

GMP Audit v14.09 Scope Outline

Audit #:	Start Time:
Date:	End Time:
uditor Name:	
Facility Name:	FDA Registration #:
Customer:	
Location:	
GPS:	
Approximate Size of the Facility (ft²or m²):	
Season Duration:	
Commodities Observed:	
Additional Commodities:	
Supervisor:	
# of Employees:	
Product washed or hydrovaced:	
Wet/High Humidity Storage:	
Cooling Equipment Audited:	
Lines Audited:	
Audit Scope (& any exclusion):	

PRIMUSLABS V14.09 GMP AUDIT Checklist

GOOD MANUFACTURING PRACTICES - SECTION 1

Category	#	Question Question	Total	Recommendations
			Points	
	1.1.1	There was no significant threat to the safety of the product that may be considered critical and warrants an automatic failure? Explain. ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.	15	
Storage Areas & Packaging Materials	1.2.1	Are all chemicals (pesticides, sanitizers, detergents, lubricants, etc.) stored securely, safely and are they labeled correctly?	15	
Storage Areas & Packaging Materials	1.2.2	Are "food grade" and "non-food grade" chemicals used appropriately, according to label and stored in a controlled manner?	10	
Storage Areas & Packaging Materials	1.2.3	Are ingredients (including ice), products, and packaging stored to prevent cross contamination (this includes iced product pallets stored above pallets of product without adequate protection as well any allergen cross contamination issues)?	15	
Storage Areas & Packaging Materials	1.2.4	Is the storage area completely enclosed?	10	
Storage Areas & Packaging Materials	1.2.5	Is the facility's use restricted to the storage of food products?	5	
Storage Areas & Packaging Materials	1.2.6	Are rejected or on hold materials clearly identified and separated from other materials?	10	
Storage Areas & Packaging Materials	1.2.7	Are raw materials, work in progress, ingredients (including water and ice), finished goods and food contact packaging within accepted tolerances for spoilage and free from adulteration? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.	15	
Storage Areas & Packaging Materials	1.2.8	Are all storage areas clean, especially the racking structures, lights, ceilings, floor areas by the walls and other hard to reach areas?	10	
Storage Areas & Packaging Materials	1.2.9	Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) properly marked with rotation codes (receipt dates, manufacture dates, etc)?	5	

Storage Areas & Packaging Materials	1.2.10	Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) rotated using FIFO policy?	5	
Storage Areas & Packaging Materials	1.2.11	Are storage areas at the appropriate temperatures for the specific products being stored?	10	
Operational Practices	1.3.1	Does the process flow, facility layout, employee control, utensil control, internal vehicle use, etc. ensure that finished goods are not contaminated by raw materials?	15	
Operational Practices	1.3.2	Are all exposed materials (product, packaging, etc.) protected from overhead contamination (e.g. ladders, motors, condensation, lubricants, walkways, loose panels, degrading insulation, etc.)?	15	
Operational Practices	1.3.3	Are packing and/or processing areas completely enclosed?	15	
Operational Practices	1.3.4	Are storage areas clean and well maintained; especially lights, floor areas by the wall and equipment, and other hard to reach areas?	15	
Operational Practices	1.3.5	Is all re-work / re-packaging handled correctly?	10	
Operational Practices	1.3.6	Are raw materials examined before use?	5	
Operational Practices	1.3.7	Are finished products coded (carton and unit packaging) for the day of production?	10	
Operational Practices	1.3.8	Does finished product coding clearly link to supplier(s) of incoming materials? (Auditor performs a live traceback test to verify documentation reviewed for 2.4.1.)	10	
Operational Practices	1.3.9	Are foreign material control methods (e.g. metal detectors, metal traps, visual inspection, etc.) in place? Are these systems regularly tested (where relevant) to ensure proper operation?	10	
Operational Practices	1.3.10	Does the facility use the appropriate test strips, test kits or test probes for verifying the concentrations of anti-microbial chemicals (product washing water, terminal sanitizers, dip stations, etc) being used and are they in operational condition?	10	
Operational Practices	1.3.11	Are hand washing stations adequate in number, appropriate in location, in working order, have warm water, adequately stocked (e.g. disposable towels, soap, etc.) and restricted to hand washing purposes only?	15	
Operational Practices	1.3.12	Are toilet facilities adequate in number and location and are they adequately stocked (e.g. toilet paper, disposable towels, soap, etc.)?	15	
Operational Practices	1.3.13	Are secondary hand sanitation stations (e.g., touch-free dispensers) adequate in number and location? Are the stations maintained properly?	5	

Operational Practices	1.3.14	Are foot dip stations adequate in number and location? Are the stations maintained properly?	3	
Operational Practices	1.3.15	Are single service containers used for their intended purpose only so that potential cross contamination is prevented?	5	
Operational Practices	1.3.16	Are re-usable containers clean and clearly designated for the specific purpose (raw product, finished product, re-work, ice, trash, etc.) such that cross contamination is prevented?	10	
Operational Practices	1.3.17	Are food safety measuring devices working properly and calibrated (where applicable)?	3	
Employee Practices	1.4.1	Are employees washing and sanitizing their hands before starting work each day, after using the restroom, after breaks and whenever hands may be contaminated?	15	
Employee Practices	1.4.2	Are employees' fingernails clean, short and free of nail polish?	5	
Employee Practices	1.4.3	Is there no sign of any employees with boils, sores, open wounds or exhibiting signs of foodborne illness working in indirect or direct contact with food?	10	
Employee Practices	1.4.4	Are first aid kits adequately stocked and readily available? Are blue metal detectable waterproof band aids used?	5	
Employee Practices	1.4.5	Are employees wearing effective hair restraints?	10	
Employee Practices	1.4.6	Is jewelry confined to a plain wedding band and watches are not worn?	3	
Employee Practices	1.4.7	Are all employees wearing outer garments suitable for the operation (e.g. smocks, aprons, sleeves and non-latex gloves)?	10	
Employee Practices	1.4.8	Do employees remove protective outer garments e.g. smocks, aprons, sleeves and gloves when on break, before using the toilets and when going home at the end of their shift?	5	
Employee Practices	1.4.9	Is there a designated area for employees to leave protective outer garments e.g. smocks, aprons, sleeves and gloves when on break and before using the toilets?	5	
Employee Practices	1.4.10	Employees personal items are not being stored in the production or material storage areas?	5	
Employee Practices	1.4.11	Is smoking, eating, chewing and drinking confined to designated areas; spitting is prohibited in all areas?	10	
Employee Practices	1.4.12	Are all items removed from garment (smock, shirt, blouse, etc) top pockets?	3	
Equipment	1.5.1	Are food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?	15	

Equipment	1.5.2	Are non-food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?	10	
Equipment	1.5.3	Does equipment design and condition (e.g. smooth surfaces, smooth weld seams, nontoxic materials, no wood, or other absorbant materials) facilitate effective cleaning and maintenance?	15	
Equipment	1.5.4	Are thermometers (independent of thermostat probes) present in all coolers and freezers?	5	
Equipment	1.5.5	Are all thermometers non-glass and non-mercury?	10	
Equipment Cleaning	1.6.1	Are food contact equipment surfaces clean?	15	
Equipment Cleaning	1.6.2	Are non-food contact equipment surfaces clean?	10	
Equipment Cleaning	1.6.3	During cleaning are foods and packaging protected from contamination?	15	
Equipment Cleaning	1.6.4	Are cooling units including coils in coolers and freezers clean and free of aged, dirty ice?	5	
Equipment Cleaning	1.6.5	Are all fan guards dust-free and the ceiling in front of the fans free of excessive black deposits?	5	
Equipment Cleaning	1.6.6	Is stored equipment that is not used on a daily basis stored in a clean condition with food-contact surfaces protected and/or are they retained on cleaning schedules in some manner, even though they are not in use?	10	
Equipment Cleaning	1.6.7	Are all utensils, hoses, and other items not being used stored clean and in a manner to prevent contamination?	10	
Equipment Cleaning	1.6.8	Are maintenance tools that are used in the production and storage areas of the facility clean, sanitary and corrosion free?	3	
Equipment Cleaning	1.6.9	Are excess lubricants removed from the equipment and are lubricant catch pans fitted where needed?	5	
General Cleaning	1.7.1	Are spills cleaned up immediately?	10	
General Cleaning	1.7.2	Are waste and garbage frequently removed from packing and storage areas?	5	
General Cleaning	1.7.3	Do floor drains appear clean, free from odors and well maintained?	5	
General Cleaning	1.7.4	Do high level areas including overhead pipes, ducts, fans, etc. appear clean?	10	
General Cleaning	1.7.5	Are plastic strip curtains maintained in a good condition, kept clean and mounted so that the tips are not touching the floor?	5	

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General Cleaning	1.7.6	Does personal protection equipment (PPE) for the sanitation crew meet label requirements of chemicals used; is it in good condition and stored to prevent cross contamination to raw materials, work in progress, ingredients, finished goods and packaging?	3	
General Cleaning	1.7.7	Is cleaning equipment maintained clean and stored properly?	10	
General Cleaning	1.7.8	Is cleaning equipment identified in order to prevent potential cross contamination issues e.g. production, maintenance, outside, restroom equipment?	10	
General Cleaning	1.7.9	Are all items used for sanitation appropriate for their designated purpose? (no steel wool, metal bristles, etc.)	5	
General Cleaning	1.7.10	Are toilet facilities and hand-wash stations clean?	15	
General Cleaning	1.7.11	Are employee break facilities clean, including microwaves and refrigerators? No rotting or out of date foodstuffs?	5	
General Cleaning	1.7.12	Is the maintenance shop organized - i.e. equipment and spares stored in a neat and tidy fashion?	5	
General Cleaning	1.7.13	Are internal transport vehicles (e.g. forklifts, bobcats, pallet jacks, trolleys, floor cleaners, etc.), clean, do not emit toxic fumes and being used in a sanitary manner?	5	
General Cleaning	1.7.14	Are shipping trucks clean and in good condition?	5	
Pest Control	1.8.1	Are products or ingredients free of insects/rodents/birds/reptiles/mammals or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.	15	
Pest Control	1.8.2	Are packaging supplies free of insects/rodents/birds/reptiles/mammals or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.	15	
Pest Control	1.8.3	Are plant and storage areas free of insects/rodents/birds/reptiles/mammals or any evidence of them?	15	
Pest Control	1.8.4	Is the area outside the facility free of evidence of pest activity?	10	
Pest Control	1.8.5	Does the operation have a pest control program? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.	15	
Pest Control	1.8.6	Are pest control devices (inc. rodent traps and insect light traps) located away from all exposed raw materials, work in progress, finished goods and packaging? Poisonous rodent bait traps are not used within the facility?	10	

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Pest Control	1.8.7	Are pest control devices maintained in a clean and intact condition and marked as monitored (or bar code scanned) on a regular basis?	5	
Pest Control	1.8.8	Are interior and exterior building perimeter pest control devices adequate in number and location?	5	
Pest Control	1.8.9	Are all pest control devices identified by a number or other code (e.g. barcode) ?	5	
Pest Control	1.8.10	Are all pest control devices properly installed and secured?	5	
Buildings and	1.9.1	Are signs supporting GMPs posted	10	
Grounds	1.5.1	appropriately?	10	
Buildings and Grounds	1.9.2	Are all lights in the facility that could potentially contaminate raw materials, work in progress, ingredients (including ice), finished goods, equipment or packaging shielded, coated or otherwise shatter resistant to protect product from contamination in the event of breakage?	15	
Buildings and Grounds	1.9.3	Has the facility eliminated or controlled any potential metal, glass or plastic contamination issues?	15	
Buildings and Grounds	1.9.4	Has the facility eliminated the use of wooden items or surfaces?	5	
Buildings and	1.9.5	Is there adequate lighting in the packing and	5	
Grounds Buildings and	1.9.6	storage areas? Are ventilation systems properly designed and	10	
Grounds		functioning to prevent product contamination from condensation, mold, dust, odors and vapors?	10	
Buildings and Grounds	1.9.7	Are floor surfaces in good condition, with no standing water, no debris trapping cracks and are they easy to clean?	10	
Buildings and Grounds	1.9.8	Are the floor drains where they are needed for drainage and cleanup?	5	
Buildings and Grounds	1.9.9	Are doors to the outside pest proof?	5	
Buildings and Grounds	1.9.10	Are dock doors fitted with buffers to seal against trucks?	5	
Buildings and Grounds	1.9.11	Are dock load levelers and shelters maintained in a good condition, pest proof and debris free?	3	
Buildings and Grounds	1.9.12	Are exterior walls free of holes to exclude pests? Are pipes, vents, air ducts designed and protected in order to prevent pest entry e.g. by using fine mesh?	5	
Buildings and Grounds	1.9.13	Are interior walls and ceilings free of cracks and crevices to prevent pest harborage and allow proper sanitation?	5	
Buildings and Grounds	1.9.14	Where used in production, storage or supporting areas do false ceiling areas have adequate access to allow for inspection and cleaning?	5	
Buildings and Grounds	1.9.15	Is an 18" (46 cm) internal wall perimeter being maintained within the facility, with adequate access to these wall perimeters thereby allowing inspection and cleaning?	5	

Buildings and Grounds	1.9.16	Is the exterior area immediately outside the facility free of litter, weeds and standing water?	5	
Buildings and Grounds	1.9.17	Are control measures being implemented for the storage of pallets, equipment, tires, etc. (e.g. out of the mud, pipe ends capped, stacked to prevent pest harborage, away from building perimeter)?	5	
Buildings and Grounds	1.9.18	Are pallets inspected to separate and replace dirty or broken pallets?	5	
Buildings and Grounds	1.9.19	Is the area around the dumpster/cull truck/trash area clean?	3	
Buildings and Grounds	1.9.20	Are outside garbage receptacles and dumpsters kept covered or closed?	5	
Buildings and Grounds	1.9.21	Are all water lines protected against back siphonage?	5	
Buildings and Grounds	1.9.22	Is the on-site laboratory (where applicable) completely enclosed and separated from production and/or storage areas?	5	

FOOD SAFETY FILE REQUIREMENTS - SECTION 2

Category	#	Question	Total Points	Recommendations
Management Systems	2.1.1	Is the operation registered as a food handling establishment?	10	
Management Systems	2.1.2	Is there a documented food safety policy reflecting the organization's ongoing commitment to providing a safe product?	5	
Management Systems	2.1.3	Is there an organizational chart showing who has food safety responsibilities and to whom they report?	3	
Management Systems	2.1.4	Is there a designated person responsible for the food safety program?	10	
Management Systems	2.1.5	Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?	5	
Control of Documents and Records	2.2.1	Is there a written document control procedure describing how documents will be maintained, updated and replaced?	3	
Control of Documents and Records	2.2.2	Are all records stored for a minimum period of 24 months?	5	
Control of Documents and Records	2.2.3	Are food safety related documents and records stored and handled in a secured manner? Records recorded in permanent ink, not pencil; errors single-lined through and initialed?	10	
General File Requirements	2.3.1	Are there written Standard Operating Procedures (SOPs) that detail work instructions for activities ensuring food safety and Good Manufacturing Practices?	5	

General File Requirements	2.3.2	Are there specific Standard Operating Procedures (SOPs) for the changing and testing of water and ice systems e.g. wash systems, hydrovacuums, hydrocoolers, ice making machines, ice injectors, etc?	10	
General File Requirements	2.3.3	Is there a documented glass and brittle plastic management policy and procedure (including company glass and brittle plastic policy, glass breakage procedure and where necessary a glass register)?	5	
General File Requirements	2.3.4	Are the SOPs available to relevant users and is a master copy maintained in a central file (SOP Manual)?	5	
Traceability	2.4.1	Is there is a documented account that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?	10	
Traceability	2.4.2	Does the facility have a documented recall program including: procedures, recall team roles, their contact details, external contact listings and (in the USA) an explanation of different recall classes?	15	
Traceability	2.4.3	Is testing of recall procedures (including trace back) performed and documented at least once every six months? Can the company identify where affected product was sent?	10	
Traceability	2.4.4	Is there a written procedure for handling on hold and rejected materials?	10	
Traceability	2.4.5	Is there a documented system for dealing with food safety complaints/feedback from consumers and buyers along with records and company responses, including corrective actions?	5	
Supplier Control	2.5.1	Are there written specifications for own grown raw materials, purchased edible raw materials/ingredients, packaging materials, processing and sanitation chemicals?	3	
Supplier Control	2.5.2	Are there written specifications for finished goods?	3	
Supplier Control	2.5.3	Is there a list of approved suppliers of purchased raw materials/ingredients, packaging materials and processing and sanitation chemicals?	5	
Supplier Control	2.5.4	Is there a written procedure for approval and continued monitoring of suppliers of purchased raw materials/ingredients, packaging materials processing and sanitation chemicals?	3	
Supplier Control	2.5.5	Does the facility have relevant third party audit reports, supplier third party audit certifications and/or supplier letters of guarantee for purchased edible raw materials/ingredients, packaging materials and processing chemicals?	15	

Supplier Control	2.5.6	Does the facility have relevant third party audit reports, supplier third party audit certifications and/or supplier letters of guarantee for packaging items?	10	
Chemicals	2.6.1	Are copies of all Materials Safety Data Sheets (detergents, sanitizers, pesticides, etc.) on file and fully accessible at all times with clear indexes?	5	
Chemicals	2.6.2	Are there copies of specimen labels for chemicals used, where the full label is not immediately accessible e.g. rodent chemicals, product sanitizers?	5	
Chemicals	2.6.3	Is there a chemical inventory and/or usage log?	3	
Pest Control	2.7.1	Is there a documented pest control program, including a copy of the contract with the extermination company (if used), Pest Control Operator license(s) (if baits are used) and insurance documents?	15	
Pest Control	2.7.2	Is there a schematic drawing of the plant showing numbered locations of all traps and bait stations, both inside and outside the plant?	10	
Pest Control	2.7.3	Are service reports created for pest control checks detailing inspection records, application records, and corrective actions of issues noted (in-house and/or contract)?	10	
Internal and External Inspections	2.8.1	Are there written procedures for handling regulatory inspections?	3	
Internal and External Inspections	2.8.2	Are there records of regulatory inspections and/or contracted third party inspections, company responses and corrective actions, if any?	5	
Internal and External Inspections	2.8.3	Is there a program for periodic facility/GMP internal (self) inspections and are records maintained detailing corrective actions?	10	
Internal and External Inspections	2.8.4	Is there a program for periodic inspections of food safety system records e.g. pest control records, temperature control records, sanitation records, maintenance records, etc.?	5	
Internal and External Inspections	2.8.5	Is there a daily pre-operation inspection log?	5	
Internal and External Inspections	2.8.6	Does the facility have incoming goods (raw materials, ingredients and packaging materials) inspection data?	5	
Internal and External Inspections	2.8.7	Are there inspection logs on incoming trailers for rodents and insects, cleanliness, holes and temperature control?	10	

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Internal and External Inspections	2.8.8	Is there an incidents report (sometimes called a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA)) used for recording infrequent and/or unusual events?	5	
Internal and External Inspections	2.8.9	Is there a current certificate of inspection for backflow prevention assemblies on water lines entering the facility?	3	
Process Control	2.9.1	Are there records for the necessary process monitoring activities (e.g. pH, water temperature, heating processes, etc.) showing the monitoring frequencies, results and where necessary the corrective actions?	10	
Process Control	2.9.2	Are there records (with corrective actions) that show anti-microbial (e.g. free chlorine, ORP, peracetic acid) strength testing of wash water and ice solutions prior to start up and throughout the production runs?	10	
Process Control	2.9.3	Are there records (with corrective actions) that show anti-microbial strength testing of hand/foot/tool dip stations? Are there stock check and replenishment records for gel and spray stations?	3	
Process Control	2.9.4	Is there a tool accountability program for knives and similar cutting hand tools used in the production process?	3	
Process Control	2.9.5	Are there written procedures for the set-up, calibration, maintenance and verification of foreign material control systems e.g. metal detectors?	10	
Process Control	2.9.6	Are there equipment calibration procedures and records for pH meters, ORP meters, thermometers and other measuring equipment related to the food safety of the product?	10	
Maintenance & Sanitation	2.10.1	Does the facility have a preventative maintenance program and with a documented schedule?	10	
Maintenance & Sanitation	2.10.2	Is there a log of maintenance work or repairs ordered and is it signed off on work completed?	10	
Maintenance & Sanitation	2.10.3	Are there logs showing that equipment is cleaned and sanitized after maintenance work has been completed?	5	
Maintenance & Sanitation	2.10.4	Is there a written cleaning schedule (Master Sanitation Schedule) that shows what and where is to be cleaned and how often?	10	
Maintenance & Sanitation	2.10.5	Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the facility and all equipment?	10	
Maintenance & Sanitation	2.10.6	Are sanitation logs on file that show what cleaning was done, when and who carried out the cleaning?	5	
Maintenance & Sanitation	2.10.7	Are there records showing verification of cleaning chemical concentrations?	5	

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Maintenance & Sanitation	2.10.8	Are there documented procedures and completion records for clean-in-place (CIP) activities, where applicable (e.g. cleaning recirculating water systems such as washing flumes, ice injectors, hydrocoolers, ice makers, etc.)?	5	
Maintenance & Sanitation	2.10.9	Is there a log indicating that floor drains are cleaned on a regular basis (minimum daily in wet and fresh-cut production areas)?	5	
Maintenance & Sanitation	2.10.10	Are there records showing cooling units are serviced and cleaned at least every 12 months or more frequently as required?	10	
Maintenance & Sanitation	2.10.11	Is there a routine program and written procedure to validate sanitation effectiveness on food contact surfaces using ATP bioluminescence testing?	5	
Personnel	2.11.1	Are there records of new employee food safety (GMP) orientation training (with topics covered and attendees) and are new employees required to sign the company's food safety hygiene and health policy?	10	
Personnel	2.11.2	Are there logs of ongoing employee food safety education training with topics covered and attendees?	10	
Personnel	2.11.3	Are there written procedures in place that require food handlers to report any cuts or grazes and/or if they are suffering any illnesses that might be a contamination risk to the products being produced? (Verbal confirmation accepted.)	З	
Personnel	2.11.4	Is there a documented training program with training logs for the sanitation employees including best practices and chemical use details?	5	
Personnel	2.11.5	Are visitors and contractors required to sign a log stating that they will comply with the operations' personal hygiene and health policies?	3	
Personnel	2.11.6	Is there an employee non- conformance/disciplinary action procedure? (Verbal confirmation accepted.)	3	
Teet	0.40.4	And the contract of maril	4.0	
Testing	2.12.1	Are there records of routine equipment microbiological testing?	10	
Testing	2.12.2	Are there records of routine environmental microbiological testing?	10	
Testing	2.12.3	Are there routine microbiological tests on water used in the facility (sampled from within the facility)?	10	
Testing	2.12.4	Are there routine microbiological tests on ice used in the facility (either produced in-house or purchased)?	5	
Testing	2.12.5	Do laboratory test results indicate test procedures meet accepted standards?	5	

Testing	2.12.6	Where testing has been performed for any reason, (e.g. buyer requirements) does the testing meet all the specification requirements (e.g. type of test, test frequency, test methodology, thresholds, corrective actions, etc.) and are proper records of tests with formal corrective actions being maintained?	5	
Temperature Controlled Storage & Distribution	2.13.1	Are there records of final product temperature checks for temperature sensitive product?	10	
Temperature Controlled Storage & Distribution	2.13.2	Are there temperature logs for the packing/processing room (if refrigerated)?	5	
Temperature Controlled Storage & Distribution	2.13.3	Are there temperature logs for storage rooms?	5	
Temperature Controlled Storage & Distribution	2.13.4	Are there records of shipping truck temperature checks, indicating that the truck was pre-cooled prior to loading?	5	
Temperature Controlled Storage & Distribution	2.13.5	Are there sanitary condition logs for shipping trucks (cleanliness, trailer condition, odor, etc.)?	10	

HACCP PROGRAM AUDIT - SECTION 3

Category	#	Question	Total Points	Recommendations
HACCP Team	3.1.1	Is there a team responsible for HACCP development, implementation and on-going maintenance?	15	
HACCP Team	3.1.2	Is there documented HACCP specific training for the HACCP team, management and operating personnel?	10	
Review of the Written HACCP Plan	3.2.1	Does a product description exist for each product produced? Do they contain the products intended use, materials and raw ingredients, and who the intended consumer is?	10	
Review of the Written HACCP Plan	3.2.2	Has the process been flow charted? Is the flow chart in sufficient detail to completely describe the process or product manufacturing steps?	15	
Review of the Written HACCP Plan	3.2.3	Has a documented hazard analysis for each process flow been conducted, showing the various types of hazard and their associated severity?	15	
Review of the Written HACCP Plan	3.2.4	Does the documented hazard analysis show the controls for each identified potential food safety hazard?	15	
Review of the Written HACCP Plan	3.2.5	Have CCP decisions been made, have CCPs been identified and where CCPs are noted, have they been developed to control the hazards identified in the hazard analysis step?	15	

Review of the	3.2.6	Have monitoring requirements and frequencies	15	
Written HACCP		been determined for the CCPs?		
Plan				
Review of the	3.2.7	Are identified CCP critical control limits	5	
Written HACCP	0.2.7	supported by validation documentation?	O	
Plan		supported by validation documentation:		
Review of the	3.2.8	Is there a clear, detailed action plan for	15	
Written HACCP		operators to follow if the CCP critical control		
Plan		limits are exceeded? Does it describe plans to		
		adjust the process back into control and		
		withhold out of compliance products if		
		necessary?		
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Review of the	3.2.9	Have recording templates (recording forms)	10	
Written HACCP		been developed for monitoring the CCPs?		
Plan				
Review of the	3.2.10	Have specific responsibilities been assigned for	10	
Written HACCP	0.2.10	the monitoring, recording and corrective action	. 0	
Plan		management of each CCP?		
Review of the	3.2.11	Have verification plans and schedules been	10	
Written HACCP		developed for each CCP?		
Plan				
_				
Execution of	3.3.1	Are all of the documents noted in the HACCP	15	
the HACCP		plan in place for real time monitoring of the		
Plan		CCPs?		
Execution of	3.3.2	Are the CCP monitoring activities and	15	
the HACCP	0.0.2	frequencies in conformance with the plan?	. •	
Plan		requericies in comormance with the plant		
Execution of	3.3.3	Do CCP operators understand basic HACCP	15	
the HACCP		principles and their role in monitoring CCPs?		
Plan		(Interview operators to verify.)		
Execution of	3.3.4	Are CCP monitoring records signed off (or	10	
the HACCP		initialed) by the operator(s) who are carrying		
Plan		out and recording the CCP check?		
i idii		out and recording the COT check.		
Execution of	3.3.5	Are corrective actions detailed in writing when	15	
the HACCP		the failure of a CCP occurs?		
Plan				
Execution of	3.3.6	Are the CCP records reviewed and signed off	10	
the HACCP		daily by the quality control supervisor and/or		
Plan		management as part of the verification plan?		
		and and and part of the form of the fact of		
Fuggitter of	0.07	le any other CCD verification or formed (10	
Execution of	3.3.7	Is any other CCP verification performed (apart	10	
the HACCP		from daily record verification) according to the		
Plan		HACCP Plan?		
Management	3.4.1	Are changes in the process, equipment,	10	
Support of	0.4.1	ingredients etc., causing timely reviews of	10	
HACCP		HACCP systems, including hazard analysis,		
		CCP decisions, CCP records and staff		
		training?		
Management	3.4.2	Is the plant conducting self-audits of the	10	
Support of		HACCP program?		
HACCP				
Management	3.4.3	Have standard operating procedures (SOPs)	10	
_	3.4.3		10	
Support of		been created for the CCP monitoring		
HACCP		processes that include how to carry out the		
		monitoring?		
			_	

Management Support of HACCP	3.4.4	Are monitoring and verification information reviewed and discussed at management level meetings?	10	
Management Support of HACCP	3.4.5	Are there independent audits e.g. third party audits, of the plant's HACCP program (at least every 12 months)?	10	

FOOD DEFENSE - SECTION 4

FOOD DEFENSE - SECTION 4					
Category	#	Question	Total Points	Recommendations	
Physical Security	4.1.1	Are the facility external areas and vulnerable entry points (i.e. those that are not permanently locked) surrounded by security fencing?	5		
Physical Security	4.1.2	Is access to the facility controlled by locks, swipe cards, alarms or other devices?	10		
Physical Security	4.1.3	Are inbound food product storage areas (fruits, vegetables, etc.) secure i.e. within the secure compound?	5		
Physical Security	4.1.4	Are chemicals such as chlorine, citric acid, fungicides and sanitation chemicals stored within secured areas with controlled access?	5		
Physical Security	4.1.5	Are packaging material (cartons, wrap film, fruit cups, etc.) storage areas secure, i.e. within the secure compound?	5		
Employee Security	4.2.1	Are background checks conducted on all personnel with special attention to employees who have access to sensitive areas and/or control of sensitive processes (verbal confirmation accepted)?	5		
Employee Security	4.2.2	Employees personal items are not being stored in the production and material storage areas?	5		
Employee Security	4.2.3	Are employees issued non-reproducible identification e.g. badges, company ID cards, etc.?	5		
Employee Security	4.2.4	Are visitors (including contractors) also required to be issued with identification e.g. badges, high visibility visitor apparel, etc?	5		
Employee Security	4.2.5	Are visitors (including contractors) required to "sign in" and "sign out" in a visitors logbook?	5		
Transport Security	4.3.1	Does the company make use of sealed and/or locked trailers on inbound loads (excluding open flatbed trucks)?	3		
Transport Security	4.3.2	Does the company make use of sealed and/or locked trailers on outbound loads?	3		
Water Supply Security	4.4.1	Are potable and non-potable water supplies clearly identified?	3		
Water Supply Security	4.4.2	Are tamper evident/tamper resistant systems (e.g. tamper tags) in place where appropriate?	3		

Water Supply Security	4.4.3	Is there restricted access to sensitive water systems, e.g. anti-microbial addition systems (like chlorine injection pumps), that helps ensure that only authorized personnel are able to adjust these systems?	3	
Food Defense Systems	4.5.1	Does the company have a documented food defense policy based on the risks associated with the operation?	10	
Food Defense Systems	4.5.2	Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?	3	
Food Defense Systems	4.5.3	Are all personnel required to undergo training on food defense issues and are training records kept?	5	
Food Defense Systems	4.5.4	Is there is a log of who has access to sensitive areas e.g. a listing of key holders for access to areas like chemical storage?	3	

MISCELLANEOUS SURVEY QUESTIONS - SECTION 5

Category	#	Question	Total Points	Recommendations
Allergens	5.1.1	Are there allergen risks handled or stored within production and storage areas?	0	
Allergens	5.1.2	Has a documented allergen management plan been developed?	5	
Allergens	5.1.3	Are there adequate storage controls (separation, identification, etc.) that ensure that allergens are not contaminating other raw materials?	5	
Allergens	5.1.4	Is there a dedicated production line or adequate clean down and production procedures that prevent allergen cross contamination?	5	
Allergens	5.1.5	Are utensils and work in progress storage containers identified in order to prevent allergen cross contamination?	5	
Allergens	5.1.6	Does re-work handling take into account the issues associated with allergen containing products?	5	
Allergens	5.1.7	Are employees trained with respect to allergen risks and the facility allergen cross contamination controls (including hand washing between production runs) and are there records of this allergen training?	5	
Allergens	5.1.8	Are all products manufactured on site, labeled correctly with respect to allergens?	5	
Country of Origin Labeling	5.2.1	Is the company labeling retail packaging with the correct country(ies) of origin? N/A for food service.	3	
Country of Origin Labeling	5.2.2	Is the company labeling the finished goods carton with the correct country(ies) of origin? N/A for food service.	3	

Country of Origin Labeling		Are there records that support the country(ies) of origin labeling e.g. bill of lading, production records, etc.?	3	
Country of Origin Labeling	5.2.4	Are steps taken in the storage and production process to ensure that there is no commingling of materials from different countries (unless product will be labeled as such)?	3	

NEW QUESTIONS (NOT PART OF OVERALL FOOD SAFETY PERCENTAGE) - SECTION 6

Category	#	Question	Total Points	Recommendations
Buildings and Grounds	6.1.1	Does the waste flow, from creation through to leaving the operation including vehicle use and flow, employee control, etc., ensure that facility and products are not contaminated?	10	
Temperature Controlled Storage & Distribution	6.1.2	Is there a written procedure requiring transportation vehicles be dedicated to produce, and that animals, animal products or other materials that may be a source of contamination are not allowed to be transported?	5	
Management Systems	6.1.3	Is there a documented food safety plan covering site and facility?	10	
Management Systems	6.1.4	Is there a documented business continuity and disaster recovery plan?	5	
Buildings and Grounds	6.1.5	Does the facility have documented evidence to ensure that any food safety hazards relevant to waste water treatments (e.g. settling ponds, land applications, etc.) are controlled?	10	
Review of the Written HACCP Plan	6.1.6	Has the operation listed the HACCP pre- requisite programs that are in effect at the facility?	10	
Review of the Written HACCP Plan	6.1.7	Where operating limits and frequencies been established for the CCPs are they being monitored?	10	