

PRIMUSLABS PACKAGING AUDIT v14.09 Checklist

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	
Storage Areas & Packaging Materials	1.2.1	Are all chemicals (pesticides, sanitizers, detergents, lubricants, etc.) stored securely, safely and are they labeled correctly?	15	
Storage Areas & Packaging Materials	1.2.2	Are "food grade" and "non-food grade" chemicals used appropriately, according to label and stored in a controlled manner?	10	
Storage Areas & Packaging Materials	1.2.3	Is packaging stored to prevent cross contamination?	15	
Storage Areas & Packaging Materials	1.2.4	Is the storage area completely enclosed?	10	
Storage Areas & Packaging Materials	1.2.5	Is the facility's use restricted to the storage of packaging materials?	5	
Storage Areas & Packaging Materials	1.2.6	Are rejected or on hold materials clearly identified and separated from other materials?	10	
Storage Areas & Packaging Materials	1.2.7	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	
Storage Areas & Packaging Materials	1.2.8	Are all storage areas clean, especially the racking structures, lights, ceilings, floor areas by the walls and other hard to reach areas?	10	
Storage Areas & Packaging Materials	1.2.9	Are packaging materials properly marked with rotation codes (receipt dates, manufacture dates, etc.)?	5	
Storage Areas & Packaging Materials	1.2.10	Are packaging materials rotated using FIFO policy?	5	

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	
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	
Operational Practices	1.3.3	Is all re-work handled correctly?	10	
Operational Practices	1.3.4	Are packaging materials examined before use?	5	
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	
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	
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	
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	
Operational Practices	1.3.9	Are single service containers used for their intended purpose only so that potential cross contamination is prevented?	5	
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	
Employee Practices	1.4.1	Are employees washing and sanitizing their hands before starting work each day, after using the restroom, after breaks and whenever hands may be contaminated?	15	
Employee Practices	1.4.2	Are employees' fingernails clean, short and free of nail polish?	5	
Employee Practices	1.4.3	Is there no sign of any employees with boils, sores, open wounds or exhibiting signs of foodborne illness working in indirect or direct contact with food?	10	
Employee Practices	1.4.4	Are first aid kits adequately stocked and readily available? Are band aids used?	5	
Employee Practices	1.4.5	Are employees wearing effective hair restraints?	10	
Employee Practices	1.4.6	Is jewelry confined to a plain wedding band and watches are not worn?	3	
Employee Practices	1.4.7	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	

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	
Employee Practices	1.4.9	Employees personal items are not being stored in the material storage areas?	5	
Employee Practices	1.4.10	Is smoking, eating, chewing and drinking confined to designated areas; spitting is prohibited in all areas?	10	
Employee Practices	1.4.11	Are all items removed from garment (shirt, blouse, etc.) top pockets?	3	
Equipment	1.5.1	Are food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?	15	
Equipment	1.5.2	Are non-food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?	10	
Equipment	1.5.3	Does equipment design and condition (e.g. smooth surfaces, smooth weld seams, non-toxic materials, no wood, or other absorbant materials) facilitate effective cleaning and maintenance?	15	
Equipment Cleaning	1.6.1	Are food contact equipment surfaces clean?	15	
Equipment Cleaning	1.6.2	Are non-food contact equipment surfaces clean?	10	
Equipment Cleaning	1.6.3	During cleaning, is packaging protected from contamination?	15	
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	
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 Cleaning	1.6.6	Are all utensils, hoses, and other items not being used stored clean and in a manner to prevent contamination?	10	
Equipment Cleaning	1.6.7	Are maintenance tools that are used in the storage areas of the facility clean, sanitary and corrosion free?	3	
Equipment Cleaning	1.6.8	Are excess lubricants removed from the equipment and are lubricant catch pans fitted where needed?	5	
General Cleaning	1.7.1	Are spills cleaned up immediately?	10	
General Cleaning	1.7.2	Are waste and garbage frequently removed from storage areas?	5	
General Cleaning	1.7.3	Do floor drains appear clean, free from odors and well maintained?	5	
General Cleaning	1.7.4	Do high level areas including overhead pipes, ducts, fans, etc. appear clean?	10	

General Cleaning	1.7.5	Are plastic strip curtains maintained in a good condition, kept clean and mounted so that the tips are not touching the floor?	5	
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	
General Cleaning	1.7.7	Is cleaning equipment maintained clean and stored properly?	10	
General Cleaning	1.7.8	Is cleaning equipment identified in order to prevent potential cross contamination issues e.g. handling, maintenance, outside, restroom equipment?	10	
General Cleaning	1.7.9	Are all items used for sanitation appropriate for their designated purpose? (no steel wool, metal bristles, etc.)	5	
General Cleaning	1.7.10	Are toilet facilities and hand-wash stations clean?	15	
General Cleaning	1.7.11	Are employee break facilities clean, including microwaves and refrigerators? No rotting or out of date foodstuffs?	5	
General Cleaning	1.7.12	Is the maintenance shop organized - i.e. equipment and spares stored in a neat and tidy fashion?	5	
General Cleaning	1.7.13	Are internal transport vehicles (e.g. forklifts, bobcats, pallet jacks, trolleys, floor cleaners, etc.), clean, do not emit toxic fumes and being used in a sanitary manner?	5	
General Cleaning	1.7.14	Are shipping trucks clean and in good condition?	5	
Pest Control	1.8.1	Are packaging supplies free of insects/rodents/birds/reptiles/mammals or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.	15	
Pest Control	1.8.2	Are facility and storage areas free of insects/rodents/birds/reptiles/mammals or any evidence of them?	15	
Pest Control	1.8.3	Is the area outside the facility free of evidence of pest activity?	10	
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	
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	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	
Pest Control	1.8.7	Are interior and exterior building perimeter pest control devices adequate in number and location?	5	
Pest Control	1.8.8	Are all pest control devices identified by a number or other code (e.g. barcode) ?	5	

Pest Control	1.8.9	Are all pest control devices properly installed and secured?	5	
Buildings and Grounds	1.9.1	Are signs supporting GMPs posted appropriately?	10	
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	
Buildings and Grounds	1.9.3	Has the facility eliminated or controlled any potential metal, glass or plastic contamination issues?	15	
Buildings and Grounds	1.9.4	Has the facility eliminated the use of wooden items or surfaces?	5	
Buildings and Grounds	1.9.5	Is there adequate lighting in the storage areas?	5	
Buildings and Grounds	1.9.6	Are ventilation systems properly designed and functioning to prevent packaging from condensation, mold, dust, odors and vapors?	10	
Buildings and Grounds	1.9.7	Are floor surfaces in good condition, with no standing water, no debris trapping cracks and are they easy to clean?	10	
Buildings and Grounds	1.9.8	Are the floor drains where they are needed for drainage and cleanup?	5	
Buildings and Grounds	1.9.9	Are doors to the outside pest proof?	5	
Buildings and Grounds	1.9.10	Are dock doors fitted with buffers to seal against trucks?	5	
Buildings and Grounds	1.9.11	Are dock load levelers and shelters maintained in a good condition, pest proof and debris free?	3	
Buildings and Grounds	1.9.12	Are exterior walls free of holes to exclude pests? Are pipes, vents, air ducts designed and protected in order to prevent pest entry e.g. by using fine mesh?	5	
Buildings and Grounds	1.9.13	Are interior walls and ceilings free of cracks and crevices to prevent pest harborage and allow proper sanitation?	5	
Buildings and Grounds	1.9.14	Where used in handling, storage or supporting areas, do false ceiling areas have adequate access to allow for inspection and cleaning?	5	
Buildings and Grounds	1.9.15	Is an 18" (46 cm) internal wall perimeter being maintained within the facility, with adequate access to these wall perimeters thereby allowing inspection and cleaning ?	5	
Buildings and Grounds	1.9.16	Is the exterior area immediately outside the facility free of litter, weeds and standing water?	5	
Buildings and Grounds	1.9.17	Are control measures being implemented for the storage of pallets, equipment, tires, etc. (e.g. out of the mud, pipe ends capped, stacked to prevent pest harborage, away from building perimeter)?	5	
Buildings and Grounds	1.9.18	Are pallets inspected to separate and replace dirty or broken pallets?	5	

Buildings and Grounds	1.9.19	Is the area around the dumpster/cull truck/trash area clean?	3	
Buildings and Grounds	1.9.20	Are outside garbage receptacles and dumpsters kept covered or closed?	5	
Buildings and Grounds	1.9.21	Are all water lines protected against back siphonage?	5	

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	
Management Systems	2.1.2	Is there an organizational chart showing who has food safety responsibilities and to whom they report?	3	
Management Systems	2.1.3	Is there a designated person responsible for the food safety program?	10	
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	
Control of Documents and Records	2.2.1	Is there a written document control procedure describing how documents will be maintained, updated and replaced?	3	
Control of Documents and Records	2.2.2	Are all records stored for a minimum period of 24 months?	5	
Control of Documents and Records	2.2.3	Are food safety related documents and records stored and handled in a secured manner? Records recorded in permanent ink, not pencil; errors single-lined through and initialed?	10	
General File Requirements	2.3.1	Are there written Standard Operating Procedures (SOPs) that detail work instructions for activities ensuring food safety and Good Manufacturing Practices?	5	
General File Requirements	2.3.2	Is there a documented glass and brittle plastic management policy and procedure (including company glass and brittle plastic policy, glass breakage procedure and where necessary a glass register)?	5	
General File Requirements	2.3.3	Are the SOPs available to relevant users and is a master copy maintained in a central file (SOP Manual)?	5	
Traceability	2.4.1	Is there a documented account that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?	10	
Traceability	2.4.2	Does the facility have a documented recall program including: procedures, recall team roles, their contact details, external contact listings and (in the USA) an explanation of different recall classes?	15	

Traceability	2.4.3	Is testing of recall procedures (including trace back) performed and documented at least once every six months? Can the company identify where affected product was sent?	10	
Traceability	2.4.4	Is there a written procedure for handling on hold and rejected materials?	10	
Traceability	2.4.5	Is there a documented system for dealing with food safety complaints/feedback from consumers and buyers along with records and company responses, including corrective actions?	5	
Supplier Control	2.5.1	Are there written specifications for packaging materials and sanitation chemicals?	3	
Supplier Control	2.5.2	Are there written specifications for finished goods?	3	
Supplier Control	2.5.3	Is there a list of approved suppliers of packaging materials and sanitation chemicals?	5	
Supplier Control	2.5.4	Is there a written procedure for approval and continued monitoring of suppliers of packaging materials and sanitation chemicals?	3	
Supplier Control	2.5.5	Does the facility have relevant third party audit reports, supplier third party audit certifications and/or supplier letters of guarantee for packaging items?	10	
Chemicals	2.6.1	Are copies of all Materials Safety Data Sheets (detergents, sanitizers, pesticides, etc.) on file and fully accessible at all times with clear indexes?	5	
Chemicals	2.6.2	Are there copies of specimen labels for chemicals used, where the full label is not immediately accessible e.g. rodent chemicals, product sanitizers?	5	
Chemicals	2.6.3	Is there a chemical inventory and/or usage log?	3	
Pest Control	2.7.1	Is there a documented pest control program, including a copy of the contract with the extermination company (if used), Pest Control Operator license(s) (if baits are used) and insurance documents?	15	
Pest Control	2.7.2	Is there a schematic drawing of the facility showing numbered locations of all traps and bait stations, both inside and outside the facility?	10	
Pest Control	2.7.3	Are service reports created for pest control checks detailing inspection records, application records, and corrective actions of issues noted (in-house and/or contract)?	10	
Internal and External Inspections	2.8.1	Are there written procedures for handling regulatory inspections?	3	

Internal and External Inspections	2.8.2	Are there records of regulatory inspections and/or contracted third party inspections, company responses and corrective actions, if any?	5	
Internal and External Inspections	2.8.3	Is there a program for periodic facility/GMP internal (self) inspections and are records maintained detailing corrective actions?	10	
Internal and External Inspections	2.8.4	Is there a program for periodic inspections of food safety system records e.g. pest control records, sanitation records, maintenance records, etc.?	5	
Internal and External Inspections	2.8.5	Is there a daily pre-operation inspection log?	5	
Internal and External Inspections	2.8.6	Does the facility have incoming packaging material inspection data?	5	
Internal and External Inspections	2.8.7	Are there inspection logs on incoming trailers for rodents and insects, cleanliness and holes?	10	
Internal and External Inspections	2.8.8	Is there an incidents report (sometimes called a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA)) used for recording infrequent and/or unusual events?	5	
Internal and External Inspections	2.8.9	Is there a current certificate of inspection for backflow prevention assemblies on water lines entering the facility?	3	
Process Control	2.9.1	Are there stock check and replenishment records for gel and spray stations?	3	
Maintenance & Sanitation	2.10.1	Does the facility have a preventative maintenance program and with a documented schedule?	10	
Maintenance & Sanitation	2.10.2	Is there a log of maintenance work or repairs ordered and is it signed off on work completed?	10	
Maintenance & Sanitation	2.10.3	Are there logs showing that equipment is cleaned and sanitized after maintenance work has been completed?	5	
Maintenance & Sanitation	2.10.4	Is there a written cleaning schedule (Master Sanitation Schedule) that shows what and where is to be cleaned and how often?	10	
Maintenance & Sanitation	2.10.5	Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the facility and all equipment?	10	
Maintenance & Sanitation	2.10.6	Are sanitation logs on file that show what cleaning was done, when and who carried out the cleaning?	5	
Maintenance & Sanitation	2.10.7	Are there records showing verification of cleaning chemical concentrations?	5	
Maintenance & Sanitation	2.10.8	Is there a log indicating that floor drains are cleaned on a regular basis?	5	

Personnel	2.11.1	Are there records of new employee food safety (GMP) orientation training (with topics covered and attendees) and are new employees required to sign the company's food safety hygiene and health policy?	10	
Personnel	2.11.2	Are there logs of ongoing employee food safety education training with topics covered and attendees?	10	
Personnel	2.11.3	Are there written procedures in place that require 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	
Personnel	2.11.4	Is there a documented training program with training logs for the sanitation employees including best practices and chemical use details?	5	
Personnel	2.11.5	Are visitors and contractors required to sign a log stating that they will comply with the operations' personal hygiene and health policies?	3	
Personnel	2.11.6	Is there an employee non-conformance/disciplinary action procedure? (Verbal confirmation accepted.)	3	
Testing	2.12.1	Are there routine microbiological tests on water used in the facility (sampled from within the facility)?	10	
Control of Storage & Distribution	2.13.1	Are there sanitary condition logs for shipping trucks (cleanliness, trailer condition, odor, etc.)?	10	

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	
Physical Security	3.1.2	Is access to the facility controlled by locks, swipe cards, alarms or other devices?	10	
Physical Security	3.1.3	Are chemicals such as chlorine, citric acid, fungicides and sanitation chemicals stored within secured areas with controlled access?	5	
Physical Security	3.1.4	Are packaging material (cartons, wrap film, fruit cups, etc.) storage areas secure, i.e. within the secure compound?	5	
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	

Employee Security	3.2.2	Employee personal items are not being stored in the material storage areas?	5	
Employee Security	3.2.3	Are employees issued non-reproducible identification e.g. badges, company ID cards, etc.?	5	
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	
Employee Security	3.2.5	Are visitors (including contractors) required to "sign in" and "sign out" in a visitors logbook?	5	
Transport Security	3.3.1	Does the company make use of sealed and/or locked trailers on inbound loads (excluding open flatbed trucks)?	3	
Transport Security	3.3.2	Does the company make use of sealed and/or locked trailers on outbound loads?	3	
Water Supply Security	3.4.1	Are potable and non-potable water supplies clearly identified?	3	
Water Supply Security	3.4.2	Are tamper evident/tamper resistant systems (e.g. tamper tags) in place where appropriate?	3	
Food Defense Systems	3.5.1	Does the company have a documented food defense policy based on the risks associated with the operation?	10	
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	
Food Defense Systems	3.5.3	Are all personnel required to undergo training on food defense issues and are training records kept?	5	
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	

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	
Management Systems	4.1.2	Is there a documented food safety plan covering site and facility?	10	
Management Systems	4.1.3	Is there a documented business continuity and disaster recovery plan?	5	
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	