GOOD MANUFACTURING PRACTICES FOR FOOD:

EXPECTATIONS MANUAL

VERSION 1.0 -

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INTRODUCTION

The following requirements outline the current Good Manufacturing Practices performance criteria expected of a modern food products manufacturing facility. The audit questions are designed to meet the food safety needs expected by the consuming public, most retail companies, foodservice buyers, and regulatory agencies. The manufacturing, storage, and delivery of safe, wholesome, and high-quality foods requires a dedicated effort of knowledgeable food professionals. While good manufacturing practices programs are the hallmark of modern food processors, high quality is the essential ingredient to ensure success with the consumer.

The scope of the audit is the determination of the range of the activities, product types, and the period of records that are to be subjected to an audit examination.

While this expectations manual and associated audit asks questions related to preventive control requirements under the FSMA Act and requirements under the SFCR, successful completion of the audit may not be considered by the FDA, USDA FSIS, or CFIA as regulatory compliant.

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OVERVIEW OF THE EXPECTATION MANUAL

This criteria document describes the content of Intertek SAI Global's Good Manufacturing Practices for Food Audit (GMP Audit). This audit evaluates the adequacy of documentation, compliance to documented procedures, effectiveness of these procedures to control the process within defined limits, and the ability to implement an affective GMP program. The criteria contained within this document are considered essential to meeting these goals on a consistent basis.

All information obtained by Intertek SAI Global prior to, during, or after the audit will be treated as confidential between Intertek SAI Global and the client. Except as required by law, Intertek SAI Global will not release any information or report of the audit to a third party without written authorization by the client.

This manual clarifies many audit criteria and expectations that help to ensure product safety and quality.

This manual is generic for all types of food and/or food packaging manufacturing, processing, and/or further processing establishments. Some criteria may not be applicable to all facilities. It is the judgment of the auditor or responsibility of the distributor to justify that specific criteria is not applicable.

Likewise, some criteria may be added based on shifting regulatory requirements, or the ever-changing food safety environment. It is important to note that this is not a regulatory compliance audit; it is the responsibility of the site's senior management to ensure a system is in place to keep informed of all relevant legal, regulatory, and industry codes of practice.

The stated criteria and expectations from the audit have been derived from the following food industry documents & regulations:

FDA: Food, Drug, and Cosmetic Act (21 CFR)	*Food Safety Modernization Act of 2011*
Food Code: 2009 Edition	*Canadian Food Inspection Agency Act/Safe Foods for Canadians Regulations*
Federal Meat Inspection Act (9 CFR)	*Egg and Egg Products Inspection Act*
Seafood-US FDA Seafood HACCP (21 CFR 123)	*Molluscan Shellfish-National Shellfish Sanitation Program (NSSP)*
US Bioterrorism Act of 2002	*Sanitary Transportation Act*
Specific client requirements and/or specifications	*FALCPA-Food Allergen Labelling & Consumer Protection Act*

DEFINITIONS

Acceptable Laboratory	A laboratory that is able to calibrate its performance standards. This shall be accomplished by performing crosscheck sample analysis with an accredited/certified lab (accreditation shall be achieved through a national accreditation service, e.g., ISO 17025) on a quarterly basis.
Allergen	Food compounds that can cause an allergic or food intolerance response in sensitive individuals. Food allergens elicit serious adverse reactions in some individuals. Allergic individuals can tolerate very little of the offending food. Allergens of regulatory significance in the U.S. include peanuts, tree nuts, eggs and egg products, milk and milk products, soy and soy products, sesame seeds, wheat and wheat products, fish, and shellfish (i.e., crustacean). In Canada, oysters, clams and mussels, sulfites over 10ppm, sesame seeds and mustard are also considered allergens. The distribution center shall identify all allergens present in the facility and shall have a written program that will prevent cross-contamination of undeclared allergens (see Sensitive Ingredients).
Calibration of Inspection, Measuring and Test Equipment	The facility shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring, and test equipment (including test software) used by the facility to demonstrate the conformance of product to specified requirements. Inspection, measuring, and test equipment shall be used in a manner to ensure that the measurement uncertainty is known and is consistent with the required measurement capability. Calibration against an accepted industry standard or certified standard shall be conducted at a frequency sufficient to confirm acceptability based on manufacturers' recommendations.
Carrier	A carrier is the person who owns, leases, or is ultimately responsible for the food transport vehicle and its driver.
Certified Laboratory	A laboratory that has met specific certification standards as defined by a laboratory accreditation body to the standard of ISO 17025 (see Acceptable Laboratory).
Certificates of Analysis (COA)	Specific microbiological, chemical or physical analysis of key ingredients or products, generally against a documented specification, prior to acceptance into inventory or receipt. COA must be lot or product code specific and should include the product identification, the description of the type of analysis, the method utilized, the sample size, and the result of the analysis. Verification of COA accuracy and product process shall be established by product testing of samples for conformance.
Client	The manufacturing, distribution, or production facility in which the audit will be conducted and whose systems and programs are evaluated. This is generally the entity responsible for payment of the audit service.
Continuing Letter of Guarantee	Document provided by supplier indicating that all food ingredients and food contact packaging materials (e.g., inks, coatings) comply with all provisions of the Food, Drug and Cosmetic Act and Amendments, Health Canada or other local regulatory requirements.
Correction	Actions, adjustments, or modifications taken by the client during the audit as a result of an audit finding by the auditor. This correction is generally in response to a finding of a non-conformance but can be taken at the finding of an opportunity for improvement as well. These actions, when observed by the auditor, will be included within the audit report.
Corrective Action	Corrective action shall be documented for any negative finding reported on a regulatory review, internal assessment, customer complaint or third- party audit finding. *The procedures for corrective action shall include:* • Investigation of the cause of the negative finding or complaint. It is important that the root cause of the issue is identified so that adequate improvements can be identified and implemented. Some examples of causes may be lack of training, equipment failure, failure to follow procedure, etc. • Determination of the corrective action needed to eliminate the cause of non-conformities and the prevention of its reoccurrence. • Application of controls to ensure that corrective action is taken and that the corrective action is effective to prevent reoccurrence of similar problems. • Determination of appropriate disposition of non-conforming or affected product.

Cross Contact	The actual or potential contamination of non- allergen-containing product or ingredients with allergen-containing product or ingredients. Cross contact can also occur with the contamination of non-like allergens as well, such as peanut contamination of a milk-based product.
Cross Contamination	The actual or potential contamination of a product or ingredient that has undergone an intervention step (e.g., cooking or washing) to reduce the microbiological level of the product or ingredient with a raw product or ingredient that has not undergone the intervention step. The presence of foreign material or non-potable water in finished or ready to eat (RTE) product.
Customer	The retail, food service, distribution or manufacturing buyer that is a user of the information obtained during the audit for the purpose of supply chain management. Generally, the customer is not the responsible party for payment of the audit, thus the customer must be given access to the audit information by the authorization of the client.
Document and Data Control	The system for the management, development, revision, correction and storage of all documents, programs, specifications, procedures, forms, and records that are used by the facility to manage its food safety and quality management systems. This system would include an identification system, an approval system and accessibility requirements for records. This system may be electronically managed or completed manually.
Food Safety Plan	A food safety plan requires a written hazard analysis and risk based preventive controls to prevent, eliminate, or reduce to a safe level all hazards where the probability of occurrence and severity of the hazard are identified. The Preventive Controls applied to known steps with probability of occurrence or potential risk are as followed: sanitation, process, allergen, and supply chain where applicable. Throughout this document, readers may see the acronym- FSP (food safety plan)
Finished Product Inspection	The analysis, inspection or review of the finished product prior to release of that product into commerce. The supplier must define what final inspection and review must be completed on each lot or batch of finished product. The requirements for the finished product inspection could include visual observation, physical inspection, microbiological or chemical analysis or record review. The supplier should evaluate the product specification, customer requirements or local regulatory requirements when defining its finished product inspection requirements.
Good Laboratory Practices (GLP)	Guidelines that are established to ensure the accuracy and precision of results from described evaluations.
Hazard	A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control
High Risk Vendor	One who is actively supplying product of increased foodborne illness risk to the end consumer. Broad categories include: RTE items, cheese, cooked or fermented meats, leafy greens and ground beef.
Hold	Product that has been identified as non-conforming or awaiting disposition and has been placed in a do not use status.
Internal /GMP Audit	An effort to evaluate the performance of a facility regarding good distribution practices and other established company protocols by internal staff. These audits assess internal and external facilities, and the results are utilized to drive continuous improvement.
Mock Recall	An evaluation of the company's product recall system that tests the effectiveness of the identification of affected product and the communication tools with key stakeholders.
Pre-Requisite Program	Supplemental programs to the HACCP/Food Safety Plan, required for the total food safety management by the facility of its product and distribution. Examples include pest management, training, maintenance, allergen management, food defense, etc.
Preventive Maintenance	A series of routines, procedures and steps taken to identify and resolve potential problems before they happen.
Primary Packaging	The packaging material that comes into direct contact with the food product.
Process Capability	The ability of a process to distribute a defect- free product (within specification 100% of the time) or service in a controlled manner of production or service environment.

Process Control	The features or mechanisms that control the execution of a process. These control mechanisms ensure a process is conducted to maximum cost effectiveness through effective set-ups and ongoing measures.
Processing	If the character, or nature of the product is changed this will be considered processing and will be judged under Good Manufacturing Practices (GMPs). Examples include cutting, dicing, slicing, washing, rinsing, cooking, and cooling. Ripening of fruit is not considered processing.
Product Traceability	The linking of all identified raw materials, primary packaging, inbound product, repacked and recouped product, rework and selected outbound product through a coding, identification or tracking system from the first level of supplier for inbound product to the first customer product distributed for outbound product.
Product Withdrawal	An activity that recovers all shipped suspect product that has only reached distribution (first customer) and has not yet entered the retail market.
Program	Documented policies, procedures, tasks, or activities that describe specific functions within the facility.
Ready To Eat	All foods that, when purchased by the consumer, do not require any further preparation i.e. pathogen elimination step prior to consumption (i.e. cooking). Products that are required to be cooked prior to consumption shall have detailed cooking instructions on the outer case for foodservice products, or on the individual inner packages for retail packaging, to heat product to a minimum internal temperature per regulation.
Receiver	The receiver is the person who receives product at its final destination.
Recoup	The reclaiming of product and subsequent review to determine the usability of that product. This could be included as returns, rework, or salvage.
Repack	Moving a unit of unexposed product from one outer case to another outer case that requires labeling linked to the original product lot code.
Repackaging	Working with an exposed product where caution must be taken to avoid contamination of the products.
Rework	Product that has been recovered or rejected from normal production and has been reprocessed, re-blended, or reformatted into the finished product.
Risk	The likelihood that a food safety hazard will happen.
Sensitive Ingredients	Food intolerances affecting a limited number of individuals that do not involve immunologic mechanisms (e.g., sulfites, MSG, FDC Yellow #5 and #6). For the most part, sensitive ingredients involve less severe manifestation and sensitive individuals can tolerate limited quantities of the offending food (see Allergens).
Shipper	The shipper is the person who initiates the shipment of food.
Standard Operating Procedures	A series of signed detailed documents that specifically define how an individual job function or activity will be performed.
Transport Vehicle	Any vehicle that is used to carry food products from one area of the distribution facility to an off- site location or customer. The off-site location may be under the control of the food production or distribution facility.

NON-CONFORMANCE CLASSIFICATION & SCORING GUIDELINES

Table A. Rating Criteria for the Intertek/SAI Global GOOD MANUFACTURING PRACTICES FOR FOOD	
Compliant	To receive the rating of Compliant, the facility fully meet the established Intertek / SAI Global criteria and can demonstrate full implementation of the criteria, employees are aware of process/procedures, and observed to be in compliance during the audit. ***Zero (0) are points deducted per question when a compliant rating is scored.***
Minor Non-Conformance	A Minor non-conformance would be an isolated occurrence of the observation (1 or 2 instances), elements missing from records or programs, some inconsistency with document vs. actual practice. ***Half (1/2) of the total value is lost for the question***
Major Non-Conformance	Major non-conformance would result in a systemic failure of the question: no program in place, employees unaware of non-compliance, more than 3 observations of the audit violation, or the potential for a food safety incident based on the observation. ***All points are lost in the question***
Critical Non-Conformance*	A significant food safety risk was identified during the audit and would constitute an automatic failure. ***50 points lost in the question; resulting in an automatic failure of the audit***
Not Applicable (N/A)	The rating of N/A would be assessed by the auditor for any question the auditor determines is not applicable for the facility being audited.

Table B. Rating Achievements and Score Ranges		
Rating: Category	**Starting Score Range**	**Ending Score Range**
Superior	**98.00**	**100.00**
Excellent	**94.00**	**97.99**
Good	**89.00**	**93.99**
Compliant	**80.00**	**88.99**
Fail	**0.0**	**79.99**

* Critical issues that require a rating of FAIL on the audit include:

- Actual adulteration of the stored ingredients, materials, food contact packaging, and product from any cause (e.g., rodents, insects, dripping condensate, dripping oil).
- Failure to have a GMP program.
- Lack of proper temperature control.
- Failure to maintain traceability during rework.
- Lack of a sufficient allergen control process.
- Use of unpotable water.
- Lack of policy to prevent cross contact that includes segregation during storage.
- Failure to have a documented product recovery program.
- Employees observed not following documented hygiene program causing direct contamination of product (repackaging areas only).
- Observation of significant evidence of pest activity on the interior of the facility.
- A numerical grade of <80.00%

Note: The rating will automatically print next to the score on the final audit report and the auditor is not required to do anything to cause this to happen.

Good Manufacturing Practices for Food

SECTION 1: FACILITY AND PERSONNEL PRACTICES

It is essential that food plants operate in total compliance with regulatory requirements specific to where products are shipped and that a positive working relationship is evident with the assigned regulators. The facility must demonstrate that there is a system in place to ensure that it is aware and in compliance with food regulation that applies to the products that are produced within the facility, including any required registrations.

The construction of the grounds, facility, and equipment must be such that it facilitates the production of wholesome product and that it meets the standard and regulatory food safety and quality requirements. The following must be included in the grounds, facility and personnel hygiene program:

PLANT GROUNDS

- Exterior of plant and grounds must be constructed to minimize dust and be free of standing water.
- The exterior structures must be maintained in good repair and no gaps or holes to the interior should be evident. The facility must ensure that the structure is maintained in a manner to prevent exterior conditions from posing a threat to products that are handled at the facility (such as leaks).
- The facility must ensure that all on-site trash disposal areas are maintained so as not to become a source of pest harbourage or potential contamination. Doors and lids to all disposal units must be kept closed between uses. The facility must ensure that the removal of all waste is adequate to prevent unnecessarybuild up that may lead to pest harbourage, odor, and potential contamination. The facility must ensure that all disposal units and areas are included on the master cleaningschedule.
- The facility must ensure that all equipment stored around the exterior of the facility is done so in a manner whereby it does not become a potential source of pest harbourage and/or contamination to the finished product. This would include capped hose ends and storage away from plant buildings.

FACILITY

- Ceiling surfaces, as well as other overhead equipment, must be clean, in good repair, free of flaking paint, rust, holes or unsealed openings, or other conditions that could result in product contamination. Ceiling panels, framework and supports must be properly secured with no missing or damaged parts. Ceiling penetrations for pipes, conveyors, wiring, etc., must be sealed to prevent harbourage, ceiling leaks and contamination. There shall be no evidence of water leaks on ceilings. Ceilings shall be constructed of a smooth, non-porous, non-absorbent and easily cleanable material. Insulation materials used overhead shall be in good repair, smooth,non- absorbent and easily cleanable. Joint areas must be sealed.
- Walls shall be constructed of a smooth, non-toxic and easily cleanable materials. They shall be free from cracks, holes and crevices that would inhibit cleaning or provide harbourage for debris and pests. They shall be free of dust, dirt, product accumulation and flaking paint. Walls shall be sealed and covered at wall/floor juncture. Wall coverings must not be attached with exposed nails, staples, or screws. Openings in walls where pipes, equipment or conveyors pass must be sealed. Windows must be closed if outside conditions exist that may expose the plant to airborne contamination. Ledges shall be sloped to avoid storage and prevent accumulation of debris. All windows shall be maintained in a clean and sound condition, with no broken panes, and must be screened when open.
- Catwalks and other walkways over or adjacent to product zones must be designed to prevent product contamination. “Toe boards or rails” are not acceptable as solid side plates. Processing line protection shields shall be knee high.
- All lighting shall be completely enclosed in protective shields or manufactured with shatterproof materials to prevent glass contamination of product. This applies to all operating areas, warehouses, and packaging, receiving and shipping docks, and storage areas. All lights must be protected, including emergency lights, forklift lights, and adjustable trailer lights on the dock. Light fixtures shall be maintained clean and free of cracks, dust or other materials that could cause contamination. Protective covers in processing areas shall be kept free of any evidence of moisture accumulation inside the covers.
- Equipment shall be designed to preclude or divert condensate away from product and product contact surfaces.

Adequate heating, ventilation or refrigeration shall be provided in all areas to maintain proper environmentaland sanitary conditions for ingredients, finished product, and equipment and packaging materials. All systems must be clean, properly functioning and designed in such a manner to prevent product contamination from condensation, mold, bacteria, insects, dust, or odours. Heating and ventilation must be balanced to prevent condensation on walls or ceilings in product areas.

- The facility must have an identification system for potable and non-potable water lines and current schematics. Dead ends on potable water lines must be eliminated. Hose drops must not be submerged in water reservoirs. If there is a chance that back siphoning could occur, hose drops must have back flow prevention devices installed. Backflow prevention can be done using an air gap or a mechanical backflow preventer. Back flow prevention devices must be checked annually. Hoses must not be left on the floor or in tanks. Hose nozzles must not be allowed to come in contact with the facility floor.
- Floors must be well drained, smooth, and easy to clean, with no aggregate exposed and no cracks, holes, or broken areas. Drains must have traps and drain covers must be maintained in place. Drains must be free from odours. Standing water must not be evident in processing or warehouse areas.
- The facility must have process and people flows that are designed to minimize cross contamination between raw and finished product. The air within the high risk/RTE room must not pose a contamination risk, positive pressure should be maintained relative to surrounding areas and the testing frequency established.
- Air used for direct processing and or comes in to contact with product or food contact surfaces shall not be a source of contamination as confirmed by testing air for contaminants and filters shall be changed at a describe frequency. There shall be a process in place to control condensation during processing and after sanitation activities are completed.

STORAGE

The facility must have policies and procedures outlining how they protect product throughout the process while being stored. The following must be included in the storage management program:

- The facility must have a detailed procedure outlining how raw materials, packaging material, as well as finished product, are rotated to ensure food safety and/or quality are not compromised. At a minimum, the facility must use a rotation program based upon first in first out (FIFO) (or if using manufacturer's dates FEFO (First Expire/First Out)) unless customers specify otherwise. The facility may use other types of rotation based upon client specification. When such systems are used, the facility must have documentation of the procedure. The system must ensure no expired or obsolete materials are appropriately managed to prevent accidental use. There shall be a process for managing obsolete packaging/labels, to ensure accidental use, appropriate disposal and records are maintained.
- All products must be properly protected from any form of contamination that could be present. This would include raw commingled with ready to eat items, chemicals commingled with food products, bags or boxes of ingredients that are not properly covered when placed in storage, etc. All ingredients should be kept clean (i.e., free of dust and debris) and properly protected from potential sources of contamination (i.e., roof or condensation leak).
- Products should be free of damage to their primary package to ensure that contaminated foods are not used or shipped to customers. Canned goods must not have any dents on their seams. Damaged goods must be removed from the general storage areas and placed into a designated area that identifies them as being damaged. This area shall be signed indicating that all products are not for use.
- Warehouse storage areas must be clean and orderly, with no long-standing spills, damaged or exposed product, debris/dust build-up, and be free of any mold growth. An 18-inch perimeter along exterior walls should also be maintained. Opened product containers shall not be stored in receiving storage areas. All racking must be in good repair and maintained in a sanitary manner so as not to cause contamination.
- If transportation vehicles are stored on site, they must be properly inspected at a prescribed frequency to ensure they do not pose a contamination threat to product that will be contained in them later. If transportation vehicles are used for outside storage of raw materials, packaging, in-process products, and finished products, they must be protected from contamination and deterioration and be locked at all times. All materials stored must be inspected prior to use or transport.

EMPLOYEE GOOD MANUFACTURING PRACTICES (GMP) PROGRAM

- The facility must have a plant-specific, documented GMP training program for all employees. All new employees (e.g., seasonal, part-time, contract) must be provided initial training covering basic GMPs and specific plant policies regarding sanitation, housekeeping, and personal hygiene. The facility must encourage adherence to GMPs via the posting of appropriate signage in those areas where compliance is required. The facility must ensure that employees are in compliance with the written GMP program.
- The program should specifically cover: good manufacturing requirements and regulatory basics, uniforms, personal items, hand washing and grooming requirements, injury, illness, plant sanitation policies and procedures, food safety (HACCP/FSP) and quality control policies, and product tampering awareness and consequences. Training shall be conducted in an effective manner and be in the appropriate language. Follow-up, continuing refresher training shall be provided annually, at a minimum. Special training to address operational deficiencies must be provided as required.
- Employees working in production areas must not wear fake fingernails, fingernail polish, jewellery, rings (with the exception of a plain wedding band, where permitted by the facility), watches, or visible piercings, etc. Outside pockets above the waist on smocks, shirts or coats shall not carry any items (pens, combs, pencils, thermometers, etc.) while in the operations areas. Alternatively, these pockets should be sewn shut.
- Fine mesh nets or other effective hairrestraints for head and facial hair must be required in all production, processing and warehouse areas by all employees (e.g., visitors, contractors, tours, management not involved in the process).
- The plant must provide, and the employeesmust use means to avoid contamination of their outer clothing when using the toilet facilities. Coat hooks are generally made available for employees to hang their outer garments outside the toilet facilities. The facility must ensure that dedicated distinctively colored outer clothing, must be provided for individuals entering or working in the high risk/RTE area. The facility must ensure that all employees adhere to the use of separate outer clothing in these cases and the results should be documented.
- Personnel access to High risk/RTE areas shall include facilities for personnel to make appropriate outer garment changes and either change footwear or put on appropriate footwear coverings prior to entering the RTE area. Access routes for personnel and materials shall be free from exposure to raw processing areas or routes exposed to raw products. The facility must provide captive footwear, use either, boot scrubbers, footbaths or floor foamers for the entrances into high risk/high care/RTE processing areas (i.e. processes that require a kill step, processes that handle high risk items, etc.). The facility must have a documented program that lists the sanitizer used and the strength of the sanitizer used, and a verification of effectiveness of the program, such as monitoring of concentration, document review or post dip swab testing. If utilizing foot baths, the facility must outline the frequency of solution change that is determined by traffic and/or time.
- Hand wash stations must have adequate room to accommodate the number of personnel in the area to prevent delays that may discourage proper hand washing procedures. The facility must have a process in place to verify compliance to this standard upon entry into processing areas and after breaks. The hand washing stations must deliver warm water within 20 seconds. Additionally, there must be an adequate supply of hand sanitizing soap and/or sanitizing agent. Single-service towels shall be available with convenient disposal at each station. Hand washing stations must be used solely for the purpose of washing hands. Hand washing facilities must be “hands-free” activated so that hand contact is not required to turn water on or off.
- The facility should have a hand washing policy including the frequency and method required. Additionally, a glove policy must be in place specifying when gloves are required and the frequency for replacement. The policy must state that gloves may only be used in conjunction with proper and washing and not as a replacement. Gloves should be worn when handling ready to eat product.
- Cafeterias should have available appropriate heating, cooling, and storage facilities such that employees can properly store food away from locker rooms. Cafeterias, kitchens, and break rooms shall be maintained clean, including microwaves, refrigerators, and food storage areas.
- Eating, drinking, or using tobacco products is not permitted except in designated areas. This must be enforced by the facility. Any exception to drinking in production areas must be clearly outlined and monitored by thefacility. If drinking is permitted in production areas, the policy must stipulate that hand washing is required following consumption of beverages.

- Locker rooms shall be adequately sized, well lit, clean, and orderly. Lockers shall be available for storing personal clothing items. Food and equipment or utensils shall not be stored in locker rooms. A routine locker-cleaning schedule shall be maintained. Locker tops shall be sloped to prevent accumulation of trash and to facilitate cleaning. Adequate and convenient hand washing facilities must be provided in or adjacent to locker rooms, in toilet facilities, and at entrances to work areas. In RTE areas and in areas where product is exposed or handled by employees, hand wash and/or sanitizing stations must be convenient to the employee workstations. Signs in appropriate languages, or graphics, shall be clearly posted in locker rooms.
- Toilet facilities must be available in locker rooms or convenient to operational areas if located distant from the locker rooms. They shall be well ventilated, well lit, clean, and orderly. Adequate toilets shall be provided and maintained to good repair. Covered receptacles must be present in the female facilities. Doors to toilet facilities shall be self-closing and must not open directly into processing, ingredient, or packaging areas. Adequate and convenient hand washing facilities must be provided in locker rooms and toilet facilities.
- GMP audits shall be scheduled routinely by site management and verified on a random basis by management. These audits shall be documented with corrective actions attached. Frequency and verification shall be based onthe need to ensure effective control; a monthly frequency is recommended, at a minimum. Audits results and corrective actions shall be reviewed and signed by management to ensure timely responses to deficiencies and needed corrective actions. Follow-up audit activities for deficiencies and repeat items shall record the effectiveness of the corrective actions taken.
- The GMP program must include a procedure that screens employees, contractor and visitors that enter the production areas for food transmissible diseases and their symptoms. This may include but is not limited to nausea, vomiting, diarrhea, fever, lesions containing pus, and jaundice. The procedure must include requirements for returning to work.
- The facility must have wound policy in place. The policy must specify that open or secreting wounds must be covered by a highly-visible plaster (preferably metal detectable) and covered with a waterproof glove or dressing. The policy must also include surface disinfection and product disposal procedures to be taken when potential contaminations occur.
- Visitors, contractors, and tours entering the facility are required to comply with the GMP program requirements.

SECTION 2: PROCESS CONTROLS

PROCESSING

The facility must have procedures to effectively ensure product safety throughout the process. The facility must also prevent potential contamination and bacterial growth due to mishandling during processing.

- Temperature sensitive areas must be properly monitored with daily logs to verify that appropriate temperatures are maintained. The probes in these areas should be properly located in the warmest area of the storage cooler/freezer. The facility must ensure that these areas are monitored at least twice daily. The implementation of the program will be verified via review of random records from the past six months or in the time period since the previous audit, as well as a verification of the accuracy of room thermometers during the physical audit of the facility.
- Temperature sensitive areas should be free of condensate and ice build-up that may lead to contamination. If product or ingredients are stored in transportation vehicles, the facility must ensure the vehicles are regularly inspected to ensure product integrity. The facility must be able to demonstrate compliance to any temperature requirements of stored products. The monitoring must occur at a documented frequency and the site shall be able to demonstrate compliance at all times. Transportation vehicles shall remain locked and all product and/or ingredients stored shall be inspected prior to use or transport.
- The facility must ensure that all perishable processing areas are equipped with a calibrated thermometer to facilitate temperature monitoring. The thermometer must be placed in the warmest area of the room and monitored often enough to maintain control (at least two times per day or during processing). The facility must have a procedure in place to ensure that temperature abuse will be prevented during processing.

- All in process products and packaging must be properly protected from any form of contamination that could be present. All ingredients should be kept off the floor, and properly protected from potential sources of contamination (i.e. cross-contamination or cross-contact).
- The facility must define the terms if they are in use and determine how much re-work or work in progress (WIP) can be utilized within a "lot" of product . Rework is generally considered the re-processing of product that has been packaged, while work in progress would be re-processed product that has not yet been packaged. The program must clearly identify that the mixing of food to "dilute" a defect (i.e. mixing rework that exceeds maximum Defect Action Levels into "good" product to minimize the overall defect in the lot) is strictly prohibited.
- The facility must have ability to trace ingredient or component product-in-process, carryover product and rework. Production records must identify rework or carryover usage in specific lots as well as specific lots capable of showing presence of specific rework. Plant must be able to trace ingredient lots to finished product. This product throughout the manufacturing process from any potential contaminant due to incidental drips, use of non-food grade lubricants or chemicals, or foreign material (possibly due to improperly filtered air and/or steam). Any such incidental contaminants could lead to direct product contamination by dripping directly into product or onto food contact services. The facility must ensure that RTE operational areas are maintained separate and effectively isolated from other operations and traffic flows that could compromise the high level of sanitation and hygiene essential to RTE product integrity.
- The facility must be able to show how by- product intended for use in animal food is controlled to prevent contamination. The food must be held under suitable conditions so that it does not become contaminated (e.g. at appropriate temperatures to prevent microbial growth if applicable). Procedures must be in place to ensure containers and equipment dedicated to this process are suitable, cleaned and properly maintained, as well as be protected from contamination from trash. Finally, animal feed must be properly identified and labelled, and shipping containers are subject to the same provisions as food intended for humans.
- The facility must ensure that all chemicals used in the cleaning process are approved for use in a food establishment. The facility must ensure that only trained individuals are allowed access and handle chemicals. These individuals must have required Safety Data Sheets (SDS) statements and Personal Protection Equipment (PPE) present for use with all chemicals. If a colour code is used to identify different chemical, it must be clearly communicated to all employees.

EQUIPMENT

- Processing, packaging, and storage equipment shall be designed, installed and maintained in such a manner as to produce a safe,wholesome and quality product. Equipment must be designed and maintained to provide easy access, disassembly and reassembly for thorough cleaning, sanitizing and inspection. Equipment must be of smooth,impervious, non-toxic, non-absorbent and corrosion- resistant material where it has direct product contact. Conveyor belts for product contact shall be of impervious, non-absorbent material. Fibre-backed or sandwiched belts shall not be used for product contact conveyors. Belts shall be maintained in good condition with no holes, cuts, frayed edges or damage that render the belt difficult to clean or present a foreign material hazard. Product contact surfaces, such as conveyor belts, shall not be closer than 18 inches to the floor or shall be effectively protected from contamination during operations. Equipment must be free of cracks and non-continuous or rough welds where product may become embedded and make cleaning difficult.
- All utensils, tools and food containers must be designed for that purpose and constructed of food grade materials. The facility must not reuse containers previously used to hold raw materials, ingredients, or other food products. Equipment previously used for any type of chemical or other non-food ingredient must not be reused during the process. Equipment previously used for food products can be used as long as they are adequately cleaned, sanitized, and they do not pose a risk to products.
- Non-foods-grade materials such as wire, tape, and string, plastic or cardboard shall not be used for temporary repair.
- The facility must ensure that all transport equipment is in good repair such that it does not pose potential contamination to the product due to dripping fluids, damaged lights and/or brittle plastic, rough welds on trolleys, over lubrication, foreign material due to torn seats, etc.

FOREIGN MATERIAL CONTROLS

- A foreign material control program must be in place. Such a program could include the use of magnets, sieves, screens, bone detection devices, and metal detectors as necessary, based on the process and the manufacturing environment. The program must include barriers to all potential physical hazards relevant to the identified process and how those hazards will be addressed. The program shall be properly communicated throughout the organization, identifying specific roles and responsibilities.
  - Glass and Brittle Plastics Management: The facility must outline how the potential hazards associated with glass and/or brittle plastics will be managed throughout the process. The program must include communication of such hazards to all within the organization (including a policy of items prohibited from the production facility). The program must also identify all glass and brittle plastic that is present in the facility and the frequency with which it is inspected. The inspection frequency should be based on risk such that materials that may directly affect product are inspected more frequently than materials that are outside of the production areas. The program must outline how the facility will address incidental breakage of glass and/or brittle plastics, including disposition of any affected product, how the area will be secured, cleaned, and inspected prior to resuming production and include inspection and potential disposal of any affected PPE.
  - Metal Detection or other foreign material control devices: There must be a written policy describing the maintenance, set-up, validation, and verification tests of the metal detectors, or other devices (e.g. x-ray machine) if used. The policy must describe the initial set-up procedures, the frequency of verification checks with actual product at start-up, during the shift and at the end of production. Test units to check equipment performance must be appropriate for the nature of the product and the size of the package. Metal detectors must be set-up prior to start-up by qualified personnel and calibrated for the specific product being run. Documentation of calibration and set-up must be part of daily production records along with initial, operational, and final verification checks. All records related to the use of the metal detection system, including rejected product logs, must be maintained.

ALLERGEN CONTROL

In facilities where allergens or sensitive ingredients are used or stored and there is a potential for cross contact, there must be detailed procedures to prevent the contamination of other products. In the U.S. the nine allergens recognized are milk, peanut, soy, tree nuts, wheat, eggs, fish, crustacean (lobster, crab and shrimp) and sesame seeds. Sulphites, over ten ppm, shell fish (oysters, clams and mussels) and mustard are also considered allergens in Canada. Any additional allergens may need to be considered depending on the area to which the facility exports product.

- Allergen Identification: The facility must review all product formulations to identify all allergens that are used in the manufacturing of the product. This should include a risk assessment of all allergen-containing ingredients used in its products (may be completed as part of the hazard analysis). The facility must then identify all ingredients from receipt and through every step of the process ensuring they are clearly identified to all employees who may handle them. The facility must ensure there is proper communication of all allergen containing ingredients and product, Work-In-Process (WIP) included and how the allergen is identified to ensure traceability and prevent cross contact.
- Prevention of Cross Contact: The facility must have a program identifying how allergens are handled from receipt, storage and throughout every step of the manufacturing process such that the risk of cross contact is controlled. Employees handling ingredients and products that are or contain allergens must not handle non-allergenic products without steps to protect against cross contact. This could include change of aprons, sleeve guards, frocks, and hand washing etc. Clothing used in allergen sensitive products shall not be co-mingled with clothing from non-allergenic production. Utensils used for these allergenic ingredients must be dedicated and not used for other ingredients unless there is a thorough cleaning and sanitizing procedure applied between uses. The allergen program should also consider allergens permitted in employee break rooms and cafeterias and appropriate controls to prevent cross-contact from these areas to production areas.
- Production of products containing allergens should be on dedicated lines or equipment where possible. If the use of dedicated line or equipment is not possible, allergen-containing products shall be scheduled sequentially. For example, scheduling non-allergen containing products first. Initial validation and subsequent verification of the cleaning process must be documented.

- Use of a Changeover Process to Prevent Cross Contact: When cleaning or flushing is implemented with the purpose of eliminating the risk of allergen contact, the facility must develop a product sequencing/cleaning matrix. Compliance with the product sequencing/ cleaning matrix and completion of cleaning shall be recorded. Following each event to remove allergenic residue (change-over), the facility must ensure that the equipment cleaning process was followed and the results documented. The equipment cleaning process must remove visible product/residue from all product contact surfaces. The efficacy of the equipment cleaning process shall be validated and subsequently verified to demonstrate that it removes visible residues from all product contact surfaces. This validation must be an allergen specific assessment of the allergenic residue removal process and must be documented.
- Label Reconciliation: Labelling for allergen-containing products must indicate the presence of the allergen or sensitizing agent, as required by regulations. The label must include the common name for each allergen. Old or obsolete labels must be properly identified and controlled to prevent their inadvertent use within the facility.

SECTION 3: RECEIVING, SHIPPING & TRANSPORTATION

RECEIVING

The facility is expected to have detailed, written policies describing how the receiving, acceptance and handling of ingredients and materials are performed and documented.

The following must be included in the receiving, storage and shipping management program:

- The facility must have a written inspection program for all inbound carriers that fully describe acceptable and/or unacceptable conditions. For contracted carriers in which each vehicle is not inspected, there must be written specifications to that contracted carrier including any specific sanitary requirements for the vehicle and transportation equipment, as well as any cleaning procedures. The specifications must also include temperature requirements for the food being received/shipped including pre-cooling phase where applicable. All railcars, trucks, etc. must be inspected at time of receiving to ensure condition, cleanliness, and that they are free of moisture and offensive odors. Materials within vehicles must be appropriately separated to prevent contamination from raw to ready to eat food and/or from incompatible materials (e.g. chemicals) or odors. Carriers must be in good repair, with no evidence of pest activity, and be free of foreign substances such as glass, chemicals, or odors. Interior of trailers, trucks or cars must be free of loose or broken boards, nails, and holes in sheet metal sides that could cause contamination or serve as pest harbourage. Trailer, railcar or tanker security seals must be verified as the original seal number applied at the original shipping point. For temperature sensitive ingredients, receiving vehicle temperature and product temperature must be documented on receiving documents. Documentation of condition of each inbound shipment and seal number (or evidence that trailer was otherwise secured) must be shown on receiving documents or equivalent.
- The plant shall ensure that incoming raw materials are not used or processed until they have been inspected or otherwise verified as conforming to internal requirements. Verification of the specified requirements shall be in accordance with the product safety and quality plan and/or documented procedures.
- When identified by the facility's approved supplier program, a list of ingredients that require COAs must to be present. The facility's program must state that the COAs are obtained prior to the usage of the ingredient. These COAs should be faxed or e-mailed to the facility upon ingredient shipment. COAs must be readily available for use. The facility's program must outline how product is handled in the event a COA is not received prior to the ingredient arriving at the facility (i.e. product rejected, product placed on hold). The facility's program must prevent the use of a material when its COA has not been received. For products in a FSP where the Supplier is responsible for controlling a food safety hazard this COA needs to be a lab analysis showing the name of the external lab, the hazard tested for, the testing method used, the lot number and name of product tested, date product tested, date report issued, findings. Where required, Continuing Letters of Guarantee must be current and maintained for all ingredient and packaging materials. The facility must ensure that these documents are present prior to the receipt into the facility or implement other suitable corrective action, (e.g., analysis by the facility).
- The facility must identify as part of its overall receiving program methods by which the traceability process is facilitated during receipt. The facility may use the lot number provided by the approved supplier or apply a

unique number and/or date; however, the facility must detail how the information provides traceability back to the original supplier.

- The facility must ensure that all perishable materials are handled during receipt in sucha way that potential contamination and/or temperature abuse does not occur. To this end, the facility must outline procedures as part of the receiving program to ensure that temperature sensitive items are not held outside of the appropriate temperature storage areas for a prolonged period of time, generally more than one hour.
- The facility must ensure those raw materials received via bulk methods do not become potentially contaminated. Depending on the delivery method used, the facility must ensure that the equipment is properly cleaned and maintained in a sanitary manner between uses. In addition, those personnel involved in the receiving process may be involved in additional training to prevent contamination of product being received or to take samples of raw material during the receiving process. To ensure the security of the process, the delivery system must be maintained secured between uses.
- Systems shall be established to handle product that is in non-compliance along with documented verification as to the disposition of that product.
- Shipping and receiving areas must be well maintained and in sanitary conditions at all times.

SHIPPING & TRANSPORTATION

- The facility must have a documented program that outlines how they will ship their finished product to customers. The program must outline the inspection that is conducted on outbound carriers prior to loading. This inspection must include checks for cleanliness, off odors, pest activity, and damage. The program must outline what is to be done in the event a trailer does not meet facility requirements (i.e. trailer is cleaned, trailer is rejected, etc.). The program must also outline the pre-cooling of trailers prior to loading if the facility is shipping temperature sensitive products. Trailers must be pre-cooled to 41°F/4°C prior to loading and trailers should be set to at least 41°F/4°C for refrigerated loads and 0°F/-18°C for frozen loads. Finally, product should be inspected prior to loading to ensure that it is within proper date, free of damage, and free of commingling.
- Documentation must be maintained that show that all outgoing carriers are being properly inspected. Corrective actions must be documented when for inspections indicate that trailers do not meet the required criterion.
- If the plant uses a third-party carrier, it is the responsibility of facility to ensure all shippers have received appropriate training to ensure the safety of the food being transported in compliance and have proof of temperature control during transit for in-bound and out bound loads. The facility shall ensure that any third-party carrier complies with defined specifications to ensure the safe transport of food, including any temperature requirements, or specifications related to incompatible materials or commingling of raw and ready to eat foods.

SECTION 4: MAINTENANCE & CALIBRATION

EQUIPMENT

- A documented procedure must be in place to evaluate equipment based on sanitary design principles prior to purchase to ensure equipment can be easily cleaned and maintained. Equipment should be designed so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact. For example, design principles include the requirement of food contact material to be made of corrosion-resistant materials and have smooth seams.
- There should be a documented procedure in place for the sanitation and inspection of equipment prior to being put into service. Where new or refurbished equipment is commissioned, procedures must be in place to ensure the equipment does not pose a contamination risk to product. For example, if equipment is being moved from

one facility to another with unlike allergens, the procedure must identify the acceptance criteria for placing the equipment in service including verification of allergen cleaning.

- Should new or refurbished equipment not meet the defined criteria, a corrective action plan must be in place before the equipment is put into service.
- Equipment must be maintained in good repair and in sanitary condition at all times.
- The facility must ensure that battery charging areas used for transport vehicles do not pose a potential threat to stored raw material, packaging material, or finished product. The facility must ensure that procedures are in place to address any emergency that may arise and that any potentially affected product is held for further disposition.

MAINTENANCE

The facility must ensure that equipment and materials used for production are suitable for the purpose intended and in good repair. The facility shall have in place and in use a written program for preventive and corrective maintenance that is up to date.

- The documented program must include a list of food handling equipment, as well as procedures detailing the maintenance required for each piece of equipment, including requirements for release back into production and frequency of maintenance. Preventive Maintenance (PM) frequency shall be adjusted in accordance with equipment history and the outcome of the last service. The facility must address repairs conducted both by internal personnel as well as contractors as they relate to part reconciliation, personal hygiene, product and facility security, and potential product contamination.
- The facility must have PM activities for all listed equipment. The program shall be tailored to the specific products or facilities. Priority shall be given to maintenance of pieces of equipment that may affect food safety, quality, or employee safety.
- The facility must ensure that there is a system in place to properly communicate all scheduled and unscheduled repairs. The tracking program must be used to verify the completion of projects as well as feed into the continuous improvement and/or long-term project program for the facility's PM program. The program should include some type of alarming system to prevent critical repairs from being missed.
- The facility must have measures to ensure the equipment and facilities are clean, sanitized, and in good repair prior to release for production after maintenance activities (e.g., drilling, cutting, polishing, welding) have occurred. The outlined program must include roles and responsibilities related to who is to be contacted.
- The facility must ensure that all records related to the maintenance activities (including PMs and emergency repairs) are maintained and adequately reviewed. These records may be electronic or paper (note: document control requirements apply) and should be maintained for a period of time to ensure regulatory and/or client requirements are met.
- The facility must document that sanitation activities have been completed once maintenance activities are finished on equipment and in food handling areas. This can be a simple sign off at the bottom of the maintenance work order or a full pre-operational inspection can be conducted. In addition, there must be documentation that all tools and parts used for the maintenance activities are accounted for upon completion of the maintenance tasks.
- The facility must ensure that only food grade lubricants are being used for the greasing and lubricating of food processing equipment. A segregation system must be in place to prevent cross contamination. This segregation system must include the proper storage of lubricants and greases, and the use of dedicated and identifiable grease guns. This program does not have to be documented. Lubricants should be assessed for allergens and if present replaced or included in the facility's allergen control program.
- Equipment repairs are intended to be permanent and must be performed using proper materials. There must be a documented temporary/emergency repair policy which outlines the proper protection of product in the event emergency repairs must be made to keep production running. The policy must identify the requirement to make any temporary repairs permanent within a reasonable time frame and clearly identify those materials that are prohibited to be used for any repair (e.g. wood, string, clear tape, cardboard, etc.).

CALIBRATION

- It is essential that all measuring, metering, or protective devices (e.g., thermometers, scales, flow meters, metal detectors) be properly calibrated to ensure the accuracy of these activities and the effectiveness of their performance. Routine annual calibration (i.e., certification) of thermometers and scales by an outside contractor is required. There must also be a program to evaluate the performance of measuring devices on a regular basis to ensure accuracy on a day- to-day basis. There must be procedures in place to verify the accuracy of thermometers used for product evaluations. The thermometers must be identifiable with documentation of calibration results. Thermometers shall be calibrated at the temperature range at which they are used. Calibration of thermometers shall be based on certified standard thermometers. It is recommended that accurate intermediate thermometers be used to verify the daily calibrations where the intermediate thermometers are checked against the certified National Institute of Standards Testing (NIST) unit weekly to prevent excess use and handling of the certified thermometer. Full documentation of the calibration of the intermediate thermometers must be available. Assigned personnel shall check receiving and distribution scales daily to verify that they are accurate. Documentation of these checks must be available and can be part of the routine daily records for the activity being measured. Personnel shall check scales used for weighing ingredients, filling, and finished product preparation daily. Standard weights in the range of the weights being produced shall be used for these verification checks. Daily calibration checks must be documented.
- Calibration procedures shall describe the frequency of testing, the testing method and the acceptable range of variation. Corrective actions shall be specified and noted when exercised. There shall be documentation of corrective actions when a non-calibrated or inaccurate measuring device has been used (e.g., thermometer, scale, flow meter, counting device, metal detector). All products produced since the last acceptable check must be reviewed to determine if they must be held for further evaluation.

SECTION 5: SANITATION

Food processing facilities must develop specific procedures to maintain sanitation. The effective management of sanitation, housekeeping and hygiene is a critical element requiring the involvement and cooperation of all operating departments and support groups. A comprehensive sanitation program requires specific policies covering requirements and expectations, training to communicate those requirements with management, support, and follow-up to ensure that the requirements are properly met and that all sanitary standards are fully enforced.

SANITATION PROGRAM

- The facility must have documented Sanitation Standard Operating Procedures (SSOPs) for all sanitation activities that are conducted at the facility. The SSOPs must be present for all pieces of food handling equipment and must cover all processing areas, storage areas, common areas, and the exterior of the facility. The SSOPs must list the method in which the task is to be completed, the chemicals used (along with concentrations or if they are from a pre-mixed dispenser), the equipment used for the task, and the person responsible for the completion of the task. Finally, the facility must have a schedule in place for the completion of all sanitation tasks. This schedule can be outlined in the documented SSOP or can be part of a separate schedule that has been implemented.
- The facility's standard cleaning methods for individual pieces of equipment and facility structures must include the level of disassembly required for cleaning and responsibility for each task, chemicals, cleaners, and sanitizers used in cleaning with verification of chemical strengths and water temperature (water temperature requirement is >140°F/60°C) for cleaning unless otherwise recommended in writing by chemical supplier).
- The facility must maintain a list of approved sanitation chemicals. These chemicals can be listed in the SSOPs that are implemented at the facility; if this is the case, a separate list is not required. In addition to the list, SDS for the chemicals must be present. SDS must be current and present for all chemicals. All chemicals used in the facility must be approved prior to their usage. All sanitation chemicals must be used per label directions to ensure that sanitation activities are effective.
- Sanitation chemicals that are used at the facility must be stored in a manner to its 5.4protect products and personnel from possible contamination or harm. All chemicals must be stored in a designated area which is

secured and has controlled access. A process must be in place specifying the actions to be taken in the event of a chemical spill.

- The facility must develop a verification procedure for the sanitation program that is relevant to the risk of the process. At minimum, management must complete a pre-operational inspection to verify the plant and equipment are clean and sanitary. All equipment, containers, utensils, walls, floors, ceilings, light fixtures, miscellaneous overhead structures, etc., shall be evaluated for visual cleanliness**.** Deficiencies noted and corrective actions taken must be documented. Employee conducting the pre-operational inspection must be appropriately trained.
- In addition to the pre-operational inspection, Adenosine triphosphate (ATP) measurements are based on the detection of ATP by bioluminescence and can be a method of choice in monitoring cleaning efficiency. It is a rapid measurement of the actual hygiene status of a sampled surface, allowing fast initiation of corrective actions in the case of inadequate cleaning. ATP measurement, however, should not completely replace traditional techniques (e.g., swabbing), and should be integrated with traditional cultural techniques as part of a coherentsurface cleanliness monitoring system. Although manufacturers of ATP measuring devices give general guidance on acceptable ranges for routine hygiene controls, internal standards have to be set for the given processing environments. If the facility is producing RTE product, the verification program must include food contact swabbing. The development of the program must include a baseline study and validation. The facility must retain all records related to the verification of the sanitation program.

SECTION 6: TRAINING

Documents must be available to demonstrate management's commitment to a planned training program for both management and food production personnel.

The following must be included in the management program:

- The formalized program must include introductory training programs for new management and new operating personnel. The training policy must address the communication of basic food handling, sanitation, food defence, refresher training for experienced employees, and job specific requirements (such as maintenance, receiving/shipping, food handling and other activities). This program must be reviewed and revised annually, to ensure that management and supervision are aware of new food safety issues and control programs.
- Training programs shall be given to all employees, including new employees, temporary employees and contract employees in the appropriate languages reflecting the work force population. A method to document understanding, typically testing or performance evaluations shall be an integral part of the training program.
- Operating personnel must be given GMP, personnel hygiene and job specific training on hire and on an at least annual basis to review and update their understanding of food handling requirements to ensure product safety and quality. This training may also be broken down into a quarterly basis. Examples of quarterly training activities could include lunch and learn presentations, departmental meetings, or in-house seminars/workshops covering appropriate food safety and sanitation topics. Training programs shall be given to all employees, including new employees, temporary employees and contract employees in the appropriate languages reflecting the work force population (note: this training can be included along with other training provided by the facility).
- The facility must ensure that those persons responsible specifically for sanitation duties receive all applicable training related to chemical handling and the proper breakdown of equipment to ensure employee and product safety. This training must be documented and all record maintained as part of the overall training program.
- The facility must develop a complete list of all training activities related to food safety, quality, process control (as applicable), sanitation, food defence, as well as other job specific duties.
- Requirements of the training record include: participants' names, description of training provided, who provided the training, verification that the training was completed, verification of competency, and the skill that was gained by the participants.
- During the audit, compliance may be evaluated by direct questions to employees to determine their knowledge level (e.g., How is the cleaning or sanitizing compound used?).

SECTION 7: PEST CONTROL

It is required that all food processing, storage, and distribution facilities operate under the authority of a licensed pest management contractor. Typically, they are individuals from outside the company. They must have a proper license, certification, and insurance. They shall be expected to provide aggressive support to the plant pest management, housekeeping, and sanitation programs especially as they relate to potential pest harbourages and conditions that compromise the evaluation of pest control. Since they are trained experts in recognizing and evaluating conditions that contribute to potential pest development such as sanitation, housekeeping, properly sealed doors and windows, perimeter accessibility and outside grounds conditions, it is expected that they will include observation comments on these situations in their activity reports with appropriate recommendations. Any comments on the activity reports must have a documented response and corrective action if appropriate.

If pest management is internal, the same level of expertise must be provided. Likewise, the same aggressive approach to the above areas of concern must be required with documented activity reports and responses. The following must be included in the pest management program:

- A written detailed pest management policy and program must be available. The policy shall outline and describe all procedures required to ensure that activities conducted by the Pest Management Provider (PMP) and trained employees are carried out in accordance with the prescribed policy. A plant-specific pest management manual shall be current and updated at least annually. Management of the pest management program shall be assigned to a qualified and trained company employee. The policy shall identify forms used by the PMP. The activity/action reports shall document what chemicals are used, if any, where, why, and with relevant observations of activity. Site maps for traps, glue boards and bait stations shall be reviewed regularly, dated, and initialled by the person having responsibility for the program, at a minimum frequency of once per year.
- The pest management provider must have a current business license and operating insurance. In addition, a PMP applicator's license and letter of insurance must be on file along with appropriate SDS for all chemicals used and copies of product labels describing how and where the pesticide can be used and against what pest target. Company employees engaged as PMPs must have proof of appropriate training and licensing as required by state or local regulations. Forms used by the PMP and the company personnel shall be the same for uniformity.
- The PMP shall conduct inspections, as needed, based on history of pest activity. PMP activity reports must indicate specific sites of activity, type of activity and recommended corrective action. Subsequent reports shall indicate the efficacy of those actions. If electronic scanners are used to check bait stations or traps, the tag or barcode must be inside the station or trap. Interior rodent traps must be monitored on a weekly basis and exterior stations monitored monthly at a minimum.
- The PMP must ensure that equipment used in servicing the facility does not pose a threat to the food safety of the product. Only mechanical traps or glue boards may be used inside the facility. No bait stations are permitted inside the plant or warehouse. If zapping or electrocution-type Insect Light Traps (ILTs) are in use, they must be placed so that they do not become a possible contamination hazard to product (especially where exposed product is stored and/or repackaging occurs). If used in the aforementioned areas, these ILTs must be appropriately located so to not pose any threat to exposed product and/or equipment.
- Trap locations shall be recommended by the PMP based on potential access points and knowledge of pest habits. Exterior opening doorways must have traps on both the left and right sides of the opening inside the doorway. Bait stations used outside shall be placed based on habitat and potential access. They shall be positioned to prevent the intrusion of casual water and rain and firmly secured to prevent removal from the assigned position or opened by unauthorized personnel. Bait shall be secured within the bait station to prevent removal from the station. Bagged or other unsecured baits shall not be used.
- The facility must ensure that interior traps are properly maintained in sanitary condition, good repair and in the appropriate position per the schematic site map. All rodent devices must be placed directly against the wall to ensure that they work properly. ILTs must be plugged in and bulbs must be operational. ILT bulbs must be shatterproof and replaced on an annual basis, at a minimum (documentation must be present). Exterior stations must be kept clean, stocked with fresh bait, anchored to the ground, free of damage, and tamperproof (i.e., locked).

- As a demonstration of the successful implementation of the program, the facility must be free of pest activity to prevent possible product contamination. The facility must ensure that trending is being conducted on the performance of the pest control program to show that it is effective. If live activity associated with pathogen-carrying pests (e.g., rodents, birds, cockroaches) is observed, it is a critical violation and will result in failure of the audit. The facility must be free of any evidence that suggests that there are pest issues present (e.g., rodent droppings, insect carcasses). Any sign of decomposed rodents in the facility (be it in a trap or in the facility) is not permitted and shows a major deficiency in the pest management program.
- PMP activity reports must indicate specific sites of activity, type of activity and recommended corrective action. Subsequent reports shall indicate effectiveness of those actions. Responsible plant personnel, noting PMP observations and comments, shall sign activity reports. There shall be a documented management response to all recommendations included on the activity report.
- Building structure must be sound with no holes, unscreened exterior openings, broken windows, etc. that may allow pest entry into the facility. All entrances, including employee doors, shipping, and receiving dock areas shall have appropriate protection to prevent the entrance of flying, crawling, or running pests.
- The facility must ensure that any pesticides housed on the premises are stored appropriately. All pesticides must be stored segregated and secured from all other chemicals. These pesticides must be properly labelled and used in such a way that they do not pose a threat to food or food packaging.

SECTION 8: SUPPLIER APPROVAL

The facility must ensure that each supplier is capable of providing product as specified. To that end, it is essential that a detailed program be developed outlining how each potential supplier will meet agreed specifications, the level of risk the potential supplier's raw material poses to the finished product, the requirement of GMPs and SSOPs at the potential supplier's facility, the fact that raw materials will be received from approved suppliers only, and the overall methods for granting supplier approval.

The following must be included in the supplier management program:

- The facility must have an approved supplier program outlining requirements for its specific facility (note: this includes facilities where the corporate office develops the supplier program). The facility should outline how it will implement and facilitate the requirements. The program must include all raw material, ingredients, chemicals, processing aids, and packaging materials.
- The facility has to have product specifications or technical data sheets available for all ingredients, packaging and chemicals entering the facility. A product specification must have key attributes of the product in biological, chemical, and physical areas. Examples can include, weight, size, count, color, taste, moisture, fat, salt, brix, aerobic plate count, coliforms, etc. The specification must include the attribute, the limit or criteria, and the sample size or monitoring.
- The facility must include ongoing monitoring and assessment of all suppliers. The facility must outline which method is used to monitor/assess the suppliers. Assessment and monitoring may include the completion of surveys, questionnaires, second- or third-party audits, or on-site audits. The type of assessment and the frequency of review must be based on risk. Suppliers of raw materials identified as "high risk" (for example those known to be susceptible to food fraud or those with allergen-free claims) should not be approved based on a supplier questionnaire only.
- Food facilities have to conduct a risk assessment as to the probability that they could be supplied with fraudulent ingredients. The factors to use when making a food fraud risk assessment are based on: if the ingredients were fraudulent would it be obvious, has there been a history of this ingredient being involved in fraud (i.e. cumin that was 10% ground peanut shells, honey, olive oil, etc.), has the supplier been involved in fraudulent products, is the supplier in a foreign country increasing the probability of food fraud. If the facility has no reason to believe that food fraud could happen to their ingredients then their assessment should demonstrate how they justified that decision. The entire risk assessment process must be documented. Records related to the approval program must be maintained (note: in cases where a corporate program has been developed, the facility must include in its program how ongoing feedback is collected and given to corporate to facilitate overall monitoring of suppliers).

SECTION 9: FINISHED PRODUCT SPECIFICATION & QUALITY CONTROLS

The facility must have written policies and procedures specifying the operational control practices required to ensure that the manufacturing process operates in control on a continuing basis. A formal program is essential to ensuring that the products are produced in accordance with specifications, that they meet quality requirements of the customer, and that they are produced under conditions that promote safe food products. Operating records must be available to verify conformance to these policies.

PRODUCT SPECIFICATIONS

As part of an overall food safety and quality program, the facility must develop finished product specifications for all products being manufactured. These specifications must comply with local regulation at a minimum, as well as those specifications developed by the facility and customers.

- Finished product specification may include biological, chemical, and physical (as applicable), but may also contain process control attributes and quality parameters.
- The facility must have a process defined to determine that the product meets the finished product specification. The facility must ensure compliance with the program as well as trending related to non-conformance. Up-to-date documents must be made available to all relevant staff.
- The program must include the method of analysis, criteria, and corrective actions to be taken when criteria are not met and the criteria must be based on sound scientific principles. The program may also tie into the hold and release program, where applicable.

QUALITY CONTROLS

The facility must have detailed policies and procedures ensuring the quality of the product from receiving, handling, manufacturing, shipping, control and evaluation of food products to ensure that the products meet internal and external client specification requirements. These policies must be well organized, available, current, dated and signed by management. The program must be communicated to the organization relative to their specific job description. The program must be validated and subsequently verified. Changes shall be clearly identified and appropriately signed and dated.

- The facility must develop a quality program addressing the specific points during the process that are critical to the quality of the finished product as identified by the facility itself or its clients. This could include weight requirements, visual requirements, sensory testing, counts, etc. The facility must maintain records to show that they are meeting the quality requirements for the products that are manufactured at the facility.
- There must be a communication chart in place and job descriptions for the key positions responsible for the quality of product. These items would only be required for key personnel responsible for ensuring quality, not line workers with no direct responsibility in the quality program. Key personnel should be able to describe the requirements are required action when a quality element does not meet specification requirements.

SECTION 10: TESTING

TESTING

- If finished product specifications require finished goods testing, a verification program must be in place to ensure that product parameters are met. The frequency of finished product testing must be determined by risk. As well as frequency, the program must outline the testing parameters, methods of testing and sample collection.
- If the location is processing ready to eat food then they must conduct environmental swabbing to ensure that areas do not pose a contamination threat to exposed products. The program must outline the frequency of testing, a sampling plan for the testing, the types of tests that are conducted and the pass/fail limits. In addition, if food contact surfaces are swabbed and/or finished products are tested, the program should describe how the product is controlled during the test and its disposition in the event of a failure. The facility must have documentation to support their testing frequency. Corrective actions must be on file for all situations where swabs do not meet the pass limits that are established. Corrective actions must also indicate a follow-up sampling plan.
- Potable water, ice, backflow, steam and wastewater management plant must demonstrate that the water supply is potable and that potability is maintained at all times. Potability must meet local requirements at a minimum (. Potability must be tested on an annual basis, at a minimum. If the facility is using water from a private well, there must be an acceptable potability test every six months. All samples for potability must be taken from the facility. A documented check of the backflow preventers must be completed at least annually.
- The air within the high risk/RTE room must not pose a contamination risk, positive pressure should be maintained relative to surrounding areas and the testing frequency established. Air used for direct processing and or comes in to contact with product or food contact surfaces shall not be a source of contamination as confirmed by testing air for contaminants, filters shall be changed at a describe frequency.

GOOD LABORATORY PRACTICES

- Laboratory procedures shall be documented. Testing procedures shall be based on recognized and approved procedures. Documentation of all testing shall be available, including records of Certificates of Analysis (COA) where in-house testing is not performed. The plant laboratory for chemical, physical and microbiological evaluation of ingredients, in- process components and finished product must be adequately equipped and staffed to provide the essential technical support to the plant. Records and reports of analytical information gathered by organizations (internal and external) must be catalogued and maintained in a fashion that can provide feedback for operational control. When an outside laboratory is used, documented procedures must be available to properly interpret and manage the information provided. Any laboratory waste outlets should be downstream of the process, at a minimum.
- It is essential that every laboratory have a detailed and documented calibration program for instruments and measuring devices. Balances and laboratory test equipment shall be calibrated (certified) by a competent certifying company at a prescribed frequency as defined by the manufacturer. Records of this certification shall be maintained.
- The laboratory shall be isolated from the production area so that it does not contribute to potential contamination. The laboratory shall be vented directly to the outside and under negative pressure. Pathogen analyses shall not be performed at a plant laboratory unless there is competent professional supervision and there is an effective program to secure pathogen organisms from misuse (e.g., locked, secured, and restricted storage, documented inventory control and formal procedures to address any potential breach of security). Microbiological testing areas shall be isolated and only designated personnel permitted access.

SECTION 11: COMPLAINTS & NON-CONFORMING PRODUCTS

COMPLAINTS

- The facility must have a written program for handling customer or consumer complaints. The policy must address responsibilities, response time, and corrective actions based on an investigation of the complaint. A log is essential to track complaints by product identification, production dates, cause, and origin of complaint. Customer information can be a valuable resource for validating criteria and, to that end, should be used as part of the continuous improvement program as well. Trending should be done to ensure that any re-occurring issue is properly addressed with a corrective and preventative action plan.

CORRECTIVE ACTIONS

- The facility must define and develop methods for the management of corrective actions. Investigations should include identification of root cause and corrective and preventive actions. A confirmation should be conducted to ensure that actions taken were effective in rectifying issues observed. All associated records must be documented and maintained.

NON-CONFORMING PRODUCTS

- The facility must establish and maintain documented procedures to ensure that product that does not conform to specified requirements, at any point of the process, is not shipped. This control must provide for identification, secured segregation, documentation, evaluation, disposition, and reconciliation of product that is placed on hold.
- A hold tag policy must include a permanent written log of each product or item placed on hold. The log shall list the date, the product, the quantity, the reason for the hold, the results of the evaluation and the disposition. Disposition must be dated and signed. The methods must include who has authority to put product on hold and who has the authority to release product that is on hold. The facility must ensure that the program is adequately communicated throughout the organization. The hold policy must include a method for physical hold and not just a systemic hold (designation or location). All records related to the hold program must be properly maintained.
- The facility must have a policy for handling returned products. Returned products must be identified and placed on hold immediately. There must be a designated, clearly identified area for returned or retained products. There shall be a physical accounting of the product on hold at least weekly to verify that that actual product quantities match records. Discrepancies shall be treated as a serious food safety failure.

SECTION 12: RECALL & TRACEABILITY

The facility must have procedures in place to effectively trace specific lots of ingredients, packaging, processing aids, and finished products through the shipping and distribution channels. The implementation of the program will be tested during the audit process.

The following must be included in the product recovery and traceability management program:

- The facility must have a program in place to trace and recall products. The system that is in place must enable the facility to trace finished product to the first customer and back to the raw materials. Additionally, the facility's program must enable them to recall ingredients through to the first customer of finished products. All raw materials rework, packaging materials, and processing aids must be covered in the program, including the appropriate steps to be taken for appropriate disposal.
- Production records must identify rework or carryover usage in specific lots as well as specific lots being capable of

showing presence of specific rework. The facility must be able to trace ingredient lots to finished product. This includes bulk ingredients that may be used from bulk silos. The program must include lot coding information for finished product(s) and definitions for all codes. The program must also address how finished product labels are reconciled and that all ingredients are properly included on the label. This traceability shall extend to the first customer (i.e., distribution center, restaurant, or secondary processor) and back to their supplier (one up and one back). The program must also include how customers are instructed to return/dispose of affected product.

- The facility's program must identify the recall team members and describe each team member's responsibilities. Current office and after-hour telephone contact numbers and email addresses of all recall team members, both at the plant and head office, if appropriate, must be available to all team members. The facility must also include notification procedures, including contact lists and customer and regulatory contacts.
- The facility's program must include conducting mock recalls once every 12 months at a minimum, including mass balance and trace one forward and one backwards. The program must include performance standards set (note: industry best practice has been set at recovery of 100+/-2 % of suspected product within four hours). Involvement of entire team in mock recalls is expected. A management review must be conducted after the exercise is completed and should include documented results of level of success and recommendations for any necessary improvements.
- The facility must have a system in place to ensure that all lot codes are being properly documented for raw materials and primary packaging that is used. Rework and work-in-progress must be effectively tracked as well. Product traceability must start at the time of receiving and be available at every step through shipping of the finished good.
- A written process must be in place outlining how lot codes are determined for finished products. This should include what the facility considers as a lot or a batch and how it is communicated to the staff. All lot codes are required to be legible.

SECTION 13: FOOD DEFENSE/SITE SECURITY & CRISIS MANAGEMENT

Food processing facilities must develop specific procedures to secure their product, to deter and to prevent intentional contamination, and will have protocols in place to quickly and accurately identify, respond to, and contain threats or acts of intentional contamination.

FOOD DEFENSE/SITE SECURITY

- The facility must develop a food defense/site security program outlining the site's procedures and strategies. The program must include clearly defined roles and responsibilities of those individuals responsible for maintaining the program and addressing access to the facility, visitors, raw materials, security inspections, employee identification and other appropriate requirements per local regulation. The program must be communicated throughout the organization and reviewed on an annual basis, and or when an incident occurs or when changes are required.
- The facility must ensure that background screening checks on employee candidates are performed. This requirement will include all levels of employees.
- The facility must ensure that there is a system in place to record, track and provide identification and appropriate restricted access of all people, including employees, visitors and contractors 24 hours per day, seven days per week. There must be a program in place to reclaim access cards/keys/computers/etc. from terminated employees, or otherwise be able to demonstrate how access to the facility is revoked.
- The facility's program must include the requirement to provide identification and require sign-in by all contractors and visitors prior to entering the facility. The program must also include that the visitor and/or contractor be escorted at all times while on the premises. In the event that visitors and/or contractors are allowed to enter and work on the premises unescorted, a documented screening procedure must be in place.
- The facility must have a documented procedure in place that addresses the protection, monitoring, of raw material ingredients and products during receiving, bulk storage, blending, processing, and packaging. The procedure must ensure that all incoming goods are inspected to ensure packaging integrity. This should also include bulk delivery systems. Once product is finished, this will also include outbound security. Where required, the facility must ensure

that all company controlled trailers are properly sealed or secured once they are loaded. Seal numbers should be documented and maintained.

- The Food Defense/Site Security Team shall conduct a documented threat assessment and shall include interior and exterior threats, and to identify vulnerabilities for potential risks to products, from a deliberate source to cause product contamination. Mitigation strategies must be developed for each vulnerability identified to prevent or mitigate the risk.
- The facility must implement routine assessment of the food defence/site security program. This will include all physical areas such as verification of restricted areas, possible evidence of tampering at any point in the process (tamper-evident packaging), etc.
- The facility must demonstrate that the restricted access policy is properly implemented; thus, doors entering the facility that should be secured must be verified as such. If doors are not secured into the facility, staff (e.g., receptionist) should monitor them continuously. In the event that closed circuit cameras and security guards and/or gates are used, the correct use must be verified and documented.
- In the event that the facility uses water treatment, bulk delivery and/or storage systems, these must be verified as secure between uses. In addition the facility must properly protect any equipment stored for future use as well as ensure that thisequipment will not be subject to contamination. In the event the facility does not fence the perimeter of the grounds, the facility must ensure all equipment is protected via alternative methods (e.g., the use of caps and/or locks).
- As part of the receiving and food defense/site security programs, documentation that incoming raw materials are received in a secure manner (via seal and/or lock) is necessary. Documentation of proper implementation must be maintained. In addition, all outbound product must be secured.
- The facility must have a list of restricted ingredients (i.e. colors and preservatives, such as sodium nitrate and sodium nitrite, potassium nitrate and sodium benzoate, sorbates, etc.) that are in use at the facility. Access to these ingredients must be controlled to prevent unauthorized access.
- The facility must be able to demonstrate thatall loading and unloading of product is properly supervised to ensure security. All bulk hoses and ports to the facility must be secured when not in use.
- Where appropriate, tamper evident packaging should be used.

CRISIS MANAGEMENT

- The Management team shall ensure a detailed Crisis Management program is in place to effectively manage the impact in the event of a crisis such as natural disaster, emergency situations, civil unrest, including disruption of services or resources to ensure product safety, quality, and legality. There shall be a documented inspection/verification of the equipment, materials and finished products, that may have been affected, including authorization for release. The facility must develop and implement a business continuity plan in the event of an interruption, and where possible have approved sub-contractors and back-up suppliers.
- The effectiveness of the crisis management Program shall be conducted at least annually, using the worst-case scenarios, and corrective actions are to be implemented based on the outcome of the mock crisis management exercise.

SECTION 14: DOCUMENT CONTROL

The facility must have a policy with specific procedures for document control, including preparing the process documents, identifying areas for control, collecting data, indexing completed forms, controlling distribution of documents, document filing, and file storage.

- The policy must identify a specific time limit for holding files and the proper disposition of outdated records. Locations for the storage of documents must be designated. Records maintained off-site must be retrievable within a reasonable time.
- Access to records shall be limited to designated individuals. The documents and data shall be reviewed at least

annually and approved for adequacy by responsible personnel prior to use. An updated list of responsible personnel shall be on file.

- A master list, or equivalent document control procedure identifying the current revision status of documents, shall be established and readily available to preclude the use of invalid and/or obsolete documents. Invalid and/or obsolete documents must be promptly removed from all points of issue or use, or otherwise protected against unintended use.

APPENDIX A: REQUIRED DOCUMENTATION

A number of critical documents will be reviewed during the audit process that will assist in evaluating GMP compliance. The auditor will randomly select records supporting the implementation and maintenance of each program over a period of six months or, in the case of a re-audit, back to the previous audit. In addition, the implementation of each program will be verified via interview of employees (where and when applicable). To facilitate a smooth, organized audit, we request that the following documents and records be readily available at the beginning of the audit. Please note this list is not all inclusive.

- Allergen control policy and program, including related compliance documents
- Analytical and microbiological test results
- Approved chemical list including relevant compliancy documentation
- Approved supplier program and related records
- Blueprint of plant showing water and sewer lines, location of backflow prevention devices, separation of ready to eat areas and plant traffic flow patterns
- Calibration of in-plant measuring policy, procedures, and related compliancy records
- Crisis Management policy and procedures including relevant records
- Customer/consumer complaint procedures manual and appropriate corrective action plan
- Deviation records and corrective action plans demonstrating compliance
- Dispatch policy and procedures, including compliancy records
- Document management and record keeping policies and procedures
- Equipment procurement policy, including all relevant documentation and records
- Facility flow diagram
- Finished product inspection policy and procedures and monitoring records
- Food defense and site security policies and procedures including compliancy records
- Food Fraud policy and procedures and related compliancy documents
- Foreign Material management policy and program including relevant compliancy records.
- GMP audit records and corrective action plan
- Good Manufacturing Program and employee hygiene policy manual
- Laboratory policies and procedures manual (laboratory methods, sampling plan), if applicable, and related compliance documents

- Master sanitation schedule, including sanitation monitoring records with corrective actions and preventive measures
- Potable water and ice testing records
- Preventive maintenance program and corrective action plan
- Product coding policy and procedures
- Product recall manual, including records of mock recalls (including product coding policy)
- Product specifications verification records
- Product traceability policies and procedures, including any related compliancy records
- Production and processing records
- Quality policies and procedures manual
- Receiving policy and procedures raw materials, ingredients, packaging materials,and processing aids, including compliancy records
- Return handling and retained product policy and procedures
- Rework policy and procedures (control and traceability), if applicable
- Rodent and pest management procedures manual, activity records and related compliance documentation
- Rotation policy and procedures of raw materials, ingredients, packaging materialsand finished products
- Sanitation verification program (including environmental monitoring when applicable), records, and corrective actions
- Health screen program and relevant records for employees and visitors
- Site registration with Regulatory body documentation
- Specification sheets for raw materials and ingredients and copies of Pure Food Guarantees and Continuing Letters of Guarantee for food packaging materials
- Standard Sanitation Operating Plan (SSOP)
- Storage policy and procedures (including temperature monitoring, when applicable) of all raw materials, ingredients, packaging materials, processing aids, and finished product(s)
- Thawing policy and procedures for raw materials and ingredients, ifapplicable
- Trailer inspections for Incoming and outgoing trailers
- Training policy and compliance records relevant to GMP and plant specific policies
- Wound control policy

APPENDIX B: CHANGE LOG

New to GMP for food	Section 2	Allergen policy in the USA now include the requirement to include sesame
New to GMP for food	Section 1	GMP program requires screening for food transmissible diseases
New to GMP for food	Section 1	GMP Program requires a written would policy
New to GMP for food	Section 6	Minimum requirements for refresher trainings
New to GMP for food	Section 7	Requirement for updating pest control maps
New to GMP for food	Section 9	Requirements for finished product testing