PRIMUSLABS V14.09 GMP AUDIT
Questions & Expectations

GOOD MANUFACTURING PRACTICES - SECTION 1

Category	#	Question	Total Points	Recommendations
	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	Any issue that is a serious threat to food safety that lacks proper corrective actions and may result in product contamination.
Storage Areas & Packaging Materials	1.2.1	Are all chemicals (pesticides, sanitizers, detergents, lubricants, etc.) stored securely, safely and are they labeled correctly?	15	Chemicals are required to be stored in a designated secured storage area (with good signage). The chemical storage area to be located away from any raw materials, packaging & finished food products. Spill controls should be in place for opened in use containers. All chemical containers should be adequately labeled.
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	Chemicals should be used according to label. Only food grade lubricants should be used anywhere near product and packaging materials. "Food grade" and "non-food grade" materials should be stored in separate designated areas and adequately labeled. Access to non-food grade materials should be limited to those entrusted with correct use of chemicals.
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	Raw materials should be stored separately from finished product. Product and packaging should be stored off the ground, protected if necessary, away from chemicals, battery chargers, etc. in order to prevent contamination. Special attention should be given to ice storage and where relevant allergen storage.
Storage Areas & Packaging Materials	1.2.4	Is the storage area completely enclosed?	10	All raw material and finished goods should be stored inside. Food contact packaging should be stored inside. Non food contact packaging should be stored inside but if stored outside, should be shroud protected.
Storage Areas & Packaging Materials	1.2.5	Is the facility's use restricted to the storage of food products?	5	To avoid any adulteration or possible cross contamination from other items, only food and related items should be stored in the facility.
Storage Areas & Packaging Materials	1.2.6	Are rejected or on hold materials clearly identified and separated from other materials?	10	Rejected or on hold materials should be kept separate in a designated area and identified from other materials to avoid accidental use or shipping. Make sure that the pallet or rejected product is properly tagged. A separate area also helps ensure that there are no accidental uses or shipping of on hold materials.
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	Raw materials, work in progress, ingredients (including water and ice), finished goods and food contact packaging that are adulterated are illegal. Adulteration can take many forms (e.g., foreign materials, misrepresentation of products, etc.). Ice should be made from potable water. Untreated surface water is not considered potable.
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	All storage areas should be kept clean and free from dust, debris and other extraneous materials. This helps avoid pest attraction and contamination of products, ingredients or packaging. Pest activity is easier to detect in a clean area.
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	Materials should be clearly marked or labeled with some kind of rotation coding that is understood by all staff, in order to ensure FIFO and effective traceback/recall procedures.
Storage Areas & Packaging Materials	1.2.10	Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) rotated using FIFO policy?	5	Should be using First In First Out principal. Proper rotation of materials can prevent stock losses due to pest infestation, decomposition, mold and other problems associated with prolonged storage.
Storage Areas & Packaging Materials	1.2.11	Are storage areas at the appropriate temperatures for the specific products being stored?	10	Products should be stored at the correct temperatures. This might mean that the operation has several cold store chambers set at different temperatures.

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	Raw materials should not be allowed to touch finished goods. Raw material handlers should not contaminate finished goods - clear controls required. Separate coded utensils required for processed products relative to raw materials. Internal vehicles should be dedicated to one area or the wheels cleaned when go from raw to processed goods areas.
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	Overhead contamination of exposed product areas can result in microbiological, chemical and/or physical contamination. Exposed materials should be protected (e.g., catwalks covered, use of kick plates, condensate catching pans, etc.).
Operational Practices	1.3.3	Are packing and/or processing areas completely enclosed?	15	Packing and/or processing areas should be completely enclosed (walls or pest proof mesh) to minimize pest entry into the facility and to avoid contamination of products.
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	Production areas should be maintained in a clean and sanitary condition.
Operational Practices	1.3.5	Is all re-work / re-packaging handled correctly?	10	Re-work product should be labeled properly to avoid mistaking it with other products and maintaining traceability. Re-work should be handled in a way to prevent contamination from the environment or from other products.
Operational Practices	1.3.6	Are raw materials examined before use?	5	Raw materials should be inspected. This inspection should look for foreign material contaminants, rotting materials and any unusual issues (e.g., unsealed packaging, visible residues, etc.).
Operational Practices	1.3.7	Are finished products coded (carton and unit packaging) for the day of production?	10	Product should be lot and/or date coded in order to ensure an effective trace back and recall program and also for inventory control.
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	Traceable lot codes asigned at receipt should follow the item (raw materials, ingredients, finished goods and packaging) through storage and use in finished product.
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	Foreign material control systems should be in place where products are cut/sliced and where otherwise prudent. These systems should be frequently checked to ensure that they are working correctly (recorded). Foreign material issues should be noted as deviations.
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	The strength (concentration, pH, etc.) of anti-microbial chemicals should be checked on a regular basis and recorded. Solutions that are too weak will be ineffective (and a potential risk), while those that are too strong may be harmful to employees or product.
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	Enough stations, in working order should be provided to ensure efficient staff flow (1 per 10 people on site). Hands free is an optimum system for food establishments. Operations packing or processing items should have hand washing locations that are situated in such a way that the hand washing discipline can be observed. Stations should have warm water, soap and paper towels.
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	At least one stall per 15 employees. Toilet facilities should not open directly into production or storage areas. Restrooms should be stocked with toilet paper, scentless soap and towels.
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	Secondary hand sanitation helps reduce microbial load between hand washing events. Stations must be maintained (checked and replenished). Stations should be placed strategically. Secondary hand sanitation does not replace proper hand washing.
Operational Practices	1.3.14	Are foot dip stations adequate in number and location? Are the stations maintained properly?	3	Foot stations filled with anti-microbial solution can help control cross contamination. Stations should be maintained (changed and checked). Stations should be placed strategically i.e. entrances to "clean areas".
Operational Practices	1.3.15	Are single service containers used for their intended purpose only so that potential cross contamination is prevented?	5	To avoid cross contamination, single service containers should not be re-used. Storage of small parts, or tools in packaging containers, should not be allowed (unless these are marked up for such use and will not be used in the food chain).
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	Identification of re-usable containers (visually or in the language understood by the workers) helps to minimize contamination of products. This is especially important where re-usable containers are a similar design to any of the product containers.
Operational Practices	1.3.17	Are food safety measuring devices working properly and calibrated (where applicable)?	3	Thermometers, chemical testing equipment, etc., should be working correctly. Where necessary, equipment should be calibrated.

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	Washing hands is the first step in avoiding food contamination. Adequate washing with soap and water is obligatory before starting work and after each absence from the work station. Hand washing signs should be posted.
Employee Practices	1.4.2	Are employees' fingernails clean, short and free of nail polish?	5	Fingernails can harbor dirt and debris and therefore should be clean and short. Fingernail polish and false nails should not be worn.
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	Employees with these afflictions have the potential to contaminate the product.
Employee Practices	1.4.4	Are first aid kits adequately stocked and readily available? Are blue metal detectable waterproof band aids used?	5	First aid kit(s) should be adequately supplied and readily available for emergency access. Date-coded materials should be within dates of expiration. Bandages should be blue in color for easy visual detection, with a metal strip behind the wound pad for detection on lines with metal detectors.
Employee Practices	1.4.5	Are employees wearing effective hair restraints?	10	Wearing hair restraints, moustache covers and beard-nets prevents hair from falling into exposed product. Hair restraints also avoids staff unintentionally touching hair, then touching product.
Employee Practices	1.4.6	Is jewelry confined to a plain wedding band and watches are not worn?	3	Jewelry except plain wedding bands should not be worn in the production areas. Jewelry can fall into product. It can also get snagged in machinery.
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	Smocks and aprons should be worn to cover street clothes that may have contaminants from the outside environment. Gloves and sleeves when properly used (if appropriate) can help reduce transmission of micro-organisms from the arms and hands (gloves do not replace hand washing). Gloves are non-latex.
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	When worn, these items should be removed anytime an employee leaves the work area. Employees cannot smoke, eat, go outside the building or use the restroom while wearing these garments.
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	Having a designated area for these items helps keep them in a sanitary condition. Avoid hanging them next to personal clothing, on packaging materials, on or near chemicals or on equipment to prevent cross contamination.
Employee Practices	1.4.10	Employees personal items are not being stored in the production or material storage areas?	5	Personal belongings should not be taken into production and storage areas. Separate areas should be provided for personal belongings. Cubbies or see through lockers are ideal, if maintained properly, mounted off the floor and with sloping tops and located outside production and storage areas.
Employee Practices	1.4.11	Is smoking, eating, chewing and drinking confined to designated areas; spitting is prohibited in all areas?	10	Eating, chewing, drinking and smoking must be restricted to designated areas on site, in order to prevent contamination of product, packaging and equipment. Drinking is not permitted near the line. Spitting should be prohibited anywhere on site.
Employee Practices	1.4.12	Are all items removed from garment (smock, shirt, blouse, etc) top pockets?	3	Items in pockets have the potential to fall into the product.
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	Food equipment should not have flaking paint, corrosion, rust and/or unhygienic materials. These can pose foreign material and/or microbiological hazards.
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	Flaking paint, corrosion, rust and/or unhygienic materials should not be present on any surfaces.
Equipment	1.5.3	Does equipment design and condition (e.g. smooth surfaces, smooth weld seams, non-toxic materials, no wood, or other absorbant materials) facilitate effective cleaning and maintenance?	15	Equipment should be made of appropriate materials that can be easily cleaned and maintained, that are not porous or toxic. Equipment should be designed to allow access and easy cleaning, with no hard to get to (debris catching) areas. Welds should be smooth and not "bobbly".
Equipment	1.5.4	Are thermometers (independent of thermostat probes) present in all coolers and freezers?	5	All cold rooms should have a thermometer to monitor and control the temperature. The monitoring thermometer(s) should be independent from the thermostat probe.
Equipment	1.5.5	Are all thermometers non-glass and non-mercury?	10	Thermometers should not pose a foreign material risk. Both glass and mercury could be contaminants if the thermometer was to break.
Equipment Cleaning	1.6.1	Are food contact equipment surfaces clean?	15	Unsanitary food contact surfaces can directly lead to contamination of the product. Food debris, bio films, excessive dust, etc. should be cleaned off equipment and facility surface in order to reduce the overall facility bio-burden.

Equipment Cleaning	1.6.2	Are non-food contact equipment surfaces clean?	10	Unsanitary non-food contact surfaces can indirectly lead to contamination of the product. Food debris, bio films, excessive dust, etc. should be cleaned off equipment and facility surface in order to reduce the overall facility bio-burden.
Equipment Cleaning	1.6.3	During cleaning are foods and packaging protected from contamination?	15	To avoid contamination, foods and packaging should be covered, screened and protected in some way or removed from the area while cleaning is taking place.
Equipment Cleaning	1.6.4	Are cooling units including coils in coolers and freezers clean and free of aged, dirty ice?	5	Cooling coils can build-up dust and other contaminants. They should be included in the master sanitation schedule.
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	Fan guards should be dust-free to prevent cross contamination. The ceiling in front of the fans (especially cooler units) should be free from excessive black deposits.
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 should be stored appropriately (e.g., covered, protected and off the floor) to prevent inappropriate use and cross contamination. Alternatively, unused equipment can be left on sanitation and maintenance programs.
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	Utensils, hoses and other items should be stored appropriately to prevent contamination. Storing off the floor, protected from splash back, dedicated lockers/storage areas, etc. should be considered as possible control steps.
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	Tools that are used for repairing equipment in the production and storage areas should be appropriately stored to ensure they do not pose a risk of direct or indirect contamination. When in production and storage areas, the should be clean, free of corrosion and in good working order i.e. fit for their intended use.
Equipment Cleaning	1.6.9	Are excess lubricants removed from the equipment and are lubricant catch pans fitted where needed?	5	Dripping caused by over lubrication is a potential chemical contaminant to the product or packaging. Frequent lubrication using minimal material and use of drip pans are control examples. Note that food grade materials are designed for incidental food contact. All efforts should be made to avoid these materials getting onto the product and packaging.
General Cleaning	1.7.1	Are spills cleaned up immediately?	10	To prevent the attraction of pests, reduce cross contamination and maintain a sanitary environment, all spills must be cleaned up immediately.
General Cleaning	1.7.2	Are waste and garbage frequently removed from packing and storage areas?	5	Waste and garbage must be removed on a frequent basis to prevent attraction of pests, reduce cross contamination, reduce bad odors and maintain a sanitary environment
General Cleaning	1.7.3	Do floor drains appear clean, free from odors and well maintained?	5	Floor drains should be cleaned on a frequent basis (daily in wet facilities) to remove residues, prevent growth of harmful bacteria and to allow for proper drainage. Drain side and bases should be made of a smooth material that does not trap debris.
General Cleaning	1.7.4	Do high level areas including overhead pipes, ducts, fans, etc. appear clean?	10	Overhead areas should be cleaned as required to prevent potential contamination.
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	Plastic strip curtains may be a source of contamination if they are not maintained clean, intact and fitted properly (so tips are not touching).
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	The sanitation crew should wear appropriate safety equipment to avoid any health problems from the chemicals that they use during the cleaning process. All safety equipment should be stored to prevent contamination to raw materials, work in progress, ingredients, finished goods and packaging.
General Cleaning	1.7.7	Is cleaning equipment maintained clean and stored properly?	10	Adequate cleaning equipment should be available (per procedures) and stored free of debris, clean and in a way to prevent cross contamination.
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	Cleaning equipment used for production areas need to be separated (physically and visually) from cleaning equipment used in non-production areas in order to prevent cross contamination from occurring. Sometimes even within production areas, there is a need to differentiate equipment even further (e.g., equipment used on the floor versus equipment used on the machinery).
General Cleaning	1.7.9	Are all items used for sanitation appropriate for their designated purpose? (no steel wool, metal bristles, etc.)	5	Sanitation equipment should be constructed of appropriate materials that will not contaminate the product. Avoid anything that flakes, made of pervious materials, of a similar color as the products, corrodes or might damage the equipment or facility.

General Cleaning	1.7.10	Are toilet facilities and hand-wash stations clean?	15	Toilet facilities should be cleaned and sanitized at least daily. Soiled tissue should be flushed down the toilet (not placed in trash cans and/or on the floor).
General Cleaning	1.7.11	Are employee break facilities clean, including microwaves and refrigerators? No rotting or out of date foodstuffs?	5	All employee break facilities should be clean to prevent the attraction of pests. Temperature sensitive foods should be stored in cold boxes or provided refrigerators. Periodic cleaning includes inside microwaves, inside and behind refrigerators, behind, under and on top of all vending machines, tables, chairs and lockers to prevent potential pest harborage that may affect the product.
General Cleaning	1.7.12	Is the maintenance shop organized - i.e. equipment and spares stored in a neat and tidy fashion?	5	The maintenance shop should be clean and well ordered. An unclean shop can result in cross contamination and pest attraction. Any food consumption in the maintenance shop should be in a designated area that does not pose a risk to tools and equipment. There should be adequate hand washing facilities provided if maintenance shops have designated break areas.
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	Vehicles and equipment used for moving raw materials, work-in-progress, finished products, and packaging throughout and within the facility are clean, well maintained, and do not transport goods outside the facility. Vehicles are part of the sanitation program. Vehicles used in food areas should not be gasoline or diesel powered. Propane (LPG) powered vehicles are acceptable, although electric powered are ideal.
General Cleaning	1.7.14	Are shipping trucks clean and in good condition?	5	Unsanitary (e.g., unclean, damaged insulation, etc.) shipping trucks could be a growth niche for bacteria and a foreign material hazard.
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	Any evidence of insects, rodents, birds, reptiles or mammals in products or ingredients are indicators of contamination, posing physical and microbiological hazards. Evidence of contamination constitutes automatic audit failure.
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	Packaging supplies are considered food-contact surfaces and therefore need to be free of insects, rodents, birds, reptiles or mammals. Evidence of contamination constitutes automatic audit failure.
Pest Control	1.8.3	Are plant and storage areas free of insects/rodents/birds/reptiles/mammals or any evidence of them?	15	Plant and storage areas need to be free of insects, rodents, birds, reptiles or mammals to prevent possible physical or microbiological contamination.
Pest Control	1.8.4	Is the area outside the facility free of evidence of pest activity?	10	Evidence of rodents, animals (e.g., humans, dogs) and/or birds in active areas outside the plant is an indication of a pest pressure on the whole facility. All possible measures should be taken to avoid attracting pests to the facility perimeter.
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	A pest control program is required to provide the basic environmental and operating conditions necessary for the production of safe, wholesome food.
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	Pest control devices should be located away from exposed food products, packaging materials, or equipment to prevent any physical or microbial contamination. Poisonous rodent bait traps should not be located within the facility.
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	All pest control devices should be maintained clean and replaced when damaged so they will accomplish their intended use. Date of inspections should be posted on the devices as well as kept on file (unless barcode scanned).
Pest Control	1.8.8	Are interior and exterior building perimeter pest control devices adequate in number and location?	5	Inside pest control: mechanical traps every 20-40 feet. Outside building perimeter: mechanical traps and/or bait stations every 25-75 feet (exterior/interior traps should be placed on both sides of doorways). Land Perimeter (if used): within 50 feet of buildings and at 50-100 feet intervals.
Pest Control	1.8.9	Are all pest control devices identified by a number or other code (e.g. barcode) ?	5	All traps should be clearly identified (e.g., numbered) to facilitate monitoring and maintenance. All traps should be located with wall signs (that state the trap number and also that they are trap identifier signs).
Pest Control	1.8.10	Are all pest control devices properly installed and secured?	5	All traps should be correctly orientated. Bait traps should be locked and tamper resistant in some way (e.g., locks, screws etc.). Bait traps should be secured to prevent removal. If mounted on slabs, then wall signs should be used to aid location.

Buildings and Grounds	1.9.1	Are signs supporting GMPs posted appropriately?	10	Highly visible and understood signs supporting appropriate Good Manufacturing Practices (GMP's) (e.g., no eating, chewing, drinking or smoking, hand washing, any specific clothing requirements, etc.) should be posted to remind workers of proper practices. Signs should especially be located at the entrance(s) to the production/storage areas, restrooms and break areas.
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	Lights should be protected against glass breakage in production, product storage, packaging storage, maintenance areas and bathrooms that open to facility.
Buildings and Grounds	1.9.3	Has the facility eliminated or controlled any potential metal, glass or plastic contamination issues?	15	All foreign material risks must be either removed and/or accounted for and controlled. Some examples include metal filings (maintenance), office windows, PC screens, staples, etc.
Buildings and Grounds	1.9.4	Has the facility eliminated the use of wooden items or surfaces?	5	Wood is a porous material and can harbor bacteria. It cannot be cleaned or sanitized effectively. Wooden materials can also splinter and pose a risk of physical contamination.
Buildings and Grounds	1.9.5	Is there adequate lighting in the packing and storage areas?	5	Proper lighting is necessary for inspection and sanitation procedures to take place. This includes storage areas, production areas, maintenance areas, restrooms, etc.
Buildings and Grounds	1.9.6	Are ventilation systems properly designed and functioning to prevent product contamination from condensation, mold, dust, odors and vapors?	10	Inadequate ventilation might allow condensate to form and prevent adequate air exchange rates. Ventilation equipment is balanced to provide an adequate air exchange rate to prevent condensation on walls or ceilings or other surfaces in product areas.
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	Floor surfaces in all areas should be smooth, without deep cracks or seams, durable, non-absorbent and easily cleanable. Exposed aggregate is hard to clean and will get progressively worse. Cracks should not trap debris or water.
Buildings and Grounds	1.9.8	Are the floor drains where they are needed for drainage and cleanup?	5	Drains and gutters should be constructed so that distance from the high point to the drain (or gutter) should never exceed 15 feet.
Buildings and Grounds	1.9.9	Are doors to the outside pest proof?	5	All exterior doors should fit tightly with a maximum allowable gap of 1/8 inch. Special attention should be given to the maintenance of weather strips. Air curtains (where used) should be operating properly.
Buildings and Grounds	1.9.10	Are dock doors fitted with buffers to seal against trucks?	5	Buffers around dock doors should seal against trucks to maintain temperature management. Door seals will also help maintain a pest free environment.
Buildings and Grounds	1.9.11	Are dock load levelers and shelters maintained in a good condition, pest proof and debris free?	3	Product debris can attract pests to the area. Gaskets (weather strips) around dock levelers should fit tightly to prevent pest entry.
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	Walls should be free of holes, crevices and cracks to prevent pest infestations. If pipe holes are needed, they should be protected to avoid pest entry. Vents and air ducts should also be protected. Mesh size should be small enough to prevent insect entry.
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	It is important to keep the building in good repair to prevent pest intrusion and the creation of difficult-to-clean surfaces.
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	False ceilings should have adequate access to safely permit monitoring of pest activities and for employees to perform their cleaning duties.
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	Aisles and working spaces that are provided should be of adequate width to safely permit the monitoring of pest activity and for employees to perform their cleaning duties.
Buildings and Grounds	1.9.16	Is the exterior area immediately outside the facility free of litter, weeds and standing water?	5	Litter, waste, refuse, uncut weeds or grass and standing water within the immediate vicinity of the building may constitute an attractant or breeding place for rodents, insects or other pests, as well as microorganisms that may cause contamination.
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	Incorrectly stored pallets and equipment can provide areas for pest harborage and/or cross contamination. Equipment should be stored at least 4 inches off the ground. Inventory checks should occur in order to ensure that these storage areas do not become full of unnecessary items. Outside storage areas should be within the scope of the pest control program.
Buildings and Grounds	1.9.18	Are pallets inspected to separate and replace dirty or broken pallets?	5	Broken or split pallets can cause a physical hazard. Dirt, mud, food debris, chemical residues and other contaminants on the pallets can cause a microbial contamination.

Buildings and Grounds	1.9.19	Is the area around the dumpster/cull truck/trash area clean?	3	Dumpster areas that are not maintained attract pests to the vicinity. These areas should be free of odor and liquid leaking from the dumpsters. Dumpsters should be cleaned from time to time.
Buildings and Grounds	1.9.20	Are outside garbage receptacles and dumpsters kept covered or closed?	5	Garbage receptacles or dumpsters should be covered to prevent attraction of pests.
Buildings and Grounds	1.9.21	Are all water lines protected against back siphonage?	5	Back siphonage protection prevents potable water from coming into contact with unsafe water.
Buildings and Grounds	1.9.22	Is the on-site laboratory (where applicable) completely enclosed and separated from production and/or storage areas?	5	On-site laboratories should not be a source of possible contamination. Pathogen analysis should be contracted to an external testing laboratory.

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	There should be documentation from relevant state, federal or recognized country authority indicating the facility is registered or permitted as a food handling establishment.
Management Systems	2.1.2	Is there a documented food safety policy reflecting the organization's ongoing commitment to providing a safe product?	5	The policy should include statements of the company's commitment to food safety, following food safety laws, adhering to industry food safety best practices and a process of continual improvement.
Management Systems	2.1.3	Is there an organizational chart showing who has food safety responsibilities and to whom they report?	3	An organizational chart is a visual representation of who is in charge of different groups within an organization illustrating to whom employees report.
Management Systems	2.1.4	Is there a designated person responsible for the food safety program?	10	There should be an appropriate person/persons (preferably manager(s)) assigned responsibility for the facility food safety program.
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	Meetings that are either devoted to or mention food safety issues, should be recorded as proof of company's ongoing commitment to food safety (minimum quarterly frequency).
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	Document control procedures ensure a better flow of information, smoother operations and timely work.
Control of Documents and Records	2.2.2	Are all records stored for a minimum period of 24 months?	5	Food safety related records should be retained for auditing purposes and in case there are legal issues, customer queries, etc. All monitoring and process control records should be held for a minimum of 24 months, regardless of the production item's shelf-life. Any records required by law to be kept longer than two years should be kept for the legally mandated period. Any records pertaining to long life product should be kept at least for the duration of the shelf-life of the product.
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	Both paper files and computer data should be stored in a secured place, with access control and backed up (electronic files). Paper files should be generated using ink (not pencil) and changes after initial entry clearly legible and tracked, avoiding the use of corrective fluid. Changes to electronic files should be traceable.
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	There should be written SOPs covering good manufacturing practice topics, such as goods receiving/supplier approval, temperature controls, pest control, food safety training, shipping, foreign material control, etc. The SOP's should show what is done, how it is done, how often, by whom, what recordings are required and any corrective action procedures when there are problems.
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	Water and ice systems should have specific SOP's which describe the process of changing the water, performing and recording antimicrobial strength testing (including parameters, frequency of testing, methodology and corrective action requirements).
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	Document should include site glass and brittle plastic policy, breakage procedure and glass register if necessary (a no glass policy should be the target). If certain glass items are allowed, a glass register should describe each item, location and quantity; items should be checked on a routine basis. Clean-up procedure after glass breakage should indicate what equipment to use and include boot and tool checks/decontamination procedures to ensure broken glass is not unintentionally transported out of the area.

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	The SOP's should be available to the users and any other interested parties. A master copy of all SOP's and recording forms should be collated in order to create (an) SOP Manual(s).
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	The tracking system should be shown in writing or in the form of a flow diagram. The auditee should be able to track back through their systems to their suppliers. Vice versa, an auditee's system should also be able to trace forward and show where their product was sent.
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	To facilitate an efficient recall, there should be written recall procedures, recall team details (contact details, roles and responsibilities), referral to customer and supplier contact details, explanations of relevant laws (e.g., class of recalls, etc.).
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	Testing of recall procedures should be performed at least once every six months. Documentation should include time taken to carry out the mock recall, reconciliation of product, copies of relevant traceback paperwork and notes of any findings from the mock recall.
Traceability	2.4.4	Is there a written procedure for handling on hold and rejected materials?	10	A written procedure is necessary to ensure the proper handling & disposition of on hold and rejected materials. Appropriate forms and tags should be used.
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	It is important to keep these records on file to support company policy, responses and actions taken when complaints occur (consumer and/or buyer complaints/ rejections)
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	Materials for use should be purchased against established specifications.
Supplier Control	2.5.2	Are there written specifications for finished goods?	3	Products should meet finished goods specifications.
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	There should be a list of approved suppliers of commodities and ingredients. All products and ingredients are ideally purchased from approved suppliers. Where exceptions are made (e.g., market conditions), approval from management should be documented.
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	Materials for use should be from approved sources. There is a written procedure for approval and continued monitoring of suppliers .
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	The supplier audit reports/certifications or letters of guarantee should ensure that the supplier is complying with regulatory requirements and best practice guidelines.
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	The supplier third party audit reports/certifications and/or supplier letters of guarantee should ensure that the supplier is complying with regulatory requirements and best practice guidelines.
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	Copies of Materials Safety Data Sheets (MSDS) should be on file to keep employees informed about the chemicals used in the facility and also be available in emergency situations.
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	When immediate access to a full label is not possible, then specimen copies should be available. Specimen labels should be kept on file and/or laminated and located where chemicals are used. Also, check State Legal Requirements.
Chemicals	2.6.3	Is there a chemical inventory and/or usage log?	3	Logs of use and/or inventory of sanitizers (product and cleaning) are required in order to confirm that procedures are being followed.
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	A pest control program is essential to plant sanitation. It should be maintained by a contracted company or an appropriately trained in-house employee (PCO required if baits used). Relevant documentation must be on file.
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	A schematic drawing of all trap stations allows the inspector to ensure that traps are in their allocated positions.

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	Service reports are necessary for the identification and correction of pest problem areas. Records should include services performed, date of service, chemicals used, signs of activity and corrective actions and trend reports.
Internal and External Inspections	2.8.1	Are there written procedures for handling regulatory inspections?	3	Written procedures for handling regulatory inspections allow employees to be aware of how to handle the inspection appropriately, including ensuring that the inspector is always accompanied, rules on taking samples, etc.
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	It is important to keep these records on file to show that the company fixed deficiencies and it also verifies good practices. Corrective actions should be recorded.
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	In depth internal inspections should be performed and recorded in order to proactively ensure safe food production. Records should show corrective actions and/or action verifications should be shown on the next inspection report.
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	Recording systems for food safety related topics should be audited on a routine basis to ensure that they are being completed properly (e.g., using the right log, right frequencies, recording results correctly, recording actions, etc.).
Internal and External Inspections	2.8.5	Is there a daily pre-operation inspection log?	5	Pre-operation inspections identify potential problems with the facility, personnel or equipment that should be corrected prior to starting production.
Internal and External Inspections	2.8.6	Does the facility have incoming goods (raw materials, ingredients and packaging materials) inspection data?	5	Incoming raw materials, ingredients and packaging should be inspected for pests, foreign materials and ensure that the materials are appropriate for use.
Internal and External Inspections	2.8.7	Are there inspection logs on incoming trailers for rodents and insects, cleanliness, holes and temperature control?	10	Incoming trailer checks should ensure that the trailer was clean, odor free, pest free and that the trailer was in an acceptable condition (e.g., no damaged insulation).
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	This documentation records unusual and infrequent events, remedial actions and preventive actions. These might include foreign object findings, chemical spills, power outs, packaging issues, glass breakage, etc.
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	There should be a backflow prevention device on main water lines entering the facility. A trained inspector should verify the principle backflow prevention system every 12 months (unless there is a stated expiration on the certificate).
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	Correctly filled logs detailing levels, time, responsible person, etc. are necessary to verify good management practices.
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	Wash water and ice production systems using anti-microbial agents should have records showing that the strength of the solution are within stated parameters. Recycled water systems should be checked by measuring the "free anti-microbial" as opposed to bound microbial (e.g., testing for free chlorine (or ORP) as opposed total chlorine).
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	The log should include target anti-microbial concentration (ppm) and frequency of verification. Where hand gel or spray stations are used, there should be monitoring logs indicating stations are regularly checked to confirm units are stocked and operational.
Process Control	2.9.4	Is there a tool accountability program for knives and similar cutting hand tools used in the production process?	3	There should be an accountability program in place for knives and similar cutting hand tools to identify potential product contamination.
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	There should be a written procedure detailing the set-up, calibration, maintenance and verification tests of detector systems. Metal detectors should be tested at least hourly.
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	Records of calibration demonstrate the accuracy of equipment used. Procedures should describe the frequency of testing, the testing method, the acceptable range of variation and corrective actions to take when calibration test does not fall into acceptable range of variation.

Maintenance & Sanitation	2.10.1	Does the facility have a preventative maintenance program and with a documented schedule?	10	Preventative maintenance program can help prevent equipment failure that can result in physical or chemical contamination of products.
Maintenance & Sanitation	2.10.2	Is there a log of maintenance work or repairs ordered and is it signed off on work completed?	10	A log for maintenance work will assist in keeping track of the condition of equipment in order to prevent hazards from occurring.
Maintenance & Sanitation	2.10.3	Are there logs showing that equipment is cleaned and sanitized after maintenance work has been completed?	5	Maintenance and repairs on machinery can leave foreign materials behind or leave food-contact surfaces dirty if the entire work area and equipment is not cleaned and sanitized after work is completed.
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	A master sanitation program must be in place that covers the entire area of the facility, equipment and all other areas of the facility. The master sanitation schedule should include a list of areas and equipment to be cleaned as well as the frequency.
Maintenance & Sanitation	2.10.5	Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the facility and all equipment?	10	The facility, all equipment, internal transport vehicles and shuttle trucks should be cleaned and sanitized on a regularly scheduled basis, based on written Sanitation Standard Operating Procedures (SSOP's).
Maintenance & Sanitation	2.10.6	Are sanitation logs on file that show what cleaning was done, when and who carried out the cleaning?	5	Sanitation logs should be on file covering the entire area of the facility and equipment. Logs should include: date, list of areas/equipment that were cleaned and the individual accountable that signed-off for each task completed.
Maintenance & Sanitation	2.10.7	Are there records showing verification of cleaning chemical concentrations?	5	The strength of cleaning chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction based test, test probe, ORP meter or as recommended by disinfectant supplier). Solutions that are too weak will be ineffective, while those too strong may be harmful to employees, product or equipment.
Maintenance & Sanitation	2.10.8	Are there documented procedures and completion records for clean-in-place (CIP) activities, where applicable (e.g. cleaning re-circulating water systems such as washing flumes, ice injectors, hydrocoolers, ice makers, etc.)?	5	Operations utilizing clean-in-place (CIP) should have detailed procedures in place. CIP activities should be monitored to ensure CIP process is effective and not a source of contamination to product.
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	It is important to include drains in the cleaning schedule to prevent cross contamination. Drains in wet processing areas should be cleaned daily and sanitized regularly to prevent harmful bacteria from growing.
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	Cooling units should be cleaned and sanitized regularly to prevent harmful bacteria from growing. Servicing ensures that coolers are working properly and efficiently.
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	ATP (adenosine tri phosphate) bioluminescence provides an instant indication of the hygiene status of product contact surfaces by measuring the ATP from food residues, bacteria, yeast, mold - either living or dead (i.e. all organic matter) in order to measure cleaning efficiency.
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	New employees should be GMP trained prior to starting to work, with records of this training being maintained. Employees should be issued a list of GMP rules in the relevant languages and confirm by signing they understand and agree to abide by the company's food safety policy rules regarding personal hygiene/GMPs and health requirements.
Personnel	2.11.2	Are there logs of ongoing employee food safety education training with topics covered and attendees?	10	Documentation of training verifies that the company is committed to ongoing employee training and education to identify and promote good manufacturing and sanitary practices.
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.)	3	There should be documented procedures that are communicated to food handlers, requiring them to report any cuts, grazes and/or any illnesses that might be a food safety cross contamination risk.
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	Sanitation training should ensure that the staff understand the importance of proper sanitation, how to use the cleaning chemicals and how to understand Sanitation Standard Operating Procedures.
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	All visitors and contractors should sign to say that they will abide by the company rules regarding personal hygiene/GMPs and health requirements.
Personnel	2.11.6	Is there an employee non-conformance/disciplinary action procedure? (Verbal confirmation accepted.)	3	There should be a procedure for reprimanding staff who systematically violate GMP's.
Testing	2.12.1	Are there records of routine equipment microbiological testing?	10	Equipment microbiological testing is used to determine effectiveness of cleaning and sanitization programs.

Testing	2.12.2	Are there records of routine environmental microbiological testing?	10	Environmental microbiological testing is used to determine effectiveness of cleaning and sanitization programs.
Testing	2.12.3	Are there routine microbiological tests on water used in the facility (sampled from within the facility)?	10	Testing of water should be performed on a routine basis to assure it meets the microbial requirements of potable water. Water samples should be taken from within the facility, in order to assess pipes and tanks (a city water result does not take into account the operations pipes and fittings).
Testing	2.12.4	Are there routine microbiological tests on ice used in the facility (either produced in-house or purchased)?	5	Testing ice helps check both the water microbial potability and ice equipment hygiene.
Testing	2.12.5	Do laboratory test results indicate test procedures meet accepted standards?	5	Testing procedures should meet accepted standards and lab reports should indicate testing procedure(s) used.
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	There should be documented evidence that tests from the laboratory meet all the specification requirements, are accurate and reliable.
Temperature Controlled Storage & Distribution	2.13.1	Are there records of final product temperature checks for temperature sensitive product?	10	Records must show the actual final product temperature and prove that the temperature sensitive product is not shipped above temperature requirements.
Temperature Controlled Storage & Distribution	2.13.2	Are there temperature logs for the packing/processing room (if refrigerated)?	5	Temperature control is important in limiting microbial growth and maintaining product shelf life.
Temperature Controlled Storage & Distribution	2.13.3	Are there temperature logs for storage rooms?	5	Temperature control is important in limiting microbial growth and extending shelf life.
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	Truck trailers should be pre-cooled when transporting temperature sensitive products and truck refrigeration unit set point should be recorded. Checking the wall of the trailer will show if the truck has been pre-cooled.
Temperature Controlled Storage & Distribution	2.13.5	Are there sanitary condition logs for shipping trucks (cleanliness, trailer condition, odor, etc.)?	10	Trucks, even those that are booked by the buyer, should be checked for their sanitary condition and records recorded.

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	There should be a formally identified multi-disiplined team in charge of development and maintenance of the HACCP program, along with their corresponding responsibilities. The size of the team will depend on the size of the company.
HACCP Team	3.1.2	Is there documented HACCP specific training for the HACCP team, management and operating personnel?	10	Formal HACCP training is important in ensuring that all employees are knowledgeable about the plan. This training should be documented.
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	A description of the product allows the people involved (staff, buyers, enforcement) with the HACCP plan to immediately understand the types of product and processes involved, as well as intended use.
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	The information on the flow diagram is used to evaluate whether or not hazards exist, associated with the various stages depicted.
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	A hazard analysis is required that lists each hazard and the controls at each stage of production. The analysis should show the logic applied when deciding which hazards are and are not CCPs.
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	Controls for each identified hazard should be detailed on the hazard analysis chart.
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	The CCP's defined in the Hazard Analysis should be developed to define in detail the parameters involved and the monitoring requirements in order to control the hazard.
Review of the Written HACCP Plan	3.2.6	Have monitoring requirements and frequencies been determined for the CCPs?	15	Monitoring facilitates the tracking of an operation and helps to determine when there is a loss of control.
Review of the Written HACCP Plan	3.2.7	Are identified CCP critical control limits supported by validation documentation?	5	All CCP's should be supported by validation documentation, showing that the critical control limits (CCL) are scientifically derived and meet any relevant legal requirements.

Review of the Written HACCP Plan	3.2.8	Is there a clear, detailed action plan for operators to follow if the CCP critical control limits are exceeded? Does it describe plans to adjust the process back into control and withhold out of compliance products if necessary?	15	Employees should have a detailed plan with procedures to follow when there is a loss of control so that adjustments can be made in a timely manner and to assure that the process is under control.
Review of the Written HACCP Plan	3.2.9	Have recording templates (recording forms) been developed for monitoring the CCPs?	10	Defined records are required for recording CCP monitoring. The parameters in the records should reflect those used in the HACCP Plan.
Review of the Written HACCP Plan	3.2.10	Have specific responsibilities been assigned for the monitoring, recording and corrective action management of each CCP?	10	Specific responsibilities should be assigned for the monitoring, recording and corrective action management of each CCP to ensure compliance.
Review of the Written HACCP Plan	3.2.11	Have verification plans and schedules been developed for each CCP?	10	Verification confirms that the plan is being implemented correctly, is controlling the risk to an acceptable level (or eliminating the risk) and detailing corrective actions.
Execution of the HACCP Plan	3.3.1	Are all of the documents noted in the HACCP plan in place for real time monitoring of the CCPs?	15	Documents noted in the HACCP System should be in place for each CCP. Records should reflect the plan requirements. Using document version control would help ensure that the documents on the production floor match those in the plan.
Execution of the HACCP Plan	3.3.2	Are the CCP monitoring activities and frequencies in conformance with the plan?	15	The monitoring records should show that the testing frequency, parameters and any other details match that what is written in the HACCP Plan.
Execution of the HACCP Plan	3.3.3	Do CCP operators understand basic HACCP principles and their role in monitoring CCPs? (Interview operators to verify.)	15	Individuals should have a basic understanding about what HACCP is in general and also how it applies to their operation. Individual should have a good understanding of the details of the CCP's that they have been assigned to monitor.
Execution of the HACCP Plan	3.3.4	Are CCP monitoring records signed off (or initialed) by the operator(s) who are carrying out and recording the CCP check?	10	Sign off should be required in order to show who actually performed the CCP monitoring tests.
Execution of the HACCP Plan	3.3.5	Are corrective actions detailed in writing when the failure of a CCP occurs?	15	When a monitoring or verification step shows a deviation against the HACCP plan, the incident should be recorded along with actions taken.
Execution of the HACCP Plan	3.3.6	Are the CCP records reviewed and signed off daily by the quality control supervisor and/or management as part of the verification plan?	10	The records should be signed off by the designated person responsible for internal verification of the company's HACCP plan. The sign off should not be done by the same person who carried out the monitoring.
Execution of the HACCP Plan	3.3.7	Is any other CCP verification performed (apart from daily record verification) according to the HACCP Plan?	10	Where verification activities have found that CCPs were not performing as required, there should be records that show that this has prompted a review of the relevant part of the HACCP program.
Management Support of HACCP	3.4.1	Are changes in the process, equipment, ingredients etc., causing timely reviews of HACCP systems, including hazard analysis, CCP decisions, CCP records and staff training?	10	When any changes are made to the process, equipment, ingredients, etc., all HACCP systems should be reviewed and the HACCP coordinator should inform all employees involved. Re-training or educational sessions may be necessary.
Management Support of HACCP	3.4.2	Is the plant conducting self-audits of the HACCP program?	10	Self audits will help to verify that the HACCP program (including the product descriptions, process flows, hazard analyses and HACCP charts) is up to date, effective and can identify deficiencies in the program.
Management Support of HACCP	3.4.3	Have standard operating procedures (SOPs) been created for the CCP monitoring processes that include how to carry out the monitoring?	10	Clear and simple standard operating procedures should be written for each CCP monitoring process that expands (in detail) the CCP monitoring in the form of work instructions. These SOP's must match what is written in the HACCP plan.
Management Support of HACCP	3.4.4	Are monitoring and verification information reviewed and discussed at management level meetings?	10	Feedback to and from management will help in the ongoing improvement of the HACCP system.
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	External audits of the entire HACCP program should be conducted (at least every 12 months) by competent auditors who have no direct connection to the day to day running of the operation.

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	The facility should be surrounded by a continuous security fence where there is external storage and/or vulnerable (not kept locked) entry points. The fence should be high enough to deter intruders.
Physical Security	4.1.2	Is access to the facility controlled by locks, swipe cards, alarms or other devices?	10	Access points to the facility should be controlled by locks, sensors and other devices.
Physical Security	4.1.3	Are inbound food product storage areas (fruits, vegetables, etc.) secure i.e. within the secure compound?	5	All food items should be stored inside or within a secure compound.

Physical Security	4.1.4	Are chemicals such as chlorine, citric acid, fungicides and sanitation chemicals stored within secured areas with controlled access?	5	All processing materials should be stored within a secure area with restricted access (e.g., a chemical storage room).
Physical Security	4.1.5	Are packaging material (cartons, wrap film, fruit cups, etc.) storage areas secure, i.e. within the secure compound?	5	All packaging items should be stored inside or within a secure compound.
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	Where practical, checks such as social security numbers, INS details, address and telephone confirmations, previous job references, etc. should be carried out. Felony crime checks would be ideal.
Employee Security	4.2.2	Employees personal items are not being stored in the production and material storage areas?	5	There should be no personal items being taken into the production and storage areas, including bags, purses, lunch boxes, etc.
Employee Security	4.2.3	Are employees issued non-reproducible identification e.g. badges, company ID cards, etc.?	5	Staff should have personal identifications that link them to the company. The ID's should have the employee's number, photo and position within the organization.
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	All visitors including contractors should be provided with identification that is valid only for the time that these visitors are on site.
Employee Security	4.2.5	Are visitors (including contractors) required to "sign in" and "sign out" in a visitors logbook?	5	Facility should have a logbook that visitors are required to sign in and out of (including date, time, reason for visit, visitor's host and employer name).
Transport Security	4.3.1	Does the company make use of sealed and/or locked trailers on inbound loads (excluding open flatbed trucks)?	3	The company should be demanding that the suppliers fit seals or locks on inbound trailers of raw material product and packaging. Seal numbers should be recorded.
Transport Security	4.3.2	Does the company make use of sealed and/or locked trailers on outbound loads?	3	The company should be fitting seals or locks onto outbound trailers of products, where the company has control over the trucks being used. Seal numbers should be recorded.
Water Supply Security	4.4.1	Are potable and non-potable water supplies clearly identified?	3	Water lines should be clearly identified, in order to ensure that the right water is used for any particular process.
Water Supply Security	4.4.2	Are tamper evident/tamper resistant systems (e.g. tamper tags) in place where appropriate?	3	Water fittings should be tamper evident or tamper resistant in order to ensure any evidence of foul play can be detected.
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	Access to water systems should be restricted.
Food Defense Systems	4.5.1	Does the company have a documented food defense policy based on the risks associated with the operation?	10	The company should have a documented food defense policy that outlines the operation security controls. These should include, for example, policies covering personnel, visitors, contractors, raw material receipt (product and packaging), trucks (incoming and outbound), storage, etc.
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	The company should have a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies. This information may be part of the recall plan.
Food Defense Systems	4.5.3	Are all personnel required to undergo training on food defense issues and are training records kept?	5	Staff should attend either external or in-house training regarding food defense requirements. Records should be kept (showing topics and attendance).
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	In order to track who has been granted access to sensitive areas and to maintain information about the whereabouts of keys, a documented log should be maintained.

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	If an allergen risk is identified, then the facility should have storage, production, equipment and personnel controls. Product must also be labeled correctly.
Allergens	5.1.2	Has a documented allergen management plan been developed?	5	There should be a documented allergen management plan giving an overview of the operation's management of control from raw material procurement, goods receiving, raw material storage, production, finished goods storage through to shipping.
Allergens	5.1.3	Are there adequate storage controls (separation, identification, etc.) that ensure that allergens are not contaminating other raw materials?	5	Allergens should be stored separately than other materials in order to avoid cross contamination. Allergen raw materials should be identified.

Allergens	5.1.4	Is there a dedicated production line or adequate clean down and production procedures that prevent allergen cross contamination?	5	If there is no separate production line for allergen containing products, then there should be special attention to production scheduling and production sanitation.
Allergens	5.1.5	Are utensils and work in progress storage containers identified in order to prevent allergen cross contamination?	5	All potential chances for cross contamination should be identified and controlled. Separate utensils and containers should be used.
Allergens	5.1.6	Does re-work handling take into account the issues associated with allergen containing products?	5	The storage and processing of re-work items that contain allergens should avoid contaminating non-allergen containing products.
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	All potential chances for cross contamination should be identified and controlled. Staff should be trained and use good practice to avoid cross contamination.
Allergens	5.1.8	Are all products manufactured on site, labeled correctly with respect to allergens?	5	Allergen containing products must be labeled as such. Other items produced on site should be risk assessed and might require an allergen warning labels.
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	Correct country of origin labeling should be indicated on retail product packaging i.e. bags, bands, twist ties, clamshells, PLU stickers or other labels, individual packages, etc.
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	Correct country of origin should be indicated on the shipping cartons i.e. the boxes, cartons, returnable plastic crates, etc., that are used to carry the products (whether bulk product or bagged/pre-packed product).
Country of Origin Labeling	5.2.3	Are there records that support the country(ies) of origin labeling e.g. bill of lading, production records, etc.?	3	Records exist that show the country of origin of the product and help prove that the label of the finished cartons and bags are correct.
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	Product should not be commingled in storage, production and dispatch. This includes ensuring that batches are processed separately and there is clear differentiation when switching batches with different countries of origin.

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	Process waste, including culls and trash, should be handled to ensure they are not creating a contamination risk to facility or products.
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	The transportation of trash, animals, raw animal products or other materials that may be a source of contamination with pathogens in vehicles that transport produce should be prohibited.
Management Systems	6.1.3	Is there a documented food safety plan covering site and facility?	10	A documented food safety plan should detail potential hazards that could affect product safety. The plan should include controls and procedures for monitoring, recall and tracing.
Management Systems	6.1.4	Is there a documented business continuity and disaster recovery plan?	5	Business continuity and disaster recovery planning are documented processes to help organizations prepare for disruptive events that may impact the ability of the auditee to assure the safety of the food product.
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	All national and local laws pertaining to on-site water treatment systems should be followed and this should be documented. Where necessary, there should be applicable permits on file and evidence of regulatory and/or third party inspections.
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	List should include a basic program description, who is responsible and where records that confirm the program are completed, documented, monitored and inspected are kept.
Review of the Written HACCP Plan	6.1.7	Where operating limits and frequencies been established for the CCPs are they being monitored?	10	Operating limits are more stringent than critical limits and are used to reduce the risk of a deviation from the critical limits.