PRIMUSLABS PACKAGING AUDIT v14.09
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 packaging. 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 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	Is packaging stored to prevent cross contamination?	15	Packaging should be stored off the ground, protected if necessary, away from chemicals, battery chargers, etc. in order to prevent contamination.
Storage Areas & Packaging Materials	1.2.4	Is the storage area completely enclosed?	10	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 packaging materials?	5	To avoid any adulteration or possible cross contamination from other items, only packaging 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 of rejected material 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	**Is food contact packaging within accepted tolerances and free from adulteration? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.**	15	Food contact packaging that is adulterated is illegal. Adulteration can take many forms (e.g., foreign materials, misrepresentation of products, etc.).

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 packaging. Pest activity is easier to detect in a clean area.
Storage Areas & Packaging Materials	1.2.9	Are packaging materials 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 packaging materials 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 and other problems associated with prolonged storage.
Operational Practices	1.3.1	Does the process flow, facility layout, employee control, utensil, internal vehicle use, etc., ensure that packaging material is not contaminated during storage?	15	Clear controls required. Internal vehicles should be dedicated to one area or the wheels cleaned when go to packaging storage.
Operational Practices	1.3.2	Are all exposed packaging materials protected from overhead contamination (e.g. ladders, motors, condensation, lubricants, walkways, loose panels, degrading insulation, etc.)?	15	Overhead contamination of exposed packaging areas can result in microbiological, chemical and/or physical contamination. Exposed materials should be protected (e.g., catwalks covered, use of kick plates, etc.).
Operational Practices	1.3.3	Is all re-work 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	1.3.4	Are packaging materials examined before use?	5	Packaging materials should be inspected. This inspection should look for foreign material contaminants, rotting materials and any unusual issues (e.g., unsealed packaging, etc.).
Operational Practices	1.3.5	Does 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 packaging item through storage.
Operational Practices	1.3.6	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). Hand washing stations should be located within close proximity of/at toilet facilities and lunchroom area. Stations should have warm water, soap and paper towels.
Operational Practices	1.3.7	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 storage areas. Restrooms should be stocked with toilet paper, scentless soap and towels.
Operational Practices	1.3.8	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	1.3.9	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	1.3.10	Are all re-usable containers clean and clearly designated for the specific purpose 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.
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 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.
Employee Practices	1.4.5	Are employees wearing effective hair restraints?	10	Wearing hair restraints, moustache covers and beard-nets prevents hair from falling onto exposed packaging. Hair restraints also avoids staff unintentionally touching hair, then touching packaging.
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 storage areas. Jewelry can fall into packaging. It can also get snagged in machinery.
Employee Practices	1.4.7	Do employees remove protective outer garments e.g. 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	1.4.8	Is there a designated area for employees to leave protective outer garments e.g. 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	1.4.9	Employees personal items are not being stored in the material storage areas?	5	Personal belongings should not be taken into 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 of storage areas.

Employee Practices	1.4.10	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 packaging and equipment. Drinking is not permitted near the line. Spitting should be prohibited anywhere on site.
Employee Practices	1.4.11	Are all items removed from garment (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 contact 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 Cleaning	1.6.1	Are food contact equipment surfaces clean?	15	Unsanitary food contact surfaces can directly lead to contamination of packaging. 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 packaging. 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, is packaging protected from contamination?	15	To avoid contamination, 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 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	1.6.5	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	1.6.6	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	1.6.7	Are maintenance tools that are used in the storage areas of the facility clean, sanitary and corrosion free?	3	Tools that are used for repairing equipment in the storage areas should be appropriately stored to ensure they do not pose a risk of direct or indirect contamination. When in storage areas, they should be clean, free of corrosion and in good working order i.e. fit for their intended use.
Equipment Cleaning	1.6.8	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 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 packaging 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 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 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 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 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. handling, maintenance, outside, restroom equipment?	10	Cleaning equipment used in the facility need to be separated (physically and visually) from cleaning equipment used in non-facility areas in order to prevent cross contamination from occurring. Sometimes even within the facility, there is a need to differentiate equipment even further, e.g. splitting flooring cleaning materials from equipment cleaning materials.

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 packaging. 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 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 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	1.8.2	Are facility and storage areas free of insects/rodents/birds/reptiles/mammals or any evidence of them?	15	Facility and storage areas need to be free of insects, rodents, birds, reptiles or mammals to prevent possible physical or microbiological contamination.

Pest Control	1.8.3	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 facility 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	1.8.4	**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 storage of food contact material.
Pest Control	1.8.5	Are pest control devices (inc. rodent traps and insect light traps) located away from all packaging? Poisonous rodent bait traps are not used within the facility?	10	Pest control devices should be located away from exposed packaging material or equipment to prevent any physical or microbial contamination. Poisonous rodent bait traps should not be located within the facility.
Pest Control	1.8.6	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	1.8.7	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	1.8.8	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	1.8.9	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 storage areas, restrooms and break areas.
Buildings and Grounds	1.9.2	Are all lights in the facility that could potentially contaminate packaging shielded, coated or otherwise shatter resistant to protect packaging from contamination in the event of breakage?	15	Lights should be protected against glass breakage in 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 storage areas?	5	Proper lighting is necessary for inspection and sanitation procedures to take place. This includes storage areas, maintenance areas, restrooms, etc.
Buildings and Grounds	1.9.6	Are ventilation systems properly designed and functioning to prevent packaging 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 packaging storage 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 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	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 handling, 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.

FOOD SAFETY FILE REQUIREMENTS - SECTION 2

Category	#	Question	Total Points	Recommendations
Management Systems	2.1.1	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	2.1.2	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	2.1.3	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	2.1.4	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 product shelf-life. Any records required by law to be kept longer than two years should be kept for the legally mandated period.
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, 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	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	2.3.3	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 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 packaging materials 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 packaging materials and sanitation chemicals?	5	There should be a list of approved packaging and sanitation chemical suppliers. All products 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 packaging materials 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 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 facility 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 facility showing numbered locations of all traps and bait stations, both inside and outside the facility?	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 packaging storage. 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, 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 daily operations.
Internal and External Inspections	2.8.6	Does the facility have incoming packaging material inspection data?	5	Incoming 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 and holes?	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 stock check and replenishment records for gel and spray stations?	3	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.
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	Is there a log indicating that floor drains are cleaned on a regular basis?	5	It is important to include drains in the cleaning schedule to prevent cross contamination.

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 packaging 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 packaging 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 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 operation's pipes and fittings).
Control of Storage & Distribution	2.13.1	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.

FOOD DEFENSE - SECTION 3

Category	#	Question	Total Points	Recommendations
Physical Security	3.1.1	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	3.1.2	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	3.1.3	Are chemicals such as chlorine, citric acid, fungicides and sanitation chemicals stored within secured areas with controlled access?	5	All chemicals should be stored within a secure area with restricted access (e.g., a chemical storage room).
Physical Security	3.1.4	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	3.2.1	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	3.2.2	Employee personal items are not being stored in the material storage areas?	5	There should be no personal items being taken into the storage areas, including bags, purses, lunch boxes, etc.
Employee Security	3.2.3	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	3.2.4	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	3.2.5	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	3.3.1	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 packaging. Seal numbers should be recorded.
Transport Security	3.3.2	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	3.4.1	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	3.4.2	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.
Food Defense Systems	3.5.1	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, receipt of packaging, trucks (incoming and outbound), storage, etc.
Food Defense Systems	3.5.2	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	3.5.3	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	3.5.4	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.

ADDITIONAL QUESTIONS (NOT PART OF OVERALL FOOD SAFETY PERCENTAGE) - SECTION 4

Category	#	Question	Total Points	Recommendations
Control of Storage & Distribution	4.1.1	Is there a written procedure requiring transportation vehicles be dedicated to produce and related packaging material, 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 packaging should be prohibited.
Management Systems	4.1.2	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	4.1.3	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	4.1.4	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.