HACCP & FOOD SAFETY PLAN VERIFICATION

Expectations Manual

Version 1

Effective from 01-March-2023

INTRODUCTION

The following requirements outline the management programs and performance criteria expected of a modern food manufacturer facility to meet the food safety needs expected by the consuming public, most retail and 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 food safety programs are the hallmark of modern food manufacturers, high quality is the essential ingredient to ensure success with the consumer. Reliable food safety systems with disciplined and knowledgeable workforce that fully understand both food safety and consistent quality are necessary to compete in today's market.

The scope of an 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: HACCP/Food Safety Plan Verification 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 corrective and preventive action plans. 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 Regulation*
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, wheat and wheat products, fish, and shellfish (i.e., crustacean). On January 1st, 2023- the USA will require allergen statements and preventive controls for sesame seeds. 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.
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.
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.
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.

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 (FSP)- terminology related to Food Safety Plans & Preventive Controls	
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)
Process Preventive Control	Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating foods. Process controls must include parameters, maximum, and/or, minimum value to control a chemical, biological, or physical hazard.
Parameters	The minimum or maximum value, or combination of values to which any hazard must be controlled to minimize, reduce, or eliminate an identified hazard.
Sanitation Preventive Control	Procedures, practices, and processes developed to ensure that the facility is maintained in sanitary condition adequate to significantly minimize or prevent hazards such as pathogens, and other biological/chemical hazards from employee handling, food production, and food allergens.
Allergen Preventive Control	Food allergen controls include procedures, practices, and processes to control food allergens.
Supply Chain Applied Control	A preventive control for a hazard in a raw material or other ingredient when the hazard is control before the receipt of the ingredient/product.
Hazard Analysis Risked Based Preventive Control (HARPC)	Hazard Analysis Risk Based Preventive Control (HARPC)- system utilized for development of a Food Safety Plan and Preventive Controls
Preventive Controls Qualified Individual (PCQI)	A qualified individual who has successfully completed the training in development and application of risk based preventive controls at least equivalent to that received under a standardized curriculum recognized as acceptable by FDA or is otherwise qualified through job experience to develop and apply a food safety system.
Foreign Supplier Verification Program (FSVP)	FDA regulated rule: Foreign Supplier Verification Programs (FSVP) rule, which requires FSVP importers to verify that the food they import meets U.S. safety standards. FSVP importers are required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies.
Hazard Analysis and Critical Control Point (HACCP)- terminology related to HACCP	
CCP Decision Tree	A sequence of questions to assist in determining whether a control point is a Critical Control Point (CCP).
Control	(a) To manage the conditions of an operation to maintain compliance with established criteria. (b) The process that states where correct procedures are being followed and criteria are being met.
Control Measure	Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.
Control Point	Any step in the process at which biological, chemical or physical hazard can be controlled, reduced or eliminated.
Corrective Action	Documented procedures followed when a process or product deviation occurs.

Criterion	A requirement on which a judgment or decision can be based.
Critical Control Point	A step at which control can be applied and is essential to prevent or eliminate a food safety hazard likely to occur or reduce it to an acceptable level.
Critical Limit	A maximum and/or minimum value to which a biological, chemical, or physical parameter shall be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard reasonably likely to occur.
Deviation	Failure to meet a critical limit.
HACCP	Hazard Analysis Critical Control Point. A systematic approach to the identification, evaluation and control of food safety hazards reasonably likely to occurs.
HACCP Plan	The written document that is based upon the principles of HACCP and that delineates the procedures to be followed.
HACCP System	The result of the implementation of the HACCP plan.
HACCP Team	The group of people representing the site management, technical and food safety experts, manufacturing, maintenance, engineering, and others who are responsible for developing, implementing, and maintaining the HACCP system.
Hazard	A biological, chemical (including radiological),or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
Hazard Analysis	The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and shall be addressed in the HACCP plan.
Monitor	To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.
Pre-requisite Programs	All procedures used in the facility that address operational conditions providing the foundation for the HACCP/FSP system.
Severity	The seriousness of the effect(s) of a hazard.
Step	A point, procedure, operation, or stage in the food system from primary production to final consumption.
Validation	That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP/FSP plan, when properly implemented, will effectively control the hazards that are reasonably likely to occur.
Verification	The application of methods, procedures, tests, and audits, in addition to monitoring, to determine compliance with the HACCP plan.
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.
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. Further examples are described later in this manual.
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 Recall	A product recall is a request to return, exchange, or replace a product after a facility or consumer discovers defects that could hinder performance, harm consumers, or produce legal issues for the manufacturer.
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.
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.
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 HACCP & Food Safety Plan Verification	
Compliant	To receive the rating of Compliant, the facility fully meets 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 HACCP program or a Food Safety Plan (FSP)..
- Failure to have documented allergen program (
- 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.

CORRECTIVE ACTION MANAGEMENT

The Intertek/SAI Global: HACCP/Food Safety Plan Verification audit will include corrective action responses for minor and major non-conformances identified at the time of the audit.

The purpose of corrective action management is to ensure the site investigates and corrects non-conformances found by the auditor.

The site will be able to provide corrective actions to all non-conformances found during the audit through Intertek/SAI Global's SAIGOL (SAI GLOBAL ONLINE) platform.

Once your audit has submitted by the auditor, you will receive an email indicating your overall audit rating and a link directing you to the non-conformance management portal.

Important Notes:
You do not need login information for this portal, just simply click on the link provided.

Once you enter the portal, you will see your open non-conformances, displayed in order of appearance in the audit
checklist.

- To view the non-conformances by severity, click the and choose the severity level
- Select the non-conformance you will be adding your corrective action evidence to. Add any comment in the comment box, then click to have them added to the record.
- To add supporting documents, click on. Browse to the document you wish to upload and click, SAVE. Then click close. Repeat this step for any other documents that need to be added. Note: attachments cannot exceed 7MB in size.
- Response for each non-conformance must include root cause evaluation findings, description of the correction, who completed it, and when it was completed, along with upload of evidence of correction. Evidence can include photographs for physical activities, and documents and/or records, depending on the non-conformance. If an existing document was revised to add something as a corrective action, BE SURE TO HIGHLIGHT the portion of the document which addresses the non-conformance before uploading. Also ensure all submitted evidence is in English.

Timeline for Corrective Action submittal is 30 days from email notification.

An electronic instruction procedure will be provided to each site to ensure ease of access to the corrective action portal.

HACCP & FOOD SAFETY PLAN AUDIT SCOPES

The Intertek/SAI Global: HACCP/Food Safety Plan standard is to be utilized by organization's that manufacture, store, and distribute ambient, refrigerated, and/or frozen food products, or food packaging materials who remained informed of the regulatory requirements for their operation. It is pertinent to ensure that the site location being audited meets the scope of this standard and is in operation on the day of the confirmed audit date. Auditors will provide a specific scope statement describing the site activities and product types applicable to your facility. The scope statement appears on the site's final audit certificate.

AUDIT CRITERIA AND GUIDANCE FOR SITES

The information below is intended to be a guidance for sites in preparation of their audit. The questions and expectation requirements are provided to aid in additional support of understanding the material and intent of each question. Each **audit question will be listed in bold font** with *guidance material directly underneath in italicized font.*

1- Plan Identification, HACCP/Food Safety TEAM & SCOPE
Has the facility developed a documented HACCP/Food Safety Plan (FSP) for each process within the control of the organization? *The facility must have a Food Safety Plan(s) (FSP) in place for all FDA regulated products requiring an FSP that are manufactured at the facility. The facility must have a food safety management plan in place for all products and processes that have been implemented at the facility. This plan will cover all of the control measures that are implemented based on a thoroughly completed hazard analysis.*
Does the HACCP/Food Safety Plan clearly identify the scope of products and services? *The HACCP/Food Safety plans must properly identify the products/groups/services that are covered in this assessment. The site should also document the segment of the food chain they are made for (regulatory authority).*
Does the HACCP/Food Safety Plan include the Company Name, site location(s), site address(es) covered by the plan? *The HACCP/Food Safety plan must properly identify the name and address of the facility. If different or multiple locations are covered by the same HACCP/Food Safety system; these addresses must be listed in the HACCP/Food Safety plan.*
Does the plan list the Company Contact ultimately responsible for the HACCP/Food Safety Plan? *The HACCP/Food Safety plan must properly identify the name of the main contact. The main contact person at the site could be the general manager, CEO, or highest member on the company organizational chart.*
Are the dates of development, plan approval, and any revisions documented? *The HACCP/Food Safety plan must properly identify the dates in which the plan was originally approved and then when subsequent revisions were made.*

Does the plan identify the name and title of the HACCP/Food Safety Team Leader/Coordinator? Does it list the skills, background, and training to qualify the HACCP/Food Safety Team Leader against the scope of the HACCP/Food Safety Plan?

The name and position of the main person that is identified as being responsible for the HACCP/Food Safety System that is implemented at the facility shall be listed (ex. John Doe – Quality Assurance Manager). The HACCP/Food Safety Team Leader/Coordinator shall have documentation showing that they have had formal training in HACCP/Food Safety from an accredited institution or organization. The team leader should also have education, experience, or training against the scope of the HACCP/Food Safety Plan.

Does the plan list the names and titles of the HACCP/Food Safety Team members? Do the team members have the appropriate skills and experience relevant to the product and process? Does at least one team member have a certificate for HACCP or PCQI, respectively?

The names and titles of all persons involved in the HACCP/Food Safety team shall be included in the HACCP/Food Safety plan (ex. John Doe - Quality Assurance Manager; Linda Sharp - Maintenance Manager, etc.).One of the first tasks in developing a HACCP/Food Safety plan is to assemble a HACCP/Food Safety team consisting of individuals who have specific knowledge and expertise appropriate to the product and process. It is the team's responsibility to develop the HACCP/Food Safety plan. The team should be multi-disciplinary and include individuals from areas such as engineering, production, sanitation, quality assurance, and food microbiology. The team shall also include local personnel who are involved in the operation as they are more familiar with the variability and limitations of the operation. In addition, this fosters a sense of ownership among those who must implement the plan.

Does the site utilize any external resources to aid in the identification of hazards associated with the specific product scope?

The HACCP/Food Safety team may need assistance from outside experts who are knowledgeable in the potential biological, chemical and/or physical hazards associated with the product and the process. Due to the technical nature of the information required for hazard analysis, it is recommended that experts who are knowledgeable in the food process should either participate in or verify the completeness of the hazard analysis and the HACCP/Food Safety plan. Such individuals should have the knowledge and experience to correctly: (a) conduct a hazard analysis; (b) identify potential hazards; (c) identify hazards which must be controlled; (d) recommend controls, critical limits, and procedures for monitoring and verification; (e) recommend appropriate corrective actions when a deviation occurs; (f) recommend research related to the HACCP/Food Safety plan if important information is not known; and (g) validate the HACCP/Food Safety plan.

Is the facility in good standing with their required regulators?

The facility must ensure that they are properly registered with all applicable regulators. In the United States this could include the FDA, USDA, and State departments of health. For Canada, this could include the CFIA. The facility must ensure that they are properly registered with destination product regulators, if applicable.

Does the facility have a documented process for the identification of regulations that are applicable to their specific process? Does this process include knowledge of regulations for products in countries in which the facility's products are exported?

The facility must have a documented procedure outlining how they ensure that all regulatory requirements are met for all applicable processes. The procedure should also include how the facility ensures regulatory requirements are met when products are exported to other countries. The facility must be able to show that

they are properly licensed to operate. This includes CFIA when products move across Province lines and/or are exported.

2 - Product Description/Specifications

Does the plan include the product/service common or usual name, and whether the product is raw or ready to eat (RTE)?

The HACCP/Food Safety plan must properly list the common/usual name of products covered.

Does the plan include the product composition, ingredients, and general processing methods?

The HACCP/Food Safety plan must properly list the product composition, ingredients, and general processing methods used.

Does the plan include information regarding product shelf life, storage conditions, and applicable product preservation?

The HACCP/Food Safety plan must outline the method of preservation for the end products, the shelf life of the products, and storage conditions for product.

Does the plan include label information of the product including the date code, lot, and batch identification? Does the label meet regulatory requirements and contain other instructions to users including cooking, safe handling instructions, storage, and country of origin labelling (COOL)?

The HACCP/Food Safety plan must properly list the type of labeling that is used on the finished products. Labeling will include product cooking requirements, if necessary. The labeling must also be in accordance with applicable laws of the destination market including allergens declared that are present in the product, either by design or potential manufacturing cross contact. The HACCP/Food Safety plan must clearly list the method in which product is being coded. The facility must have a documented procedure outlining how the country of origin for all applicable products and ingredients will be tracked.
Country of Origin Labeling (COOL) is a USA and Canada labeling law that requires retailers, such as full-line grocery stores, supermarkets, and club warehouse stores, to notify their customers with information regarding the source of certain foods. Food products covered by the law include muscle cut and ground meats: lamb, goat, and chicken; wild and farm-raised fish and shellfish; fresh and frozen fruits and vegetables; peanuts, pecans, and macadamia nuts; and ginseng.

Are the methods of product distribution included in the HACCP/Food Safety plan (i.e. frozen, refrigerated, ambient temperatures)?

The method of distribution shall be described along with information on whether the food is to be distributed frozen, refrigerated, or at ambient temperature.

Has the plan identified all raw materials, ingredients, processing aids, additives, and packaging materials associated with product manufacturing/processing?

The HACCP/Food Safety plan should include information for all raw materials, processing aids, additives, and packaging materials used in the finished product. This information should be in the form of unique specifications and should indicate the composition of each item listed.

3 – Intended Use and Consumers of the Product

Does the plan describe the intended use of the product and the destination of product upon shipment?

The HACCP/Food Safety plan must properly identify the intended use of the product - will the product go for further processing? How will it be used? Or will the product go directly to consumer, what is the expectation of the intended use to the consumer? The HACCP/Food Safety plan shall state the intended destination of the product produced (e.g. retail, food service, further processing).

Does the plan identify 'other uses' of the product or unintended uses by consumer which may warrant additional control measures by the site?

The HACCP/Food Safety plan should include any 'unintended' or 'known other uses' of the product by consumers that could warrant a food safety measure. For example, consumers may consume raw cookie dough, the site should take this into consideration and provide warning statements on products to ensure consumer safety. If product should be fully cooked or not to be consumed frozen; the site should alert this in the plan and on packaging.

Does the plan identify any vulnerable members of the population or sensitive consumers to be considered? If the plan has identified vulnerable or sensitive members of the population, does the plan state any control methods used to ensure verification that food is safe?

The HACCP/Food Safety plan shall properly outline if the product is intended for vulnerable populations (e.g. infants, elderly, immune-compromised), if applicable. The HACCP/Food Safety plan shall properly state if the products are intended for sensitive consumers (e.g. intolerances, allergies, etc.). For example, if product that does not contain a sensitive allergen such as 'peanuts' is produced near or on the same line as a non-allergen product- the site would alert the potential of the allergen if applicable.

4- Flow Diagram: Development, Review, and Approval

Has a flow diagram(s) been created that identifies all steps in the production/manufacturing process and overall plant layout?

A flow diagram must be established and included in the HACCP/Food Safety program. The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process. In addition, the flow diagram can include steps in the food chain which are before and after the processing that occurs in the facility. A plant layout shall be included in the HACCP/Food Safety plan. This should indicate all the process and storage areas that are present.

Is the flow diagram(s) specific to the product or product type(s) in which the site has identified in the HACCP/Food Safety plan scope?

The scope of the flow diagram must cover all the steps in the process which are directly under the control of the facility. These steps could include the following: receipt of raw materials, storage,

preparation, in-process steps, process inputs (water, air, rework, etc.), final processing, packaging, palletizing, finished product storage, distribution, point of sale, and the final delivery to consumer.

Are the flow diagrams clear and easily interpreted? Does the flow diagram accurately capture and detail all steps in the product flow process?

The flow diagram must be designed appropriately so that it is easy to interpret. Flow chart symbols (rectangles, diamonds, rounded rectangles, etc.) shall be used to define processes, terminators, decisions, etc.

Does the flow diagram include all inputs and outputs associated with the production process? Have they identified the inputs of all ingredients, processing aids, packaging materials, water, and air? Have they identified the outputs such as waste, or offal?

Does the plan sufficiently identify the sequence and interaction of the steps in the operation?
•where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow
•any outsourced processes
•where applicable reworking and recycling take place
•where end products, intermediate products, waste, and by-products are released or removed

Does the flow diagram(s) identify the locations of each CCP/PPC?

The HACCP/Food Safety plan flow chart must properly identify the location of all CCPs/PPCs that have been established. This can simply by stating "CCP1" or similar at the processing/handling step on the flow diagram.

Has each flow diagram(s) been verified and have received sign off by HACCP/Food Safety team members, or Team Leader?

The HACCP/Food Safety team shall perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. Modifications should be made to the flow diagram as necessary and documented. The verification on the HACCP/Food Safety flow diagram shall be dated and signed/initialed by appropriate personnel.

5- Hazard Analysis and Control Measures

Has the facility completed a hazard analysis, complete with identification of food safety hazards at each step of the process and classified each potential biological, chemical, radiological, and physical hazard?

The hazard analysis shall identify all potential hazards associated with each raw material, ingredient, process operation, and post-production step. A hazard is defined as a biological, chemical, radiological or physical agent that is reasonably likely to cause illness or injury in the absence of its control. Hazard identification focuses on developing a list of potential hazards associated with each process step under direct control of the food operation. Knowledge of any adverse health-related events historically associated with the product will be of value in this exercise. The hazard analysis must properly identify each hazard as being either biological (B),

chemical (C), radiological (R) or physical (P). . Documented evidence of a hazard analysis performed by a Preventive Control Qualified Individual (PCQI) identifying known or reasonably foreseeable hazards for each type of food manufactured, processed, packed or held at the facility that may be present in the food and include biological, chemical (including radiological) hazards and physical hazards must be included. The hazard analysis must also include an evaluation of potential environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not then receive post-packaging treatment or have some sort of control measure to significantly minimize the environmental pathogen. Unintentional contamination (e.g. allergen cross-contact), naturally occurring (e.g. mycotoxins) and intentional contamination for economic gain (food fraud), allergen mislabeling must be considered in the hazard analysis. The type of food (e.g. animal feed, pet food, human food) and its production stage (raw material, ingredient or finished food), must be considered in determining the necessary conditions and controls. Hazard analysis must be based on illness data, scientific reports, and other information and include all steps within each process under the HACCP/ FSP.

Has the facility evaluated each potential hazard on its likelihood of occurrence and the severity of its effects to determine if it is a significant risk?

The hazard analysis must use a recognized method for determining the probability or the likelihood that a hazard is to occur. These can include the High/Medium/Low set up or another form of decision matrix. Hazards which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. Hazards that are not reasonably likely to occur would not require further consideration within a HACCP/Food Safety plan. Severity is the seriousness of the consequences of exposure to the hazard. Considerations of severity (e.g., impact of condition or secondary injuries, and magnitude and duration of illness or injury) can be helpful in understanding the public health impact of the hazard. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data, and information in technical literature. When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and severity of the potential consequences if the hazard is not controlled.

Has the facility identified control measures for known or reasonably foreseeable hazards at each step of the process? Has the facility accurately defined each potential hazard that was introduced, controlled, or enhanced during each step in the hazard analysis? Have they listed the specific pathogen type when biological hazards are identified?

The hazard analysis must include an evaluation of the foreseeable hazards identified to assess the severity of the illness or injury to the consumer and the probability that the hazard will occur in the absence of controls to determine if a preventive control is necessary. For each hazard that requires a preventive control in order to eliminate or prevent the hazard or to reduce it to acceptable levels, preventive control points must be in place. . For those controls that are not preventive controls (i.e. those where the control is achieved through existing or prerequisite programs), those programs must be stated. (Examples of pre-requisite programs could include but are not limited to - Sanitation (other than Environmental Monitoring), Preventative Maintenance, Purchasing, Intentional Adulteration (Food Defense) Program, or other controls (ex. personnel health and hygiene training, compliance with current good manufacturing practices regulations.

Has the site identified control measures to be applied for each known hazard step? Is the control measure(s) appropriate for controlling the identified hazard?

The hazard analysis must include an evaluation of the hazards identified to assess the severity of the illness or injury to the consumer and the probability that the hazard will occur in the absence of controls, to determine if a control is necessary. For each hazard that requires control in order to eliminate the hazard or to reduce it to acceptable levels, control points must be reviewed to determine those that are critical. Definition of critical control is that in a process where if a control of a hazard is not implemented at this step in the process, then there is no step later to take care of this identified hazard. Often, the use of a decision tree facilitates this decision. For those controls that are not critical (i.e. those where the control is achieved through existing or prerequisite programs), those programs must be stated. Examples of pre-requisite programs could include, but are not limited to - Sanitation, Preventative Maintenance, Purchasing, Intentional Adulteration Program, or other controls (ex. personnel health and hygiene training, compliance with current good manufacturing program regulations.)

Has the site identified potential food fraud hazard/intentional adulteration from raw material? Do they have a documented food fraud plan or documented risk assessment to control the hazard?

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 this risk assessment may include, but are not limited to: 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.

6-Determination of Critical Control Points (CCPs)/Preventive Process Controls (PPCs)

Based off the results of the hazard analysis, has the site applied Critical Control Points (CCPs)/ Process Preventive Controls (PPCs) for each process step where a known hazard is likely to occur?

The identified Critical Control Points /Process Preventive Controls are to be appropriate and supported by a risk assessment methodology for control of identified significant hazards. Critical control points are located at any step where hazards can be either prevented, eliminated, or reduced to acceptable levels. Examples of CCPs /PPCs may include thermal processing, chilling, testing ingredients for chemical residues, product formulation control, and testing product for metal contaminants. CCPs/PPCs must be carefully developed and documented. In addition, they must be used only for purposes of product safety. Different facilities preparing similar food items can differ in the hazards identified and the steps which are CCPs/PPCs. This can be due to differences in each facility's layout, equipment, selection of ingredients, processes employed, etc.

Has the site utilized a valid methodology in determination of the CCP/PPC?

Sites may utilize a CODEX CCP Decision Tree, or NACMCF CCP Decision tree, or other regulatory tools to assist in the determination of CCPs/PPCs.

Were employees that were interviewed at each CCP/PPC aware of their responsibilities? Were they aware of the critical limits that have been established, the frequency of monitoring, and corrective actions that are to be implemented in the event there is a deviation?

Employees who are responsible for the monitoring of all CCP/PPCs must be aware of the critical limits that are present, the frequency in which CCPs/PPCs are checked, and what corrective actions are to be implemented in the event there is a deviation in the CCP/PPC being monitored. Employees responsible for conducting verification activities must also be aware of their responsibilities and what they are to do in the event they find a deviation. This question is not assessing an employee's knowledge of HACCP/Food Safety in general (i.e. "do you know what HACCP/Food Safety stands for?"); this question is designed to ensure that employees who have a responsibility in the HACCP/Food Safety system are aware of their responsibility and how it is to be fulfilled.

7- Critical Limits

Has at least 1 critical limit been established for each CCP/PPC that has been identified?

At least one critical limit must be identified for each CCP/PPC. Each critical limit must be quantifiable, control each identified hazard and be measurable. Each critical limit must be validated demonstrating that the identified limit adequately controls the identified CCP/PPC.

Have all critical limits been validated for each CCP/PPC?

Appropriate information must be used to determine the critical limits that are used in the HACCP/Food Safety plan. The critical limits and criteria for food safety may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental results, and experts. The critical limits must be suitable or applicable for the specific operations or products that are covered in the HACCP/Food Safety plan. If the critical limits are based on based on legal/published results, there must be evidence of records or references that they are appropriate for the CCP/PPC in relation to the site's production and manufacturing of the food product.

8 – Monitoring Procedures

Has a documented monitoring procedure been defined for each critical limit?

There must be procedures or work instructions that are available for each CCP/PPC including reference to monitoring devices used.

Does the monitoring procedure clearly identify what is to be monitored or measured to ensure the CCP/PPC is within the established critical limit?

At every CCP/PPC, a control measure is implemented to control the identified hazard. The site must document what specifically will be monitored and how each critical limit will be monitored. Examples of monitoring can be visual observations, measuring pH, measuring temperatures, and measuring moisture levels.

Does the monitoring procedure for each CCP/PPC identify the frequency at which the monitoring will occur?
Each CCP/PPC shall have clear instructions regarding the frequency at which the check should be performed to ensure compliance.

Does the monitoring procedure identify who will perform the monitoring of the CCP/PPC?

Assignment of the responsibility for monitoring is an important consideration for each CCP/PPC. Specific assignments will depend on the number of CCP/PPCs, control measures and the complexity of monitoring. Personnel who monitor CCP/PPCs are often associated with production (e.g., line supervisors, selected line workers and maintenance personnel) and, as required, quality control personnel.

Are monitoring procedures able to detect a deviation of the CCP/PPC and allow timely segregation and evaluation of the product?

The effectiveness of the monitoring procedures should ensure 3 main purposes: tracking of production to ensure no potential trend to loss of control or deviation; capturing a deviation or loss of control from an established critical limit in order for the facility to start immediately implementing corrective actions; and to provide written documentation for use in verification purposes.

Do the associates who are responsible for monitoring of CCPs/PPCs trained on the site's HACCP/Food Safety plan and have specific training against the latest version of the monitoring procedure?

Training for team member responsible for performing CCP/PPC monitoring shall be documented; training information shall include CCP/PPC review and date / document ID of most recent version.

Are the CCP/PPC monitoring records filled out in accordance with the written policy? Are they accurately completed, and demonstrate 'real time' data entry? Is there white out or illegible writings on the monitoring document that could cause a potential oversight of potential critical limit deviation?

The monitoring of CCP/PPC must be real time data; monitoring forms shall not be completed showing future quantity, or numerical values. The monitoring forms shall be free from data entry crossed out or the use of white out on the monitoring forms.

9- Corrective Actions

Have corrective actions been developed and written for potential deviations at each critical limit of each identified CCP/PPC?

Corrective action procedures shall be documented for all CCP and PPC checks, in the event of a monitoring check not meeting the critical limit, the site shall document the actions it will take to segregate the product, examine the product, determination of product disposition, and authority to release product back into production or to render condemned and unfit for human consumption.

Do the corrective actions include determination/root cause analysis of the deviation from the critical limit?

Corrective action procedures shall include the root cause of why the critical limit has not been met. The site is responsible for such determination and ensuring that it documents and reassesses the current critical limits.

When critical limits are not met, do the corrective actions include product analysis and disposition of product?

The HACCP/Food Safety plan corrective action management should ensure that appropriate tests, and verifications have been performed to indicate that the product can be safely released back into the manufacturing practices or released into commerce without posing a food safety hazard or concern.

Has the site identified the individual responsible for initiating corrective actions, the records for review, corrective action oversight, and product disposition?

The HACCP/Food Safety plan must clearly state who will have the responsibility to oversee the corrective actions that are defined in the plan. Individuals who have a thorough understanding of the process, product and HACCP/Food Safety plan should be assigned the responsibility for oversight of corrective actions. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.

Does the site maintain records of their corrective actions? Is the site following the corrective action procedures in accordance with the written HACCP/Food Safety Plan?

Where there is a deviation from established critical limits, corrective actions are necessary. Therefore, corrective actions must include the following elements: (a) determination of the cause of non-compliance (Root Cause Analysis); (b) determination of the disposition of non-compliant product and (c) records of the corrective actions that have been taken. Specific corrective actions should be developed in advance for each CCP/PPC non-compliance and be included in the HACCP/Food Safety plan. As a minimum, the HACCP/Food Safety plan should specify what is done when a deviation occurs, who is responsible for implementing the corrective actions, and that a record will be developed and maintained of the actions taken.

10 - Validation of HACCP/Food Safety Plan and Establishing Verification Procedures

Has the site validated their HACCP/Food Safety plan, and do they have a verification system in place to ensure that they are operating according to the plan?

The primary objective in validation of the HACCP/Food Safety plan is to make an overall review and evaluation to determine the effectiveness of the plan to control or eliminate potential hazards from occurring in the food manufacturing process. Part of effective validation would include review of verification activities to ensure the frequency and monitoring procedures are adequate in controlling potential hazards and monitoring of pre-requisite programs.

Does the site have verification activities that ensure that the following components of the HACCP/Food Safety plan are being verified: **1. Critical Control Points/Process Preventive Controls** **2. Preventive Controls/Pre-Requisite Programs** **3. Effectiveness of the overall HACCP/Food Safety Plan and system** *The HACCP/Food Safety plan must clearly list the verification inspections schedules that have been established at the facility. This would be a listing of the frequency in which verification activities are completed. The verification activities shall be completed in a time frame that is reasonable.*
Has a review and/or revalidation of HACCP/Food Safety plan been performed when there has been any change which may impact food safety? Is there a review completed to serve as verification of the HACCP/Food Safety system? *A periodic comprehensive verification of the HACCP/Food Safety system should be conducted by an unbiased, independent authority. Such authorities can be internal or external to the food operation. This should include a technical evaluation of the hazard analysis and each element of the HACCP/Food Safety plan as well as on-site review of all flow diagrams and appropriate records from operation of the plan. A comprehensive verification is independent of other verification procedures and must be performed to ensure that the HACCP/Food Safety plan is resulting in the control of the hazards. If the result of the comprehensive verification identifies deficiencies, the HACCP/Food Safety team modifies the HACCP/Food Safety plan as necessary.*
Are verification activities documented to be performed at a set frequency and carried out by someone other than the person who is responsible for monitoring? *Verification activities shall be documented and maintained in accordance with the written program. The team member who is performing the verification activity shall be independent of the team member who documented the check. Can be like departments, but team members who had performed the monitoring check would not be suitable for ensuring the verification that the monitoring check was performed accurately and in accordance with the written program.*
Are measuring devices used for the monitoring of CCPs/PPCs at the facility calibrated in accordance with risk assessment, industry guidance, or manufacturer's recommendations? Are all calibrations being performed, documented, and reviewed to ensure all CCPs/PPCs are accurately being measured? *In the event measuring devices are used in the monitoring of CCP/PPCs at the facility, calibration activities shall be included in the HACCP/Food Safety plan. Ensure that in the event these types of devices are used (thermometers, metal detectors, etc.), there are clear calibration activities listed in the HACCP/Food Safety plan.*
Is a qualified individual designated to perform verification activities? Do records include the verification signature/initials of the team member designated responsible within the written program? *Responsibilities shall be clearly listed within the HACCP/Food Safety plan for the verification activities. Verification activities are carried out by individuals within a company, third party experts,*

and regulatory agencies. It is important that individuals doing verification have appropriate technical expertise to perform this function.

Has the person responsible for verification activities been trained in each verification task? Are they technically competent and can demonstrate expertise to the scope of the HACCP/Food Safety Plan?

Team members who are responsible for verification activities associated with the HACCP/Food Safety Plan shall be trained in the process and monitoring form of each verification activity, with documentation maintained. The team member shall be knowledgeable of the food safety product scope to ensure accurate verification.

11 - Recordkeeping and Documentation Procedures

Are all monitoring activities and records completed, reviewed, and verified in accordance to the HACCP/Food Safety plan's written monitoring procedure?
Records that are to be completed are for the monitoring activities shall be properly outlined in the HACCP/Food Safety plan.

Are there records to support prerequisite programs and control points that were identified in the written HACCP/Food Safety plan? Are they available for review and being completed in accordance with the documented procedures?

The HACCP/Food Safety plan shall identify pre-requisite programs, daily operational, and control points records that aid in support of compliance and adherence to the HACCP/Food Safety plan and hazards controlled.

Are all verification activities documented on records and following the procedures of the HACCP/Food Safety plan to ensure all testing requirements are being performed at the set frequency?

The HACCP/Food Safety plan shall identify records used for all verification activities.

Are all modifications to the HACCP/Food Safety plan being documented including the plan modification log, revision dates, and HACCP/Food Safety designated team member review/sign off? Are version histories kept on file in accordance with regulatory requirements?

The HACCP/Food Safety plan must have records identified for the modifications of HACCP/Food Safety plan(s), a version change log is useful in determining version numbers and modifications that were made from one version to the next.

Are all initial validations, and support material that was utilized in verification of the HACCP/Food Safety Plan on file? Are annual reviews documented and signed off by the HACCP/Food Safety Team?
The facility shall have required supporting documentation on file to support the implementation of the HACCP/Food Safety plan. These records could include the following: supplier certification records documenting compliance of an ingredient with a critical limit, processor audit records verifying supplier compliance, processing, storage and distribution records, data establishing the safe shelf life of the product, or employee training records that are pertinent to CCPs and the

HACCP/Food Safety plan. A documented annual review must be conducted and documented, including the sign off by the HACCP/Food Safety Team.

Does the facility have a documented record retention policy?

Records must be kept as original records, true copies, or electronic records. Records must be retained for a period defined by the company, taking into consideration the shelf life of the product and any regulatory or customer requirements. Records should be retained for a period of at least the shelf life of the product plus 12 months or 2 years, whichever is longer. Should records be stored off-site, they must be older than 6 months from the date they were created, and they must be available for review during the scheduled on-site facility audit or within 24 hours (whichever is shorter) should the auditor request them. The Food Safety Plan must not be stored off site.

12-PREQUISITE PROGRAMS TO HACCP/Food Safety PLAN

Does the establishment have documented procedures for adequate maintenance of the grounds and exterior building? Do exterior grounds appear to be maintained and are not posing a risk of insanitary conditions or pest harborage?

The site should ensure that the grounds are kept in sanitary condition to prevent the potential contamination of food. Sites should ensure that they are maintaining the following conditions:

- *Proper Storage of Equipment*
- *Maintaining Litter and waste controls*
- *Trimming High Weeds*
- *Maintaining roads and yards with minimal amounts of standing water*
- *Adequate draining*

Is the building interior in good repair and free from flaking paint, cracks in floor, ceiling, and walls? Is there evidence of roof leaks? Can all building surfaces be made of a material that can be cleaned and maintained?

The facility must ensure that ceilings, walls, windows, and doors are constructed and maintained in such a manner to prevent possible foreign material hazards. The facility must ensure all floors are maintained in such a manner to prevent product contamination, potential pest harborage, and ensure appropriate sanitation.

Are traffic patterns designated to ensure no cross contamination from unprocessed raw materials, or areas where there is less than daily sanitation to in process product flow?

The separation should be physical by means of a complete wall with no doors if possible. All traffic must be controlled, including cook operators and maintenance. Traffic should be reduced to pass from raw materials processing to finished product processing. If an intervention step is utilized, auditor should "audit backwards" and start at finished product and follow flow to raw materials to avoid contamination.

Does the facility have a documented program which they follow when they approve a new supplier? Is the program specific to the facility? Does the program cover all raw materials, ingredients, chemicals, and packaging suppliers? *Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of continuing supplier guarantee and supplier HACCP/Food Safety system verification.*
Are processing equipment, conveyors, racking and pallets in good repair? Are they installed and used in a manner that does not pose a threat to products at the facility? *All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented.*
Has the facility established Sanitation Standard Operating Procedures (SSOPs) for all sanitation activities which includes a description of the task, lists any chemicals and equipment necessary to complete the task, the methods of completing the task, the frequency in which the activity is to be performed, and who is responsible for completing the task? Are the SSOPs found to be effective and completed at the appropriate frequency? *Sanitation: The facility shall develop written sanitation procedures to include the description of all cleaning activities, including chemical and sanitizer usage, and frequency of sanitation. The site shall develop a master sanitation schedule to ensure sanitary tasks are being completed in the set frequency and are verified for completion and effectiveness. The site shall include preoperational inspection verification records, and environmental monitoring to ensure no additional hazards are being introduced as a result of the sanitation process.*
Does the manufacturing of Ready-to-Eat (RTE) products include environmental monitoring for foreseeable pathogens? *If the facility is manufacturing RTE products then they are required to be doing environmental monitoring for Listeria monocytogenes and, if applicable, Salmonella and E. coli, if the finished product is exposed to the environment prior to packaging. This is not required if the product is subjected after packaging to further processing that will kill off any environmental pathogens that may have contaminated the product (i.e. High Pressure Pasteurization, use of a listericidal chemical, etc.). Monitoring can be for Listeria species and for an indicator organism for Salmonella and E. coli, where applicable.*
Has the facility developed a documented Good Manufacturing Practice (GMP) program which includes employee hygiene practices for all employees? Is there evidence of documented training for all employees? *All employees and other persons who enter the manufacturing plant should follow the requirements for personal hygiene. This would include policies regarding illnesses, jewelry, consumption (eating/drinking/smoking), and clothing.*

Does the facility have a documented HACCP/ Food Safety Plan training program for employees based on position and responsibilities? Are requirements for refresher training outlined in the documented program? Are materials used for training adequate to ensure effective training and in the appropriate language?

All employees should receive documented training in personal hygiene, GMP, cleaning and sanitation procedures, personal safety, and their role in the HACCP/Food Safety program. The site should include in their training procedure the frequency of training and the training methods and resources used to appropriately provide adequate training for all employees.

Are all sanitizers and cleaners being used at the appropriate concentration? Does the facility maintain a list of approved chemicals that are used in the facility for sanitation purposes? Are up to date SDS on file for all chemicals that are in use?

Documented procedures must be in place to assure the segregation and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant. A list of approved chemicals should be on file, and all SDS should be up to date and stored in a location that would allow for prompt access and availability.

Does the facility have a documented program for receiving of raw materials, ingredients, and packaging? Are storage facilities designed and maintained in a manner that allows for effective pest control and sanitation?

All raw materials and products should be stored under sanitary conditions and the proper environmental conditions such as temperature and humidity to assure their safety and wholesomeness. All storage locations should designed in a manner that allows for pest control services and frequent sanitation operations.

Does the facility have a documented product recovery (Recall) program in place? Does the program include the provision for tracking product one customer forward from one supplier backward?

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 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.

Does the facility have a documented integrated pest prevention program established? Does it include a designated pest management professional, schedule of service, pesticides utilized or could be utilized within the facility and location (map) of all pest control devices on the facility grounds and within all buildings?

Effective pest control programs should be in place. This should include the service of the interior and exterior of the facility. A Map of the facility with bait stations and trap shall be provided. Service reports, findings, and corrective actions shall be documented.

Is there a documented program for capturing and processing of customer complaints? Does this process include a categorizing for trending of complaints and an investigation process?

The facility must have written program outlining how customer complaints will be investigated and handled wherever they occur throughout the process. The methods should include trend analysis to ensure continuous improvement. The facility must maintain records related to the complaint management program.

12.15-Is there a documented program for placing product on hold? Does the product hold program include identification of product, isolation of product and a listing of product holds which includes product description, reason for the hold and disposition of the product?

The facility must have outlined procedures for placing product (raw material and finished goods) on hold at any point during the process. The methods must address product identification, isolation/segregation procedures and areas, current list of product(s) that are on hold (including reason for hold, physical location in the facility, any additional applicable notes). 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. All records related to the hold program must be properly maintained.

Does the facility have a documented allergen control program? Has the facility identified the ingredients that would be considered allergens by local and country of destination regulations? Has a risk assessment been conducted to show where controls must be implemented to prevent cross contact?

The facility must have a documented program that outlines the allergens that are controlled at the facility. This program must include a risk assessment to identify the allergens of concern and areas where controls must be implemented. The program should also consider allergens permitted in employee break rooms and cafeterias and the appropriate controls to prevent cross-contact to production areas. This question simply deals with the facility's identification of allergens in their facility and an evaluation of where controls must be implemented. The method and implementation of control are listed in other questions in the allergen category. all allergens identified by local regulation and by regulation in countries that receive product must be included.

Are all employees with responsibilities in the allergen control program aware of their responsibilities? Are all employees trained on allergen awareness?

All employees with responsibilities in the allergen program must be aware of the controls that are implemented at the facility to ensure that all allergens are properly identified, segregated, and cross contact is avoided. Employees at each stage of allergen control must be interviewed to verify that

they are aware of the controls that are in place. This includes persons responsible for designing label artwork, receiving labels and the packaging operator.

Has the facility developed a documented foreign material control program? Have controls been identified and established for foreign material hazards?

The facility must outline controls and procedures that are used to prevent hazards due to foreign material where they may exist throughout the process whether due to the facility, equipment, employees, or any ingredient and/or processing aid. The facility should include the methods of control used to address foreign material hazards as they occur during the process. This program needs be more than a glass and hard plastics policy. This must outline how all possible foreign materials will be controlled in the facility. This could include items such as the control of wood pallets, the inspection of raw materials upon receipt for foreign materials, and any other controls that are present to prevent the introduction of foreign materials in the process. Metal detection, X-ray machines, magnets, screens, sieves, etc. can be mentioned in this section, but the method in which they will be used should be defined in other questions in this section. Finally, the facility must have a system in place that outlines how corrective actions will be implemented and documented in the event deviations are observed.

Has the facility developed a documented glass and brittle plastics program that includes a register of items within the processing area including the frequency of inspection? Does the policy also include instructions for when a breakage occurs in the processing area? Is the list verified on a regular basis to ensure that it is accurate?

Methods must be developed to prevent potential contamination due to glass and/or brittle plastics. The program must include a complete list of glass and brittle plastic within the processing area and identify the inspection frequency of each item, usually based on risk. This list must be verified on a regular basis (annually, monthly, etc.) to ensure that it is accurate.

Does the facility have a documented food defense/site security program addressing access to the facility, visitors, raw materials, security inspections, employee identification and other appropriate food defense requirements per local regulation?

The program must outline how the facility is properly protecting the building from unwanted access. This can be through key cards at doors, only one access point that is monitored at all times, etc. The program should also outline the procedures in place to reclaim access cards/keys/etc. from terminated employees or otherwise show how these employees access to the facility is revoked. The program must also outline how visitors are properly screened prior to entry. All visitors must provide photo identification prior to entry and must sign-in prior to being granted entrance to the facility. The program should also require that all visitors are accompanied at all times.

APPENDIX A: REQUIRED DOCUMENTATION

Several critical documents will be reviewed during the audit process that will assist in evaluating HACCP/Food Safety Plan, Sanitation, GMP and Management System 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 may also be verified via interview of employees (where and when applicable).

To facilitate a smooth, organized audit, Intertek SAI Global requests that the following documents and records be readily available at the beginning of the audit. This section has been developed for sites to easily checkoff required documents to aid in preparation for their HACCP/ Food Safety Plan audit.

DOCUMENT/POLICY	√	DOCUMENT/POLICY	√
HACCP / Food Safety PLAN:		Pre-Requisite PROGRAMS:	
Product Description		Training Records	
Intended Use/Consumers		Pest Prevention Management	
Product Distribution		Sanitation Procedures/ Environmental Monitoring Programs	
Flow Diagram		Supplier Approval Program	
Hazard Analysis		Approved Chemical Policy and SDS	
CCP / Preventive Control Determination-Allergen/Supplier/Process/Sanitation		Shipping, Receiving and Storage Program	
Critical Limit Determination and Validation		Complaint Program	
Monitoring Procedure for CCPs/ PCs		Non-Conforming Product-'HOLD' program	
Corrective Actions for CCPs/PCs		Allergen Control Program	
Verification Procedures		Glass and Brittle Policy/ Foreign Material	
Calibration Procedures		Food Defense/Crisis Management Policy	
Recordkeeping Procedures		Product Recall/Traceability Program	
Product Specifications		Good Manufacturing Practices Procedure	

APPENDIX B: MODIFICATION LOG

SECTION/CHECKLIST	MODIFICATION MADE	VERSION #
EXPECTATIONS MANUAL	NEW STANDARD: HACCP & FOOD SAFETY PLAN VERIFICATION	1