperature degradation of products?	7						
		*Food Safety Section Total Points	20		0	0	0	0	0
		Other Section Total Points	46		0	0	0	0	0
SECTION B: HACCP PLAN AND PROCESS PRACTICES									
General Expectation: An accurate and documented Hazard Analysis Critical Control Points (HACCP) Plan is developed and implemented. The HACCP Plan complies with Codex Alimentarius Commission and National Advisory Committee for Microbiological Criteria for Foods' definitions for HACCP. The plan addresses physical, chemical, and biological hazards. Frequency of checks and required record keeping are documented. Verification procedures document that the HACCP Plan is working and is continuously effective.									
1.0 MANAGEMENT RESPONSIBILITY									
1.1 Management Commitment and Review									
Mgmt. Commitment	1.1.1*	Does management appear to be committed to executing an adequate HACCP/Hazard Prevention food safety management program?	7						
		Other Section Total Points	7		0	0	0	0	0
2.0 FUNDAMENTALS									
2.1 HACCP/Hazard Prevention Program									
HACCP	2.1.1	Does the facility have a documented Hazard Prevention program?	7						
HACCP	2.1.2	Is the facility Hazard Prevention program HACCP-based?	7						

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
HACCP	2.1.3	Does the facility operate under a government regulated HACCP or Hazard Prevention program?			Describe				
HACCP	2.1.4	1. Is there a food safety management (HACCP) team identified and documented? 2. Is the HACCP team comprised of employees with diverse responsibilities and does it include a person trained in HACCP?	4						
HACCP	2.1.5	1. Does the HACCP team meet periodically to address food safety issues and/or review the HACCP program? 2. Are records of the meetings kept on file and available for review?	4						
<p>General Expectation: Are there documented HACCP program(s), detailing the 7 principles, and is it established, up-to-date, and available for review? The HACCP Plan must be developed following the required steps: 1) Conduct a hazard analysis. 2) Determine the critical control points (yes/no). 3) Establish critical limits (if any CCPs). 4) Establish monitoring procedures (if any CCPs). 5) Establish corrective actions (if any CCPs). 6) Establish verification procedures (if any CCPs). 7) Establish record-keeping, documentation, and validation procedures (if any CCPs).</p>									
<p>(a) Product Description(s), Process-Flow Diagram(s), Hazard Analysis Worksheet(s)</p>									
Product Description(s)	2.1.6	Do HACCP/Hazard Prevention plan(s) include product descriptions, distribution, intended uses, and target customers (channels of trades), and are they accurate?	7						
Process-Flow Diagram(s)	2.1.7	1. Are process-flow diagram(s) current for all HACCP/Hazard prevention plan(s), and are they accurate? 2. Are critical control or control point(s) identified on the process-flow diagram(s)?	7						
Hazard Analysis Worksheet(s)	2.1.8*	Do Hazard Analysis Worksheet(s) exist and do they identify the hazards (biological, chemical, and physical), and consider the severity and likelihood of occurrence?	10						
<p>(b) HACCP Plan(s) and CCPs</p>									
HACCP Plan(s) CCPs	2.1.9*	Do HACCP plan(s) exist, which if necessary, adequately summarize the key elements of HACCP: a. name of CCPs that control hazards b. critical limits c. monitoring procedures and frequency d. corrective actions taken if critical limits are violated e. plan verification procedures f. record keeping and documentation procedures	10						
<p>(c) Monitoring Procedures</p>									
Monitoring	2.1.10*	1. Is each critical control point as specified in HACCP/Hazard Prevention plan, monitored at scheduled intervals, documented, and reviewed? 2. Are HACCP records signed and/or initialed by the individual performing the task? 3. Are HACCP records signed and/or initialed by the individual reviewing the records? 4. Are records accurate and legible?	10						
Monitoring	2.1.11*	Are CCPs in compliance with the critical limits stated?	10						
<p>(d) Corrective Actions</p>									

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Corrective Actions	2.1.12*	1. When critical limit(s) are not met, are identified corrective actions as specified on the HACCP Plan(s) implemented to bring critical control point(s) under control? 2. Are deviation and corrective actions properly documented and reviewed (initialed and dated)? 3. Are records accurate and legible?	10						
Corrective Actions	2.1.13*	Is disposition of non-compliant product documented?	10						
(e) Verification Procedures									
Verification	2.1.14*	Is the HACCP plan signed and/or initialed and dated by the food safety manager or another member of management?	10						
Verification	2.1.15*	Are verification procedures (e.g., calibration, testing), which determine the validity of the HACCP plan and food safety management practices, defined in a written document?	10						
Verification	2.1.16*	1. Is calibration and/or testing conducted and documented as required in the verification procedures? 2. Are records accurate and legible?	10						
Verification	2.1.17*	Were all CCPs verified by the auditor during inspection and were all CCPs in compliance with the HACCP Plan(s)?	10						
(f) Validation Procedures									
Validation	2.1.18*	1. Are audits or reviews of HACCP/Hazard Prevention procedures conducted on a regular basis to ensure they are executed according to the facility's plan? 2. Are records available for review?	10						
Validation	2.1.19*	Has the facility validated all critical limits or key elements, and is support documentation maintained and available for review? (e.g., cite number and dates of in-house study, scientific reference, regulatory requirements)	10						
Validation	2.1.20*	1. Were copies of the HACCP/Hazard Prevention plan(s) in use during the audit current and up-to-date? 2. Do these documents provide the date of last assessment?	10						
Validation	2.1.21*	Are all copies of HACCP/Hazard Prevention plan(s) signed by authorized individuals?	10						
Validation	2.1.22*	Are targeted sampling and testing conducted on products, and is it documented as required in the verification procedures?	10						
Validation	2.1.23*	Are audits of the HACCP plan conducted on a regular basis and records of results maintained?	10						
(g) Record Keeping									
Record Keeping	2.1.24*	1. Are all records associated with the food safety management program maintained for a specified number of years (at least 1 year)? 2. Are all records accurate and legible?	10						
		*Food Safety Section Total Points	170		0	0	0	0	0
		Other Section Total Points	36		0	0	0	0	0
2.2 Allergens									

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note	
General Expectation: Develop food allergen program based on a. the eight food groups, b. food additives, c. color additives, d. allergens used in the products (refer to 21 CFR)										
	2.2.1*	Are allergens and/or sensitizing chemicals stored in the facility and used in the products? If yes go to 2.2.2.		Unscored question						
Allergens	2.2.2	Is there a list indicating all allergens and/or sensitizing chemicals stored in the facility? (e.g., eight major allergens recognized by the USDA and Codex include: proteins from peanuts, tree nuts, dairy, egg, soy, milk, wheat, fin fish, and crustacea. Sensitizing chemicals include: sulfites, and some food colorings such as Yellow 5)	7							
Allergens	2.2.3	Are there written procedures on management of allergen-containing products?	7							
Allergens	2.2.4*	Are allergens stored in a manner that protects other non-allergenic materials from inadvertent contamination?	10							
Allergens	2.2.5*	Does the operation repack and/or co pack allergen-containing product? If yes go to 2.2.5.a.		Unscored question Yes/No						
Allergens	2.2.5.a*	Are containers, equipment, and/or utensils used in handling allergens identified to prevent cross contamination from allergens to non-allergen containing products?	10							
Allergens	2.2.5.b*	Are proper product handling procedures in place to prevent cross contamination from allergens to non-allergen containing products? (e.g., production sequencing and equipment sanitation [i.e., nonallergen-containing product is produced first], or sanitation protocols are followed to ensure that equipment used for the production of allergen-containing products is strictly used for its purpose)	10							
Allergens	2.2.5.c *	1. Are effective sanitation procedures practiced to prevent cross contamination from allergen to non-allergen containing products or during change-overs? 2. Is cleaning documented when switching from allergen to non-allergen containing products and are the equipment, containers, and/or utensils checked for removal of potential allergenic-product residue?	10							
Allergens	2.2.5.d*	Rework or Work in Progress (WIP): Are there written procedures on proper handling of rework or WIP material (if applicable)?	10							
Allergens	2.2.5.d1*	Is the policy enforced to prevent cross contamination from allergens to non-allergen containing products and also to ensure that rework or WIP is only incorporated into similar products?	10							
Allergens	2.2.6	Are there written labeling and packaging procedures for products containing allergens?	7							
Allergens	2.2.7*	1. Are labels reviewed for accuracy upon receipt or printing and upon use? 2. Are all allergens declared on the label using common terms as dictated by the FDA Food Allergen Labeling and Protection Act of 2004 (effective Jan 2006)?	10							
Allergens	2.2.8*	Is there an established verification program to ensure allergen control procedures are in compliance?	10							
		*Food Safety Section Total Points	80		0	0	0	0	0	
		Other Section Total Points	21		0	0	0	0	0	
2.3		Training and Education								
General Expectation: (21 CFR 110.10). Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles.										

Section	#	CATEGORY/REQUIREMENTS	Possible Points	N/A	S	NI	US	Auto	Auditor's Note
Training & Educ.	2.3.1*	Is there an ongoing (refresher) HACCP training for employees who monitor HACCP parameters?	10						
Training & Educ.	2.3.2	Is there an assigned person responsible for conducting HACCP training?	7						
Training & Educ.	2.3.3	Is the general content of the training sessions described in a document maintained by the company?	7						
Training & Educ.	2.3.4	Does the HACCP training include evaluation criteria for knowledge learned?	7						
Training & Educ.	2.3.5	Is worker participation in the HACCP training program documented and available for review, and does the training documentation include the employee's signature?	7						
Training & Educ.	2.3.6*	Are employees who are monitoring CCPs aware of critical limits, monitoring requirements, corrective actions, and other HACCP-related activities in their immediate work areas?	10						
Training & Educ.	2.3.7*	Is there a supervisor with relevant educational background and/or experience, who oversees the HACCP program?	10						
		*Food Safety Section Total Points	30		0	0	0	0	0
		Other Section Total Points	28		0	0	0	0	0
3.0 SECTION C: DOCUMENT CONTROL									
Document Control	3.1.1.	Does the facility employ a formal system to manage and control all food safety related documentation, data and records?	4						
Document Control	3.1.2	Are procedures in place to control document transmission, changes and removal of obsolete documents?	4						
Document Control	3.1.3	Is there an authorized person to issue food safety documents?	4						
Document Control	3.1.4	Do document control procedures ensure customer confidentiality?	4						
Document Control	3.1.5	Does a document control system protect physical and electronic documents against loss and unauthorized access?	4						
Document Control	3.1.6	Is there a records retention policy for food safety related documentation, data and records?	4						
		Other Section Total Points	24		0	0	0	0	0

AUDIT SCORING SYSTEM

SCORE			RATING	DESCRIPTION	DOCUMENTATION COMPLIANCE
10 pts	7 pts	4 pts	AUTO	Automatic Unsatisfactory (Refer to Next Page)	
N/A	N/A	N/A	N/A	Not Applicable	Not Applicable
				The particular question doesn't apply to the facility in question or are not controlled at the facility.	The particular question doesn't apply to the facility in question or are not controlled at the facility.
0	0	0	US	Unsatisfactory	Unsatisfactory
				Critical food safety hazards, which compromise the safety of the product, are observed.	A) No written Food Safety Program in place. B) Records Review: No records available.
1	1	1	NI	Needs Improvement	Needs Improvement
				Serious food safety hazards, which may eventually compromise the safety of the product, are observed. Significant improvements in operational practices and procedures are needed to avoid food safety hazards.	A) Written Food Safety Program in place and/or needs serious improvement. B) Records Review: Very few records may be available and/or current.
3	2	2	NI	Needs Improvement	Needs Improvement
				Major food safety hazards, which may not immediately compromise the safety of the product, are observed. Partial improvements in operational practices and procedures are needed to avoid food safety hazards.	A) Written Food Safety Program in place and/or needs major improvement. B) Records Review: Some records may be unavailable and/or current.
5	4	3	NI	Needs Improvement	Needs Improvement
				Minor food safety hazards, which may not immediately compromise the safety of the product, are observed. Minimum improvements in operational practices and procedures are needed to avoid food safety hazards.	A) Written Food Safety Program in place and/or needs minor improvement. B) Records Review: Very few records may be unavailable and/or not current.
10	7	4	S	Satisfactory	Satisfactory
				No food safety hazards are observed. Meets the intent of the checklist in design and execution.	A) A complete written Food Safety Program in place. B) Records Review: All records are available and kept current.

Conditions for an Automatic Failure

A. General

1. An immediate food safety risk is present due to a violation of the Good Manufacturing Practices (Code of Federal Regulations Title 21, Part 110).
2. Product is washed, cooled, packed, or held under conditions that promote or cause the food to become contaminated, and thus rendered harmful to one's health.
3. Sanitation procedures are not in place.
4. Products are stored at improper conditions e.g., temperature, humidity).
5. Presence or evidence of contaminated food with foreign material or filth (e.g., flaking paint, rust, glass, wood, metal, jewelry, lubricants, etc.), during packing or storage.
6. Seepage or runoff from composting area (phase I) reached growing areas.

B. Rodents, Insects, Birds, Animals, and other Pests

1. Absence of pest control program in the packing, product cooling areas including packaging material and product storage areas.
2. Presence or evidence of rodents, insects, or other pests in the product during packing, or storage (e.g., excreta, bird feathers, etc.)
3. Presence or evidence of decomposed rodent(s) in pest control traps.
4. Extensive infestation in packing, processing, storage and distribution areas, including infestation of the area overhead where food or packaging material is present (e.g., presence of birds' nests).
5. Any roach activity in food handling or storage areas.
6. Presence of animals inside the facility (e.g., dogs, cats, etc.)

C. Cleaning Chemicals, Pesticides and other Poisonous Materials

1. Food is adulterated as defined by the Food, Drug and Cosmetic Act, Section 402.
2. An imminent food safety risk is present due to violation of the Environmental Protection Agency (EPA) and/or State pesticide regulations.
3. Illegal use of pesticides (e.g., pesticides not meeting EPA or other regulatory standards).
4. Recommended guidelines for the preparation and handling of pesticides are not followed (i.e., not following label instructions).
5. Non-food grade cleaning agents (detergents and sanitizers) are used.
6. Presence or evidence of contaminated food with chemicals, pesticides or other poisonous materials.
7. Food products stored with toxic substances.

D. Employee Practices

1. Observation of employee practices that jeopardize or may jeopardize the safety of the product (e.g. open sores and boils on employees who have direct contact with product or product handling areas, employees not following hand washing requirements, etc.)
2. Gross negligence or actions, which render food unsafe or harmful to one's health.

E. Sanitary Facilities

1. Toilet facilities and hand washing stations not provided.

F. Water

1. Water known to be contaminated comes in contact with the product.
2. Ice known to be contaminated comes in contact with the product.

G. HACCP/Hazard Prevention Program

1. No HACCP program exists where legally mandated, and in the case of sprouted seeds, i.e., documented HACCP program, detailing 7 principles, is not established, is not up-to-date, and is not available for review.
2. Identified Critical Control Points not implemented and monitored and is not available for review.
3. Falsification of CCP (Critical Control Point(s)) records.

Food Safety Assessment Rating System

This rating system describes the status of processing, packing, storage operations in regards to food safety issues associated with the particular operations they perform. It should be noted that it is not possible to completely eliminate the risk of contamination associated with production (GMPs) / food environment. This fact remains true regardless of the practices employed or the rating level achieved as a result of an audit. The Good Manufacturing Practices (21 CFR, Part 110) are used as references to assess the levels of risk associated with these operations.

Percentage	Assessment	Description
95.00 or more	Superior (Pass)	The food is produced in an exemplary environment.
90.00-94.99	Excellent (Pass)	The food is being produced in an environment that significantly reduces the likelihood of contamination.
80.00-89.99	Good (Pass)	Procedures and guidelines to protect the food product against contamination need some improvement. However, there is a low likelihood that current practices will lead to contamination of the food product.
Less than 79.99	Fair (Fail)	The food is being produced in an environment where critical deficiencies and/or serious potential or actual contamination were observed. Immediate improvements in procedures and operating practices should occur.