Food Safety Plan

THE ORGANIC SNACK COMPANY

14 Commerce Court
Bedford, PA 15522

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1.0 Company Information

The Organic Snack Company LLC (Tram Bar, LLC) is a privately held corporation based in Altoona, PA. The company specializes in the production of organic snack foods in the RTE space such as energy bars and bites.

2.0 Plant Responsibilities:

Responsible Party	Responsibilities
CEO *(Backup PCQI)*	● Oversee the program ● Provide resources for system management ● Participate in the food safety review process
Chief Production Officer *(Facility PCQI)*	● Manage activities of team as required ● Manage implementation of the Food Safety Plan ● Oversee food safety documentation ● Lead the Food Safety Team ● Approve all food safety processes prior to product release ● Monitor trends and standards ● Ensure compliance to the Food Safety Plan ● Lead investigations for food safety deviations ● Train Qualified Individuals and Designees in Food Safety Plan requirements
QA Director	● Assist PCQI with execution of the food safety plan ● Perform testing and analysis
Food Safety Team	● Create and manage the Food Safety Plan ● Set standards for facility training ● Meet as needed to review and manage plan ● Review and approve suppliers ● Lead the system review meetings ● Audit and oversee program
Qualified Individuals	● Perform activities for food safety according to the Food Safety Plan ● Document food safety activities as required ● Assist with investigations and corrective actions

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3.0 Definitions:

Correction	An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).
Critical Control Point	A point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.
Correction	An action to identify and correct a problem that occurred during the production of food, including actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).
Corrective Action	An action to identify and correct a problem that occurred during the production of food, including actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).
Environmental Pathogen	A pathogen capable of surviving and persisting with the manufacturing processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens include Listeria monocytogenes and Salmonella spp. but do not include the spores of pathogenic spore forming bacteria.
Food-Contact Surfaces	Those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operation. “Food contact surfaces” includes utensils and food-contact surfaces of equipment.
Food Safety Plan	A set of written documents that is based upon food safety principles and incorporates hazard analysis, preventive controls, and delineates monitoring, corrective action, and verification procedures to be followed, including a recall plan.
Hazard Analysis	The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which should be addressed through a preventive control.
Hazard Requiring a Preventive Control	A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls) establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification and records) as

	appropriate to the food, the facility and the nature of the preventive control and its role in the facility's food safety system.
Known or Reasonably Foreseeable Hazard	A potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.
Monitor	To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.
Prerequisite Programs	Procedures, including Current Good Manufacturing Practices (cGMPs), that provide the basic environmental and operating conditions necessary to support the Food Safety Plan.
Preventive Controls	Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.
Preventive Controls Qualified Individual (PCQI)	A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.
Qualified Individual	A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.
RTE (ready to eat) Food	Any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.
Sanitize	To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
Validation	Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

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4.0 Food Safety Activities

4.1 Scope

This food safety plan applies to all food safety programs that occur in the facility, beginning at receipt of raw materials and continuing until the finished product is distributed from the facility.

4.2 Facility Description

The facility is located in Bedford, PA and is 19,500 square feet. It is located in an industrial park and was built in 2020. It was designed for the manufacture of food products with a separation of office and production/ warehouse areas. The facility employs less than 20 people. The plant produces RTE Energy bars under FDA and PA Department of Agriculture authorities. Product is sold and distributed in the United States.

4.3 Food Safety Team Members

Food Safety Team			
Name	Position	Location	Applicable Training
Matt Blair (Primary PCQI)	Chief Production Officer	Bedford,PA	Preventive Controls Qualified Individual
Mark Thaler (Backup PCQI)	CEO	Bedford, PA	Preventive Controls Qualified Individual
McKenzie Blair	Chief Operations Officer	Bedford, PA	Qualified Individual
Shanzie Taylor	Quality Director	Bedford, PA	Qualified Individual

All personnel who manufacture, process, pack, or hold food are required to be Qualified Individuals, meaning that they must have the necessary education, training, and experience to ensure food is clean and safe, as appropriate to their assigned duties. Such personnel also receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene.

4.4 Prerequisite Programs

The following prerequisite programs are in place at the facility. Many of the programs explained in this section correspond to the explanations provided in the hazard analysis, below, under the heading "*What prerequisite program can be applied at this step to minimize a food safety hazard?".*

Calibration
All measurement equipment that is relevant to food safety is calibrated prior to use and maintained on a set schedule to ensure accuracy of measurement. Any deviations noted to the limits of operation are investigated and a disposition of product documented.

Corrective Action
Issues involving food safety critical control points or preventive controls are subject to corrective action processes if found to be out of standard. Results of investigations are documented, and product disposition is evaluated as provided in the Food Safety Plan Master Summary.

Chemical Control
All food contact chemicals and lubricants used in the plant meet required regulations. Copies of the SDS records are available for review. All chemicals are labeled as to their identity and used for their intended purposes and stored appropriately when not in use.

Facility, Equipment Design and Construction
The facility is designed for food manufacturing and follows all applicable regulations. The environment is controlled and monitored according to process risk. Proposed changes to the facility design are reviewed to determine their impact on food safety operations. Production equipment relative to food safety is selected and maintained to ensure the safe production of food and to discourage potential food safety issues.

Finished Product Storage and Shipping
Finished goods are maintained in such a way as to maintain their integrity while in storage prior and during shipment. Shipments leaving the facility are controlled to prevent tampering during shipment.

Food Safety Change Management
A change that impacts the food safety control system for a product is first reviewed by the Food Safety Team prior to implementation. This evaluation is documented in the Food Safety program. Training is updated if needed.

Food Safety Complaints
A system is in place via mail, phone or email via the website for users of our products to contact us if a food safety complaint is alleged. Any allegations of food safety issues are immediately routed to Quality Assurance for evaluation and investigation as required. If information necessary for an investigation is sufficient, a review

of production records will take place at the manufacturing facility. If a food safety issue is identified, the Food Safety management procedures will be initiated.

Food Safety Training

The facility has a training program for employees relative to their food safety responsibilities and these are refreshed as needed. This supports the status of all personnel as qualified individuals. Training can be given by presentation or by computer-based activities. Verification of training is documented. Records for employee training are maintained.

Glass and Hard Plastic Program

The facility has a glass and hard plastic program in place for materials relevant to food safety. Materials present in a GMP controlled area are tracked and inspected for breakage or loss on a periodic basis. If deviations are identified, an investigation is conducted to determine if they present any issues for food safety.

cGMP's

The facility has a current Good Manufacturing Practices program in place and is compliant with regulatory requirements under 21 CFR Part 117, Subpart B. The facility has a training program for employees relative to their GMP impact. Training documentation follows plant procedure and is updated annually. Visitors are briefed on the facility GMP requirements prior to entering a controlled area. New employees are required to complete GMP training prior to working in a GMP controlled area.

Material and Finished Product Traceability

All finished products are tracked in an inventory management system. All production records contain the information necessary for tracking to the manufacturing location or user and ingredients used in that product. All products shipped from this facility are recorded on Bills of Lading. This document records the customer who purchased the product they received.

Pre-Operational Inspection

Prior to startup in the facility, equipment that is involved in food safety is inspected. This can involve visual, sampling or other methods to verify that procedures were properly executed.

Pest Control

This facility utilizes a licensed third-party vendor for pest management. The facility is designed to discourage and mitigate the threat of pests in the facility. The pest control service includes maintenance of indoor traps, outdoor bait stations, and all insecticide applications. All records of pest control program activities are maintained and reviewed by plant management.

Preventive Maintenance

The facility has a program in place for the identification, management and maintenance schedules for equipment necessary to maintain food safety standards. The maintenance personnel performing tasks in food contact areas are trained in the procedures necessary to prevent cross contamination issues.

Raw Material Specifications

Raw materials have specifications as determined by Chief Operations Officer/Quality Assurance. Ingredients are managed according to risk and supplier profile. Materials are reviewed and received according to procedure.

Raw Material Receipt and Storage
Raw materials are received and stored to maintain the integrity of the materials. Materials are stored according to recommended specifications prior to use and to prevent unintentional contamination. Documents such as Certificates of Analysis are reviewed prior to material use according to risk.

Record Review
Food Safety records are reviewed by the PCQI or by trained, designated employees operating under their authority. Batch production records are verified and signed off prior to release of product.

Sanitary Transport
The Organic Snack Company utilizes LTL carriers to deliver product to distribution centers. Carriers are screened for acceptability prior to use. The company is exempt from the requirements of the Sanitary Transport rule based on transportation of a food that is completely enclosed by a container and is not temperature controlled for food safety.

Supplier Verification
Suppliers are approved on a periodic basis according to risk. Suppliers are approved for food safety prior to use. Changes to suppliers are included in this category. The PCQI and the Food Safety Team follow procedures for review and receipt. Materials are managed and ordered at the facility.

Water Supply
The facility is supplied with water from an approved municipal source that is certified acceptable for human consumption and for use in the manufacturing and sanitation processes. Testing results are supplied by the relevant authority on a periodic basis and reviewed for compliance to state testing standards. Water samples are also gathered for microbiological testing by the facility on a periodic basis at point of use. If found to be out of compliance, an investigation is performed.

4.5 Preventive Control Programs

Allergen Preventive Control
The facility has the following allergens present in the facility from the list of the Big Eight allergens (milk, almonds, coconut, peanuts). A program is in place to select suppliers and control for allergens in the facility and finished product.

Process Preventive Control: Metal Inclusion
A program is in place to identify and keep out of product any relevant hazardous foreign materials. A metal detector is in use. Prior to the start of production, inspections of key components and parts are completed to verify proper fit and finish as well as a verification of parts that could potentially cause a hazard. If an issue is identified at startup, Quality Assurance then investigates issues and determines necessary actions.

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Recall Plan Preventive Control
A system is in place for the evaluation of food safety and recall contingency planning activities. A recall coordinator has been designated for the company with authority to manage and oversee recall or crisis management functions. A management process is in place for the communication and execution of plans to relevant stakeholders.

Sanitation Preventive Control
The facility has a sanitation program that is focused on minimizing the potential for contamination of the finished food. The process of sanitation is designed in conjunction with industry sanitation experts for chemical usage, flow and temperature. All sanitation chemicals are used in an approved manner for food manufacturing. Records are reviewed for compliance. Environmental monitoring and product testing are used as verification activities for the sanitation preventive control. Samples are submitted to an approved and accredited testing lab and results that are out of compliance are investigated and corrective actions are implemented according to procedure. Chemicals are validated for efficacy and control of food safety threats when used appropriately.

Supply-Chain-Applied Preventive Control/ Foreign Supplier Verification Program/ Food Fraud
Suppliers that control hazards identified as "hazards requiring a preventive control" are managed under a supply-chain program that is consistent with the requirements in 21 CFR Part 117, Subpart G. Prior to use they are required to submit documentation for control of identified food safety hazards impacting the process or product. Supplier information is routed to QA for review and suitability. If needed, an audit of the supplier may be conducted to determine suitability of control. If needed, Certificates of Analysis are used for each lot/ batch and reviewed by the PCQI or designee as a verification activity. If applicable, FSP rules will be followed if a foreign supplier is utilized. Food fraud activity is used in the analysis of the supplier and materials purchased.

4.6 Finished Product Profiles

Product Name(s)	Kate's Real Food Bar (RTE Energy Bar Products)
Product Description, including Important Food Safety Characteristics	Energy bar The presence of unintended allergens is the primary risk to the consumer
Ingredients	Honey, Peanut Butter, Sea Salt, Dark Chocolate, Cocoa Nibs, Cocoa Powder, Rolled Oats, Sesame Seeds, Sunflower Seeds, Crisp Rice, Raisins, Apricots, Milk Chocolate, Rolled Oats, Sesame Seeds, Sunflower Seeds, Crisp Rice, Flax Seeds, Hemp Seeds, Almonds, Dried Cherries, Ginger Powder, Almond Butter, Lemon Extract, Peppermint Extract, Coconut, Mango, Cinnamon
Allergens	Dairy, Almond, Peanut, Coconut
Primary Packaging Used	Food Grade FDA Compliant High Barrier Saran-Coated OPP Film
Water Activity:	Finished Product Range of 0.46 A_w to 0.52 A_w

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Safe Harbor	This product has a pH (>5.0) and an A_w range that does not promote the growth of pathogenic organisms under normal conditions. (IFT 2001 – "Evaluation and Definition of Potentially Hazardous Foods." IFT/FDA Contract No. 223-987-2333)
Intended Use	Ambient energy bar for RTE consumption
Intended Consumers	General Population
Shelf Life	12 months from manufacture
Labeling Instructions*	N/A

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4.7 Process Flow Diagram:

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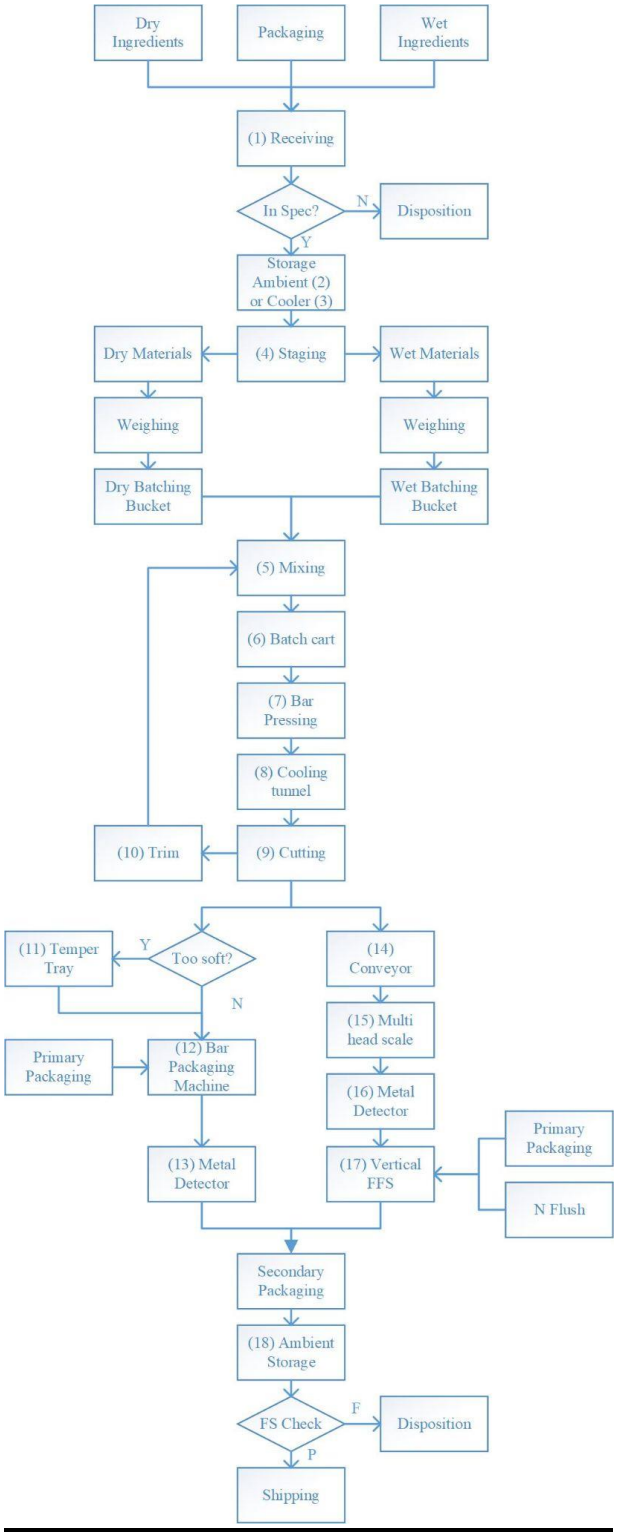

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4.8 Threat Analysis

The following potential hazards were identified and evaluated in each of these categories as part of the hazard analysis and food fraud determination:

Biological Threats
Bacillus cereus
Campylobacter spp.
Pathogenic E. Coli
Salmonella spp.
Listeria monocytogenes
Staphylococcus aureus
Clostridium botulinum
Clostridium perfringens
Norovirus
Hepatitis

Chemical Threats
Mycotoxins/ Natural Toxins
Unapproved Colors & Additives
Heavy metals
Industrial chemicals
Undeclared allergens
Pesticides
Radiological

Physical Threats
Metal
Plastic
Glass

Food fraud potential was evaluated for each material, source location and likelihood of contamination.

(Key references for this threat analysis are listed at the end of this document)

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4.9 Risk Assessment Matrix

	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Severe (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare (1)	1	2	3	4	5

Severity
Severe: Widespread public health issue
Major: Illness and hospitalizations reported
Moderate: Indications of a potential outbreak
Minor: Isolated report of suspect health issue
Insignificant: Unconfirmed or potential health issue

Likelihood
Almost Certain: Instances in the last 1-2 years
Likely: Instances in the last 2 - 5 years
Possible: Instances in the last 5 - 10 years
Unlikely: Instances in the last 10 - 25 years
Rare: No known instances

Low (Green): Risk is acceptable
Medium (Yellow): Risk may require mitigation (Preventive Control)
High (Red): Risk requires control (Preventive Control/ CCP)

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4.10 Ingredient Hazard Analysis

(1) Ingredient	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	Risk Rating	(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What prerequisite program/ preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Chocolate (Milk, Dark, Cocoa Powder, and Cocoa Nibs)	B: Salmonella spp.	H	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: Undeclared allergens, Ochratoxin, Unapproved colors and additives, Heavy metals (lead and cadmium)	M	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control Finished product labeling - dairy allergen	X	
	P: Brittle plastic Pieces	M	X					
Peppermint Oil	B: None				Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control	X	
	C: None				Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control	X	
	P: None							
Dried Fruits (Cherries, Mango, Raisins, Apricots, Cranberries)	B: Bacillus cereus, Pathogenic E. coli, L. monocytogenes, Salmonella spp., S. aureus	M	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control	X	
	C: Undeclared sulfites, Mycotoxins, Unapproved colors and additives	M	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control	X	
	P: None							
Dried Coconut	B: Bacillus cereus, Pathogenic E. coli, L. monocytogenes, Salmonella spp., S. aureus	M	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: Undeclared sulfites, Mycotoxins, Unapproved colors and additives	M	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control	X	
	P: None							
Sea Salt	B: None				Low A_w			
	C: None				GRAS			
	P: None							

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Lemon Extract	B: Salmonella spp.	L		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control	X	
	C: Unapproved colors and additives	L		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control	X	
	P: None							
Cinnamon (Ground)	B: Bacillus cereus, Clostridium botulinum, C. perfringens, Pathogenic E. Coli, Salmonella spp.	M		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: Unapproved additives and colors	M		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control	X	
	P: Heavy metals, Mycotoxins & natural toxins	M		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control	X	
Seeds (Hemp, Flax, Sunflower, Sesame)	B: Salmonella spp., L. monocytogenes	L		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: Mycotoxins & natural toxins	L		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control		
	P: None							
Vanilla Extract	B: None				Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: None				Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control		
	P: None							
Oats	B: Bacillus cereus, Pathogenic E. Coli	L		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: Mycotoxins/ Natural Toxins, Pesticides, Heavy metals	L		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control		
	P: Foreign material	L		X				
Almonds	B: Pathogenic E. Coli, Salmonella spp.	L		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: Mycotoxins & natural toxins	L		X	Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control		
	P: None							
Peanut Butter	B: Salmonella spp.	L	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control	X	

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					Low A_w	Certificate of Analysis by lot		
	C: Mycotoxins & natural toxins	M	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	P: Metal shavings	L	X			Certificate of Guarantee		
Almond Butter	B: Salmonella spp.	L	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: Mycotoxins & natural toxins	M	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	P: Metal shavings	L	X			Certificate of Guarantee		
Food Contact Packaging	B: None							
	C: Non-FDA approved chemicals (i.e. migration of chemical components), non-food grade chemicals	L	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Letter of Conformance		
	P: None							
Honey	B: Clostridium botulinum	M	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: Drug residue, mislabeling and substitution, Unapproved colors and additives, pesticides	M	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	P: None							
Ground Ginger (Untreated)	B: Bacillus cereus, Clostridium botulinum, C. perfringens, Pathogenic E. coli, Salmonella spp	M	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: Heavy metals, mycotoxins & natural toxins, Unapp_____roved colors and additives	L	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot		
	P: None							
Rice Crisps	B: Salmonella spp.	L	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance Low A_w	Certificate of Guarantee Supply Chain Preventive Control Certificate of Analysis by lot	X	
	C: Heavy metals, Mycotoxins & natural toxins	L	X		Appendix 1 to FDA's Preventive Controls for Human Food Guidance	Certificate of Guarantee Supply Chain Preventive Control		
	P: None							
Food contact	B: None							

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compressed air knife and Nitrogen gas flush (Internally generated)	C: None							
	P: None							

4.11 Process Hazard Analysis

(1) Process Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What prerequisite program/ preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
(1) Ingredient and Packaging Receiving	B: None						
	C: Undeclared/ mislabeled allergens	X		Issues with printing of packaging	Receiving inspection	X	
	P: None			Sealed material	Receiving inspection		
(2) Ambient Storage	B: None						
	C: None						
	P: None			Sealed or closed material	Storage procedures		
(3) Cooler Storage	B: Pathogen growth		X		Controlled temperature to limit growth		
	C: None						
	P: None			Sealed or closed material	Storage procedure		
(4) Ingredient Staging	B: Pathogen growth		X	Short dwell time limits growth	cGMP's Sanitation preventive control		
	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	
	P: Foreign material		X	Short exposure time	cGMP's		
(5) Mixing	B: Pathogen growth		X	Short dwell time limits growth	cGMP's Sanitation preventive control	X	
	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	
	P: Brittle plastic, metal		X	Pre op inspection	Metal detection		X
(6) Batch Cart	B: Pathogen growth		X	Short dwell time limits growth	cGMP's Sanitation preventive control		

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	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	
	P: None		X				
(7) Bar Pressing	B: Pathogen growth	X		Short dwell time limits growth Employee contact with food	cGMP's Sanitation preventive control	X	
	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	
	P: Foreign material	X		Pre op inspection Brittle plastic	Metal detection		X
(8) Cooling Tunnel	B: Pathogen growth	X		Short dwell time limits growth Condensate	cGMP's Sanitation preventive control	X	
	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	
	P: Brittle plastic, metal	X		Pre op inspection	Metal detection		X
(9) Cutting	B: Pathogen growth	X		Short dwell time limits growth	cGMP's Sanitation preventive control	X	
	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	
	P: Brittle plastic, metal	X		Pre op inspection	Metal detection		X
(10) Trim Collection	B: Pathogen growth	X		Dwell time Low A_w	cGMP's Sanitation preventive control	X	
	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	
	P: None						
(11) Temper Tray Cooling	B: Pathogen growth		X	Dwell time Low A_w	cGMP's Operating procedure Sanitation preventive control	X	
	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	
	P: Metal	X		Pre op inspection	Metal detection		X
(12) Bar Packaging Machine	B: None			Dwell time			
	C: Undeclared/ mislabeled allergens	X		Cross contamination	Sanitation preventive control Packaging label check	X	
	P: Brittle plastic, metal	X		Pre op inspection	Metal detection		X
(13) Bar Metal Detector	B: None						
	C: None						
	P: Foreign material	X		Metal from upstream process		X	
(14) Bites Conveyor	B: Pathogen growth		X	Short dwell time limits growth	cGMP's Sanitation preventive control		
	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	

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	P: Foreign material	X		Pre op inspection Brittle plastic	Metal detector		X
(15) Bites Multihead Scale	B: Pathogen growth		X	Short dwell time limits growth	cGMP's Sanitation preventive control		
	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	
	P: Foreign material	X		Pre op inspection Brittle plastic	Metal detector		X
(16) Bites Metal Detector	B: None						
	C: Undeclared allergens	X		Cross contamination	Sanitation preventive control	X	
	P: Foreign material	X		Metal from upstream processes	Metal detector	X	
(17) Bites Vertical FSS Packaging Machine	B: None						
	C: Undeclared/ mislabeled allergens	X		Cross contamination	Sanitation preventive control Packaging label check	X	
	P: None						
(18) Storage	B: None						
	C: None						
	P: None			Sealed packages			
	B:						
	C:						
	P:						

4.12 Process Preventive Controls

			Monitoring	**Corrective Actions**	**Verification**	**Records**

PCQI Approval: _____ Date: _____

Process Preventive Control	**Hazard(s) Controlled**	**Parameters, values or critical limits**	**What**	**How**	**Frequency**	**Who**			
Supply Chain	Undeclared allergens, Pathogens	Not present at detectable level	Supplier approval	Visual review	Each lot	PCQI or Designee	QA to investigate and disposition	Receiving inspection Periodic supplier testing if needed Supplier review and approval program	Receiving review log Supplier approval process
Sanitation	L. mono Salmonella spp.	Not present at test detectable level	Equipment and indirect food contact surfaces during production	Swab and sponge sampling	One day each production month	PCQI or Designee	If pathogens are confirmed, production run held product lot to be destroyed. Perform root cause investigation as to cause.	Swab and sponge surface testing.	Testing logs Laboratory COA Sanitation logs Inspection logs
Foreign Material	Metal inclusion	Metal detector present and operating	All product passes through an operating metal detector	Visual examination that the detector is on and the reject device is working	Every hour	PCQI or QI	If the product is processed without metal detection, hold it for metal detection. Correct operating procedures to ensure that the product is not processed without metal detection.	Pass 1.2 mm Ferrous, 1.5 mm Non-Ferrous and 2.0 mm Stainless steel wands through the detector at start-up and every hour to assure equipment is functioning. Review of metal detector log and corrective action verification within 7 working days.	Metal detector log Manufacturer records on validation of settings and sensitivity standards
		No metal that can cause injury present	Kick out of product for the presence of metal fragments	Examine product to determine cause of kick out	When rejected	PCQI or QI	If metal is found in the product, segregate product, inspect back to the last good check, discard product depending on metal type and prevalence. Identify the source of the metal found and fix damaged equipment if relevant.		

4.13 Food Allergen Preventive Controls

PCQI Approval: _____ Date: _____

Allergen Control	**Hazard(s)**	**Criterion**	**Monitoring**				**Corrective Actions**	**Verification**	**Records**
			What	**How**	**Frequency**	**Who**			
Supply Chain	Undeclared allergens	Not present	Supplier approval	Visual review	Each lot	QA or Designee	QA to investigate and disposition	Periodic supplier testing if needed Supplier review and approval program	Receiving review log Supplier approval process
Sanitation	Allergen cross contamination	Not present or detectable above trigger level	Presence or Surface testing	Visual inspection or Allergen Test kit	Each production run	QA or Designee	If residual allergens present above the detectable level of 3 ug per test, perform a correction by recleaning and sanitizing. Reample surface. Perform investigation to determine the root cause.	Reinspect or re test for allergens	Allergen testing logs
Label Review	Incorrect labeling for allergens in product	Correct label on package/ secondary box	Ingredient listing matches product	Visual check	Each lot	Receiver, Flow Wrappers or Packaging Operator	If the label is incorrect at receipt, reject. Cross check during manufacture and packaging for match	Review of label verification activities within 7 working days	Receiving log Primary packaging and Secondary packaging logs

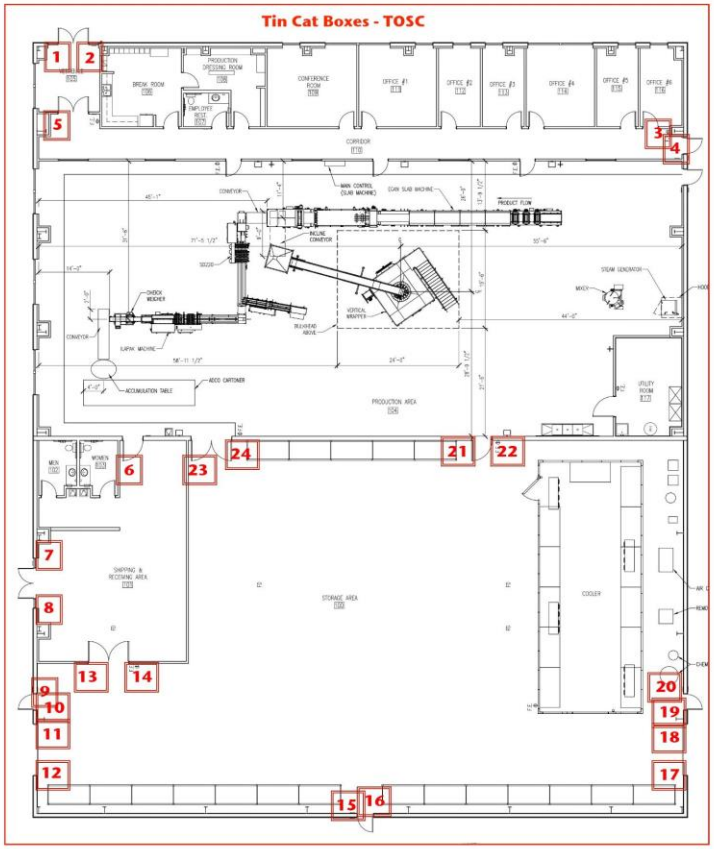
4.14 Food Allergen Ingredient Analysis

PCQI Approval: _____ Date: _____

Raw Material Name	Approved Supplier	Food Allergens in Ingredient Formulation								Allergens in Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (Almond, Coconut)	Peanut	Fish	Shellfish	
Peanut Butter	Sunco Foods Inc. (Food Guys Broker)	No	No	No	No	No	X	No	No	Yes
Milk Chocolate	Guittard	No	X	No	No	No	No	No	No	Yes
Almond Butter	Sunco Foods Inc. (Food Guys Broker)	No	No	No	No	X	No	No	No	Yes
Coconut	Multiple Organics	No	No	No	No	X	No	No	No	Yes
Almonds	Tradin Organic USA	No	No	No	No	X	No	No	No	Yes

4.15 Pest Control/ Environmental Monitoring Maps

PCQI Approval: _____ Date: _____



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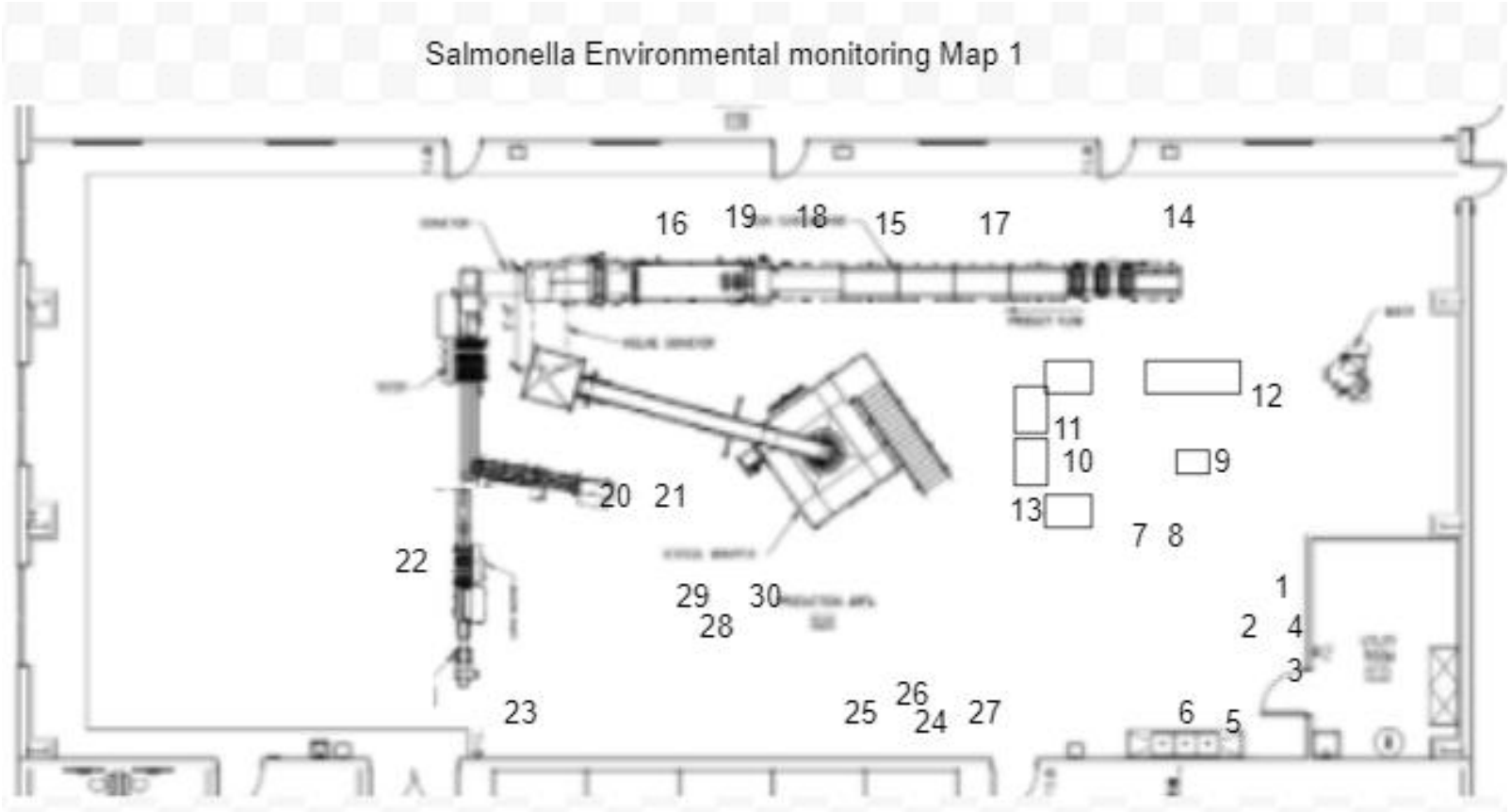

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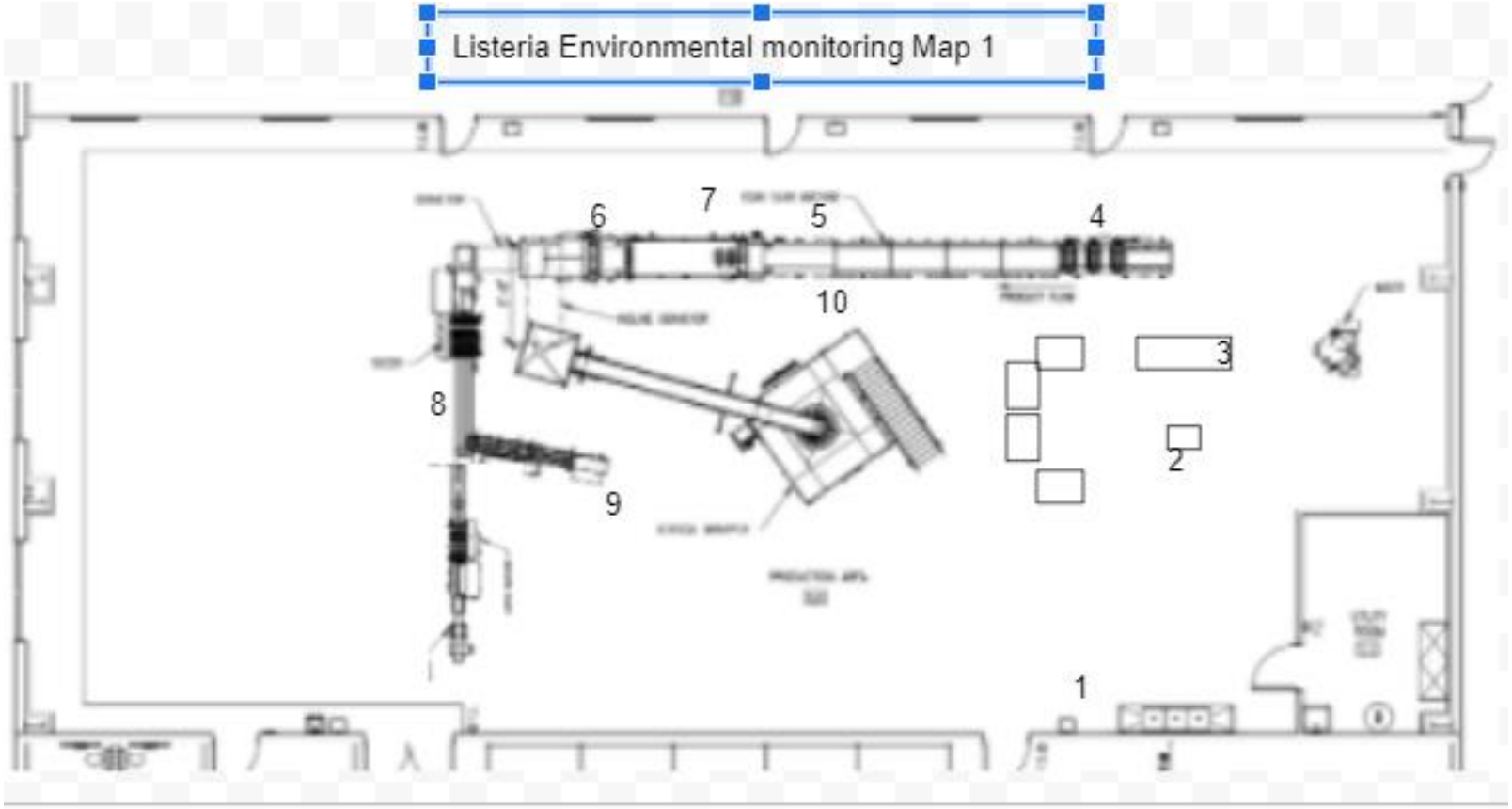

PCQI Approval: _____ Date: _____

Location:	Production/ Warehouse Storage
Purpose:	Test for the presence of environmental pathogens
Frequency:	Monthly or according to procedure
Who:	QI or Designee
Procedure:	Follow procedure to sample during production run Product held until negative results obtained from lab
Monitoring:	Monthly unless potential issues are identified
Corrections:	Investigate and reclean the area, perform a vector analysis and resample
Records:	Environmental monitoring logs

4.16 Food Allergen Label Verification Listing

Product	**Allergen Statement**
DCCA Bar/ Bite	Contains: Tree nuts (Almonds). Made in a facility that also processes Peanuts, Tree nuts (Coconut) Sesame and Milk. Organic foods may contain pits, stems, and/ or nut shell fragments. *Organic, made in the USA.
PBHF Bar/ Bite	Contains: Peanuts. Made in a facility that also processes Tree nuts (Coconut, Almonds) Sesame and Milk. Organic foods may contain pits, stems, and/ or nut shell fragments. *Organic, made in the USA.
MC Bar	Contains: Tree Nuts (Almond, Coconut). Made in a facility that also processes Peanuts, Sesame and Milk. Organic foods may contain pits, stems, and/ or nut shell fragments. *Organic, made in the USA.
LC Bar	Contains: Tree Nuts (Almond, Coconut). Made in a facility that also processes Peanuts, Sesame and Milk. Organic foods may contain pits, stems, and/ or nut shell fragments. *Organic, made in the USA.
PBDC Bar/ Bites	Contains: Peanuts. Made in a facility that also processes Tree nuts (Coconut, Almonds), Sesame, and Milk. Organic foods may contain pits, stems, and/ or nut shell fragments. *Organic, made in the USA.

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PBMC Bar	Contains: Peanuts, Sesame, and Milk. Made in a facility that also processes Tree nuts (Coconut, Almonds). Organic foods may contain pits, stems, and/ or nut shell fragments. *Organic, made in the USA.
DCM Bar	Contains: Peanuts and Tree Nuts (Coconut). Made in a facility that also processes Peanuts, Tree nuts (Coconut, Almonds) Sesame and Milk. Organic foods may contain pits, stems, and/ or nut shell fragments. *Organic, made in the USA.
OCA Bar	Contains: Tree Nuts (Almonds). Made in a facility that also processes Peanuts, Tree nuts (Coconut, Almonds) Sesame and Milk. Organic foods may contain pits, stems, and/ or nut shell fragments. *Organic, made in the USA.

4.17 Sanitation Preventive Controls Overview

Location:	Production
Purpose:	Test for the presence of Allergens and ATP monitoring
Frequency:	Daily or according to procedure
Who:	QA or Designee
Procedure:	1. Follow procedure to sample after cleaning
Monitoring:	Daily or when product changes
Corrections:	Investigate and reclean the area and resample Disposition product if required for undeclared allergens
Records:	Sanitation monitoring logs
Verification:	Allergens not detected per 3 ug detection limit or ATP in range for test surface

4.18 Environmental Monitoring for Sanitation Control Verification Overview

Purpose	Verification of sanitation
Sample identification	Listed on map key
Sampling procedure	1. Follow training and laboratory sampling procedure

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Laboratory	Approved ISO17025 facility
Test conducted	Monthly
Interpretation of results	Lab interpretation and reviewed by PCQI
Action of a positive result	Vector analysis sampling

PCQI Approval: _____ Date: _____

5.0 Reference Material:

Adulteration Involving hard or Sharp Foreign Objects in Food

Evaluation and Definition of Potentially Hazardous Foods, Chapter III, Table 3-5 Page 23

Food Safety Preventive Controls Alliance, Preventive Controls for Human Food, 2016 - Version 1.2
- Table A4 – 1: Limiting Conditions for Pathogen Growth
- Table A4 – 2: Cumulative Time and Temperature Guidance for Pathogen Growth

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry – Jan 2018
- Appendix 1 – Potential Hazards for Foods and Processes

21 CFR Part 117
- Subpart A - General Provisions
- Subpart B - Current Good Manufacturing Practice
- Subpart C - Hazard Analysis and Preventive Risk Based Controls
- Subpart F - Requirements Applying to Records That Must be Established and Maintained
- Subpart G - Supply-Chain Program

21 CFR part 1 Subpart L - Foreign Supplier Verification Program

FDA Bad Bug Book, 2nd Edition

Center for Disease Control: Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by using Outbreak Data, United States, 1998–2008
- Technical Appendix 3 Foodborne disease outbreaks attributed to each food commodity outbreak data

Reportable Food Registry Annual Report, Table 4 and Table 5
http://www.fda.gov/downloads/Food/ComplianceEnforcement/RFR/UCM502117.pdf
http://www.fda.gov/downloads/Food/ComplianceEnforcement/UCM211534.pdf

Environmental Protection Agency, Water
- National Primary Drinking Water Regulations - 21 CFR 141

University of Nebraska Food Allergy Research and Resource Program
https://farrp.unl.edu/informallbig8

Status of Coconut as an allergen for labeling
https://www.registrarcorp.com/frequently-asked-fridays-does-fda-consider-coconut-an-allergen/

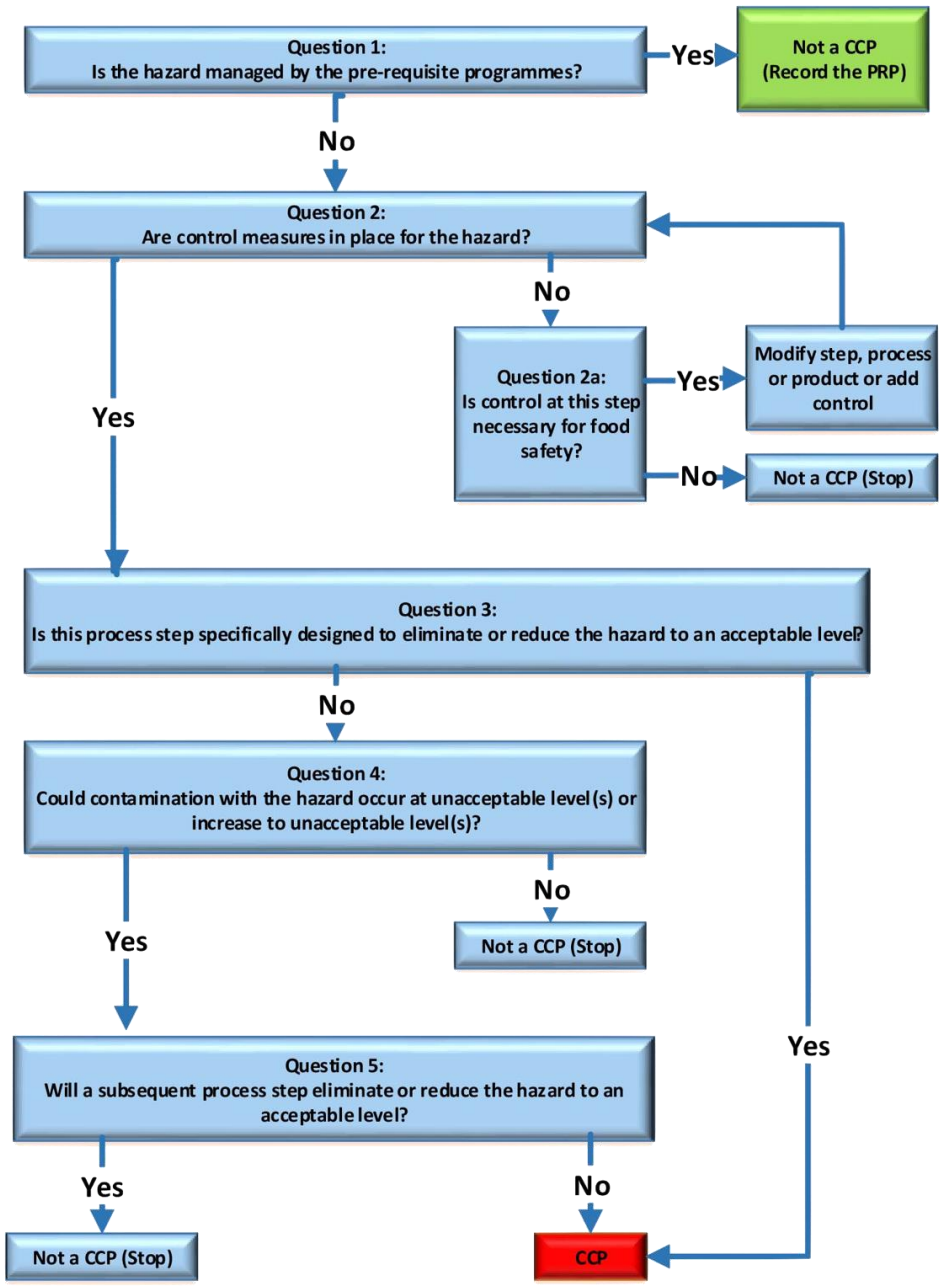
Water Activity in Foods
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-technical-guides/water-activity-aw-foods

https://safefood360.com/resources/Water-Activity.pdf

https://trello.com/b/aoFO1UEf/food-fraud-risk-information

PCQI Approval: _____ Date: _____

Codex CCP Decision Tree



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