Audit Report

Global Standard Food Safety Issue 8

1. Audit Summary

Company name	KLN Family Brands	Site Code	4582553
Site name	Kenny's Candy and Confections, Inc.		
Scope of audit	The mixing, cooking, cooling, and forming of licorice and gummy products, including gummy dietary supplements, the extrusion of snack products, the popping and coating of popcorn and coating of pre-made snacks and nuts for retail sale packed into poly film, metalized film, resealable pouches, form and fill bags, bulk containers, tins, and PVC/PET tubs		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit Start Date	2022-12-05	Audit Finish Date	2022-12-08
Re-audit due date	2023-12-29	Head Office	No

Additional modules included

Modules	Result	Scope	Exclusions from Scope

2. Audit Results

Audit result	Certificated	Audit grade	AA	Audit Programme	Announced
Previous audit grade	AA	Previous audit date	2021-12-14		
Certificate issue date	2023-01-05	Certificate expiry date	2024-02-09		
Number of non-conformities		Fundamental	0		
		Critical	0		
		Major	0		
		Minor	3		

3. Company Details

Address	609 and 505 Pinewood Lane Perham, Minnesota 56573

3. Company Details			
Country	United States of America	Site Telephone Number	1 218 346 2340
Commercial representative Name	Bryan Miller	Email	bmiller@klmfamilybrands.com
Technical representative Name	Bryan Miller	Email	bmiller@klmfamilybrands.com

4. Company Profile					
Plant size (metres square)	>25K sq.m s	No. of employees	51-500	No. of HACCP plans	>7

Shift Pattern	3 8-hour shifts / five days a week
Subcontracted processes	No
Other certificates held	Kosher, Organic, RSPO, Gluten Free, Non-GMO, and NSF Dietary Supplement
Regions exported to	Asia North America Europe
Company registration number	Confidential
Major changes since last BRCGS audit	The site removed all of the small bagger platforms (3) and replaced it with one large platform for the licorice bags and pouches. The baggers were moved to the large platform and add two new case packers that receives product from the baggers.

Company Description

Kenny's Candy Company, Inc. was part of KLN Family Brands, a family-owned company located in Perham, Minnesota selling licorice twists and bites since 1987. In 2007 premium licorice was made with real fruit juice and gourmet soft were incorporated. Chocolate factory opened producing popcorns, licorice, and pretzels. Also, a gummy line (rings, bears and worms) was introduced in 2013 and the company begun producing fruit snacks to finally merge into Kenny´s Candy & Confections in 2016. They had been a major supplier of Private Label / Store Brands and currently ships product all across the USA and internationally. The company worked three 8-hour shifts, five days a week. Building #1 had 5 licorice, 2 gummy and 1 panning (candy) lines and building #2 had 2 chocolate, 3 popcorn, and 1 extruded line. The plants employed around 380 people and consisted of 266,000 square feet.

5. Product Characteristics					
Product categories	16 - Confectionery 17 - Cereals and snacks				
Finished product safety rationale	Ambient stable and low Aw (<.80)				
High care	No	High risk	No	Ambient high care	No
Justification for area	Low risk based on BRCGS guidelines appendix 2				
Allergens handled on site	Cereals containing gluten Milk Egg Peanuts Nuts Soya				
Product claims made e.g. IP, organic	Kosher, Organic, RSPO, Gluten Free, and Non-GMO,				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	Kettle Popcorn (Item number: 350100/lot number: 597174, Bulk Carmel Corn (Item Number: 360100/BB- 2023-02-02, Crunchy curls (Item number: 6006/lot number: 592603, Assorted Fruit gummies (Item number: 555004/Best before date: 04-Sept 2023), Strawberry licorice bites (Item number: 1214111/lot number: 596869*3), Bulk sour beans (Item number: 220644/lot number: 596852*2), Watermelon licorice (Item number: 120097/lot number: 597402*3), and Pistachios Nuts (Item Number: 450105/lot597372				

6. Audit Duration Details			
Total audit duration	28 man hours	Duration of production facility inspection	11 man hours
Reasons for deviation from typical or expected audit duration	The warehouse total for both locations are 266,000 (facilities) and 144,000 square feet warehouses).		
Next audit type selected	Unannounced		

Audit Duration per day			
Audit Day	Date	Start Time	Finish time
1	2022-12-05	09:00	17:30
2	2022-12-06	07:45	16:15

3	2022-12-07	07:45	16:15
4	2022-12-08	08:00	12:00

Audit Team	Auditor number	Name	Role
Lead Auditor	21248	Karen M. Lane	Lead Auditor

Present at audit				
Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11)				
Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Andy Peeters / General Manager	X			X
Sheila Hamlett / Corporate Food Safety Director	X		X	X
Bryan Miller / Regulatory Manager	X	X	X	X
Keith Nordick / Food Safety Specialist	X	X	X	X

GFSI Post Farm Gate Audit History		
Date	Scheme/Standard	Announced/Unannounced
2020-12-01	BRCGS Food Safety Issue 8	Announced
2021-12-14	BRCGS Food Safety Issue 8	Announced

Document control			
CB Report number	BRC-FD-511		
Template Name	F834 Food Safety Audit Report Template v11		
Standard Issue	8	*Template issue date*	2022-02-15
Directory allocation	Food	*Version*	1.0

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No.	Clause	Detail	Critical or Major	Re-audit date

Critical			
No.	Clause	Detail	Re-audit date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	3.8.1	Three ingredients which was placed on automatic hold within the site's electronic management warehouse system did not have hold tags on the ingredients. The site's	There were three ingredient containers that did not have a hold tag applied to the pallet for this non-conformance (two containers were the same ingredient and on	Our electronic hold system was modified to add a field for the verification of the hold tags being applied. Completion of this field will be a requirement moving forward. Our Hold	There was no requirement to verify that hold tags actually were placed on-hold product in our existing procedure. These pallets were automatically put on hold	2022-01-01	Karen M. Lane

Minor							
		non-conforming process was not followed which requires hold tags to be placed on them.	the same pallet). The ingredients in question had a hold tag physically applied to each pallet.	Procedure WI-0770 has been updated to assign responsibility for this verification to the lead QC technicians on each shift. QC personnel have been trained on the updated procedure. The finding was reviewed with the GMP audit inspectors as things to look for during the GMP audits.	in the system and needed to be moved by inventory control in order to be accessible to apply tags to them. The QC techs printed hold tags and gave them to inventory control to apply, which did not happen. There was no follow up verification done by QC to ensure that the tags had been placed on the affected product.		
2	4.6.1	a. Four stainless steel product zone scoops used for popcorn and the sifting mesh screen drum was cracked and/or missing pieces on-line A. b. The rubber sleeve around the conduit pipe (5) on the popper kettles were missing small pieces of the rubber.	a. All of the popcorn scoops were inspected, and all damaged scoops were replaced with new ones. The damaged mesh on the sifting drum was fixed by maintenance during the audit. b. The kettles with damaged conduit sleeves were taken out of service, and the damaged sleeves were replaced with new.	a. The pre-start up inspection checklists for all three lines were updated to include a check specifically for the popcorn scoops and instruction to look at the condition of the sifting drum mesh as a part of that equipment check. Operators have been trained on the updated checklists and what is acceptable in regards to the equipment condition. Maintenance personnel were also retrained on what is acceptable for the sifting drum mesh PM. The	a. The popcorn scoops will wear out with use and need to be monitored accordingly. The operators were not specifically checking the condition of these during the pre-start inspections. The sifting drum mesh also will wear out with use and needs to be monitored accordingly. The mesh is on a PM program, but the operators were not specifically checking the condition of the	2022-01-01	Karen M. Lane

Minor							
				finding was reviewed with the GMP audit inspectors as things to look for during the GMP audits. b. The pre-start up inspection checklists for all three lines were updated to include instructions to look at the condition of the conduit/wiring as a part of that equipment check. Operators have been trained on the updated checklists and what is acceptable in regards to the equipment condition. The finding was reviewed with the GMP audit inspectors as things to look for during the GMP audits.	screen during the pre-start inspections. b. The damage to the rubber sleeve on the conduit is caused by melting due to the high temperature of the kettles. The temperature of the kettle will eventually cause melting and wear over a variable length of time and need to monitored accordingly in case damage occurs between PMs. The operators were not specifically checking the condition of the conduit sleeve during the pre-start inspections.		
3	7.1.1	One employee was using cornmeal which is an ingredient as an absorbent to clean-up cheese slurry that had spilled on the floor.	The bucket with corn meal being used for spill clean-up was discarded. Maintenance had just placed an order for absorbent mats that were acceptable for use. These were made available for use to production	The department operators were trained on the fact that they cannot use ingredients for spill clean ups, and that, when necessary, they should use the available absorbent mats. The finding was reviewed with the GMP audit inspectors as things to	Employees did not have access to absorbent spill mats for proper clean-up of this type of material, which is unique in our facilities. Employees in this area had alternatively started	2022-01-01	Karen M. Lane

Minor							
			employees for slurry spills in the extruded snacks room.	look for during the GMP audits.	using damaged bags of corn meal to clean up slurry spills. This was not identified during previous GMP inspections.		

Comments on non-conformities
No comments

Additional Modules / Head Office Non-Conformity Summary Sheet

Critical			
No	Clause	Detail	Re-audit date

Major							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

The company has a documented food safety and quality policy dated 2022-08-29 and signed by the CEO, and the General Manager (3). It is communicated to the staff and top management through postings and new hire.

There are documented objectives listed in the below table. Objectives are measurable and include targets. The objectives are communicated to staff through postings and reviewed at management review meetings.

Objective: ATP Swabbing
Current Situation: 97.12%
Target: 98% first time pass rate
Results: Goal not met

Objective: Complaints
Current Situation: 6.57 branded complaints
Target: No more than 4.6 branded complaints per 1,000,000 brand units sold
Results: Goal not met

Objective: Environmental Swabbing
Current Situation0 pathogen positives/ 100%:
Target: >99% pass on pathogenic positive
Results: Goal met

The site's management review meetings are held every four weeks/once every period, the last review was conducted on 2022-09-29, 2022-10-20, and 2022-11-21. The meeting was attended by the product manager, the general manager, the food safety specialist, the purchasing manager, the director of operational support, and various managers. The site's management review meeting consisted of review of the Food Safety plan, any changes to the food safety plan, complaints and trends, recalls, potential or upcoming changes to the food safety plan, hold products, results from internal/external/verification audits, regulatory audits, customer audits, GMP results, allergen issues, review of incidents, environmental swabbing results and trends, food safety goals, objectives, supplier performance, etc.

Records of the management review were available and included decisions and actions which are communicated to appropriate staff and completed within a defined timescale.

The site has adequate resources to maintain compliance to the Standard.

There are also regular meetings that include food safety, legality, integrity, and quality issues. Examples of those meeting include the following: daily continuous improvement meetings and monthly management review meetings.

The company ensures that they are kept informed of scientific and technical developments, industry code of practices as applicable as well as new risks to authenticity of raw materials and relevant legislation through candy industry articles, food safety and quality articles, regulatory updates, and FDA notification.

The site's food safety culture plan is the responsibility of the Quality Assurance Corporate Director, these matters were discussed with the auditor.

The site's food safety culture plan included the following activities: employee survey. The plan did include all of the site that impacted food safety such as department and roles. The site had an action plan which identified how activities would be completed. The measurement was as followed: survey results, goals, and objectives results. The plan did include intended time scales. A review of the site's plan was completed for the completed activities to ensure effectiveness. Effectiveness will be managed through tracking and trending. The survey results were reviewed, and final results were completed on 2022-11-27.

Effectiveness will be managed through tracking and trending.

Interviewed employees confirmed that they were aware that non-conforming product issues could be reported to their supervisor and/or their management team for action.

The company has an anonymous and confidential reporting system. The systems work in the following manner: the employees can dial the Corporate Quality Assurance Director from a company phone at any time to speak directly or leave a message concerning food safety matters. The Corporate Quality Assurance Director's phone number is posted and listed within the site's phone list.

A genuine copy of BRCGS standard was available. They organization remains updated on changes in the standard via participate, certification body.

The logo was not used.

The company have ensured certification is maintained, the audit due date through Certification Body/corporate.

The General Manager attended both the opening and closing meeting.

Three non-conformities were identified at the previous audit against clauses 4.6.1, 4.11.6, and 4.15. Identified root cause analysis and provided actions seen to have been effectively addressed to prevent recurrence.

1.2 Organisational structure, responsibilities and management authority

The company has a clear organizational structure in place and dated 2022-11-30. The person responsible for food safety, legality and quality is the Quality Managers who reports directly to the Director of Production Support. Alternatives/Deputies is documented on the site's job descriptions. The general manager, quality manager, and production supervisor job descriptions were reviewed and compliant. The organization ensures that employees are aware of their responsibilities through on the job training, job descriptions, work instructions, SOP's, and programs. Interviewed staff appeared to be aware of their responsibilities and documented work instructions are in place.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
1.1.13	The BRCGS logo is not used

2 The Food Safety Plan – HACCP

The plan has been developed and maintained by a multidisciplinary team including: The team is listed in the below table.

Food Safety Specialist/Team Coordinator-4 years snack food industry, HACCP certified on September 29, 2020, and PCQI certified on October 29, 2020.

General Manager-16 years manufacturing responsibilities and 10 years in the confection and snack industry, and in-house annual HACCP / HARPC training on 2022-03-21.

Director of Order Fulfilment -3-year supply chain manager, 6 years raw material inventory management, and 4 years procurement for salty snacks, and in-house annual HACCP / HARPC training on 2022-03-21.

Director of Production- 11 years in supply chain consulting, 9 years in snack food supply chain/manufacturing, 3 years in licorice industry, and in-house annual HACCP / HARPC training on 2022-03-11.

QA Manager- 6 years in Licorice Industry, 5.5 years in Snack food industry, and in-house annual HACCP / HARPC training on 2022-03-05.

Regulatory Manager- 7 years quality management snack food and confectionary industry, HACCP last recert (2018-05-09) by AIBI and PCQI certified 2016-09-23 by FSPCA, and in-house annual HACCP / HARPC training on 2022-03-11.

Warehouse Director- 25 years management responsibilities (34 years Logistic experience), and in-house annual HACCP / HARPC training on 2022-04-10.

Purchasing Manager- 40+ years management responsibilities (10+ years Logistic experience), and In-house annual HACCP / HARPC training on 2022-04-04.

Food Technologist- 9 years in Licorice Industry In-house annual HACCP / HARPC training on 2022-03-09. Shift manager for building one and building two (4). The In-house annual HACCP / HARPC training certifications were reviewed and dated 2022-03-29, 2022-03-08, 2022-03-12, and 2022-03-07.

Production Manager (Building 1) 25 years in Licorice Industry and in-house annual HACCP / HARPC training on May 13, 2021.

Production Manager (Building 2)- 7 years in manufacturing, 3 years in municipality utility supply In-house annual HACCP / HARPC training on March 17, 2021.

KLN Corporate Food Safety and Safety Director- 13 years in food safety with the US Army, 9 years in snack food industry, 8 years in the confectionary industry, experienced in HACCP development, GMP audits, food safety and warehouse management, and HACCP last recert (July 17, 2019) by NSF and FSPCA- PCQI dated 2021-04-08.

The company has a fully implemented and effective Food Safety Plan based on Codex Alimentarius HACCP principles. There are eight HACCP studies which includes Licorice, Gummy, Panning, Extruded snacks, Supplements, Enrobed products, popcorn, and Coated nuts. Ready to eat (some varieties not appropriate for individuals allergic to dairy, tree nuts (pistachios, almonds, cashew, coconut, pecan/some varieties not appropriate for individuals allergic to wheat or soy or those with celiac disease / not appropriate for individuals under age three, choking hazard/ not appropriate for individuals allergic to dairy, soy, peanuts, tree nuts, wheat or those with Celiac disease/some formulas may not be appropriate for certain demographics (i.e. children) due to type and concentration for people under the age of three.

Each product or group of products includes a full description which includes all relevant information on food safety. The intended use of the product is identified as Ready to eat general public (Not appropriate for individuals under age three, choking hazard and/or food allergic individuals). There are no alternative uses for Licorice, Gummy, Panning, Extruded snacks, Enrobed products, popcorn, and Coated nuts. Alternative uses for dietary supplements are taking more recommended dosage.

Pre-requisites are documented within the HACCP Plan and include the following: Allergen Control, Sanitation, Preventative Maintenance, Storage and Transportation, Personal Hygiene/GMP's, Training and Education, Allergen Program, Foreign body Detection and Physical Product Contamination Control, Pest Control, Supply Chain, Recall, Traceability, Shipping, Approved Supplier, Receiving, etc. The pre-requisites are reviewed as part of the HACCP review process.

Product groups descriptions were developed that included relevant information on food safety.

Product groups descriptions were developed that included relevant information on food safety.
A few examples within the product descriptions were but not limited to: Product Name, Target Market and Intended use, Composition, Physical or Chemical properties, Packaging Materials, Intended Consumers, Handling and Preparation, Processing, Shelf-life, Labelling Instructions, Food Safety Information, and Storage and Distribution.

Flow diagrams are in place covering relevant inputs and outputs. The following is a list of existing flow diagrams:

Flow diagram: Licorice Flow Chart
Issue date: 2022-04-08
Verification Method: Physical verification
Documented on the HACCP- Process Flow Diagram form. Also walked during the audit.

Flow diagram: Gummy Flow Chart
Issue date: 2022-12-01
Verification Method: Physical verification
Documented on the HACCP- Process Flow Diagram form.

Flow diagram: Panning Flow Chart
Issue date: 2022-12-01
Verification Method: Physical verification
Documented on the HACCP- Process Flow Diagram form.

Flow diagram: Supplements Flow Charts
Issue date: 2022-12-01
Verification Method: Physical verification
Documented on the HACCP- Process Flow Diagram form.

Flow diagram: Popcorn Flow Chart
Issue date: 2022-12-01
Verification Method: Physical verification
Documented on the HACCP- Process Flow Diagram form.

Flow diagram: Extruded Snacks Flow Chart
Issue date: 2022-12-01
Verification Method: Physical verification
Documented on the HACCP- Process Flow Diagram form.

Flow diagram: Enrobed Product Flow Chart

Issue date: 2022-12-01
Verification Method: Physical verification
Documented on the HACCP- Process Flow Diagram form.

Flow diagram: Coated Nuts Flow Chart
Issue date: 2022-06-23
Verification Method: Physical verification
Documented on the HACCP- Process Flow Diagram form.

Relevant information has been used to conduct the hazard analysis including CPG Sec. 555.425 Foods, Adulteration Involving hard or sharp foreign objects, FDA, EPA Safe Water Drinking standard, Popcorn critical temperature, jump, and sound, etc.

Flow diagrams are in place covering relevant inputs and outputs.

Process steps summary: Receiving – storage- rework- process steps (temper tank, enrobing, panning, cooling tunnel, sprinkle application, mix color, mix slurry, panning, extrude, lump buster, sprinkler applicator, etc)- finished products, rework- intermediate/semi-processed products, and waste.

The HACCP team have identified and recorded potential hazards that are reasonably expected to occur at each step of the process, and this includes raw materials. Identified hazards were determined for microbiological, chemical, radiological, physical and allergens. The auditor verified that the risk assessment was done in compliance with the standard. Food fraud and malicious contamination is addressed within the site's threat assessment plan which contains a vulnerability assessment.

The site had a documented Radiological risk assessment. The site's Food fraud and malicious contamination is addressed within the site's threat assessment plan which contains a vulnerability assessment.

Examples of the hazards/microorganisms assessed were as followed:

Hazard Category: Biological:
Specific Hazard: Salmonella, E. coli, B. Cereus, C. botulinum (low), Mycotoxin, L. Momo, staph (medium)
Risk Determination: See above

Hazard Category: Physical:
Specific Hazard: metal (medium)
Risk Determination:

Hazard Category: Chemical:
Specific Hazard: allergens (low), Aflatoxin (medium), heavy metals, agricultural run-off/ pesticide, fertilizer (medium)
Risk Determination: See above

A hazard analysis has been conducted based on likelihood x severity. Control measures have been identified and documented within the site's HACCP plans.

Critical control points have been determined by using a risk matrix/codex decision tree.

Critical control points identified are:

CCP: 1
Process Step: Metal detection
Critical Limit: 1.5 FE, 1.5 Brass/Non-FE, and 2.0 SS

Monitoring: Start of each shift, at a minimum of every four hours, and at the end of weekly production.

Corrective Action: shut down the line, notify the supervisor, determine the root cause, and hold product back to the last good check of the metal detector. The Held product was required to be passed through a functioning metal detector.

Documented procedures define corrective actions expected to be implemented if critical limits are exceeded. CCPs were validated as follows:

CCP: 1 – metal detection
Means of Validation: Outside service provider testing and completing diagnostics of the metal detection units. The units were tested by testing the front, back, and middle of the products. Alternative and consecutive rejections for each unit.
Date of Last Validation: 2022-10-22 and 2022-10-11.

The site's CCP records are signed by operative and verified by the Production supervisor or designee, or visually observed by the QA tech or line operator.

The Food Safety team conducts verification of the site's HACCP plan. The plan's last review was on 2022-09-12 (Licorice), 2022-12-01 (Gummies, Panning, supplements, Popcorn, enrobed, extruder, coated nuts) which, included the following: internal audits, review of customer complaints and withdrawals or recalls, etc. This information is made available to the HACCP food safety team.

During the auditing process multiple records were reviewed, properly documented, and maintained.

The last HACCP Plan review was last conducted on 2022-09-12 (Licorice), 2022-12-01 (Gummies, Panning, supplements, Popcorn, enrobed, extruder, coated nuts).

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
N/A	

3. Food safety and quality management system

3.1 Food safety and quality manual

The organization demonstrated a documented quality system manual based on the BRCGS requirements. The manual and their parts are made available as needed to the staff through a browser-based collaboration and document management system. Verified procedures and work instructions were clearly legible and available English and Spanish. During the interview process the auditor observed that these were properly understood by the relevant staff.

3.2 Document Control

There is a document control procedure in place dated 2020-11-02 (rev.13). Documents are controlled by a browser-based collaboration and document management system. A record of the reason for change is retained. A list with all controlled documents were provided and verified during the audit. Computer data is backed up daily through a server system and the Cloud.

The following documents were reviewed and compared to the site's control list: Panning room metal detection log, Maintenance repairs and post work order inspection form, Tailing examination log, and Batch

Production record. The reviewed documents and the site's document control list matched and complied. The following elements were reviewed: document reference, the issue or version number, the title of the document, the date of issue, and the page number and total number of pages.

3.3 Record completion and maintenance

The records reviewed were legible and easily retrievable. The site's records are retained for five years. The retained records properly cover the maximum product shelf life of two years plus three years.

3.4 Internal audits

There is a planned program of internal audits based upon risk for which the organization considers the following criteria: The Food Safety Plan, Recall, Food Fraud, Food Defense and Food Prevention Plan, Traceability, Preventative Maintenance, Receiving, Shipping, IPM, GMP's, CAPA, Non-Conformance, Document Control, etc. The site's internal audit consisted of the site's HACCP/Food Safety Plan, Quality System and BRCGS requirements. This also included the prerequisite programs and procedures. The site's schedule issued, and reports demonstrates that all system requirements are covered four different audit dates, spread throughout the year, and that all activities are covered at least annually.

The site determines the risk and frequency of the audits through the following methods: audit results, corrective actions generated, systemic problem identified, external audits, the importance of the area, or relevant information.

The facility used a Word document to document and track their audit schedule.

Currently there are 20 available auditors to cover all aspects of the organization and ensure independence. Auditors were demonstrably competent, and evidence included:

The team of auditors consisted of, COO, CFO, CTO, Regulator manager, Food Safety Specialist, Supplier Approval Specialist, Quality Control, R&D Manager, Office admin, employees, supervisors, and maintenance. All twenty in-house 2022 internal auditing training certificates were reviewed, compare to the list, and was compliant. The training was conducted on 2022-05-13, 2022-05-18, 2022-08-12, 2022-10-26, 2022-11-20, etc.

Audit reports include objective evidence of conformity as well as non-conformity and are reported to personnel responsible for the activity audited. Corrective actions and timescales are agreed, and completion of corrective actions are verified by the Senior Director of Food Safety and EHS.

During the audit the results of the following audit activities conducted throughout the year were reviewed:

Date Audit 1: March 01-2022
Area/Requirement: Food Safety and Quality Management (Internal audits)
NCs: 0
Corrected: N/A

Date Audit 2: May 10-2022
Area/Requirement: HACCP
NCs: 1
Corrected: Yes

Date Audit 3: July 07-2022
Area/Requirement: Selection four (Foreign body detection)
NCs: 0
Corrected: N/A

Date Audit 4: September 23-2022 (Labeling and pack control)
Area/Requirement: Process Control

NCs: 0
Corrected: 0

The above audits dates were also compared to the site's audit schedule. The site was compliant through the documented schedule in comparison to when the audits were completed.

In addition to the internal audit program there is a program of planned inspections for hygiene and housekeeping as well as fabrication. Inspections are conducted once per per/every four weeks, records seen for July through September 2022 and cover all process areas. Deviations identified are reported to the management and implemented actions are verified by the Senior Director of Food Safety and EHS.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

There is a documented supplier approval and monitoring system in place and indicated within the site's the Approved Supplier Program dated 2022-05-03 (rev.18) This requires that the organization performs a risk assessment of each raw material/group of raw materials to identify potential risks to product safety, legality and quality including allergen contamination, foreign body risks, micro contamination, chemical contamination and substitution or fraud.

Existing methods to accept raw materials are consistent with the reviewed risk assessment which includes the following means of control: 3rd. Party Audits, GFSI, supplier questionnaire for low-risk ingredients, COA, Packaging Compliance letter, Approved Audit Scheme, Food Safety Audit, Corporate Audit, and Supplier Audits with a scope that includes product safety, traceability, HACCP review and Good Manufacturing Practices.

During the audit a sample of supplier assurance records was conducted:

Item: White Wafer (Item number: 17065)
Risk Rating: medium
Method of Assessment: GFSI/SQF
Valid Until: 2023-06-13

Item: Pure Cane Sugar (Item number: 12010)
Risk Rating: low
Method of Assessment: GFSI/BRCGS
Valid Until: 2023-01-14

Item: Metallize Packaging Film (Item number: 35275C)
Risk Rating: low
Method of Assessment: GFSI/SQF
Valid Until: 2023-02-18

All six ingredients within the finished product (Drizzled Popcorn- item number: 350070) recipe GFSI certifications were reviewed and compliant.

The site had an up-to-date list of approved suppliers. The site's list was through a third-party electronic database.

Evidence of raw material changes being communicated to goods in was provided via email.

Exceptions to the site's supplier approval process include the following controls: the use of back-up suppliers. The site also uses spot purchases which must provide product that meets the specification, be

reviewed by management during management meetings, evaluate per FSMA requirements, third-party audits, HACCP Plan, related certificates (Kosher, GMO), letter of Guarantee, etc.

Describe types of controls 100% inspection of the product, certificate of analysis, increased microbiological sampling, review of third-party audit report, A formally agreed specification, Certification of Conformance with customer codes and practice.

Materials purchased via agents/brokers are assessed in the same manner as direct suppliers and evidence for this included third-party audits, GFSI audits, supplier questionnaire for low-risk ingredients, Food Safety Audits, Corporate Audits, and Supplier Audits with a scope that includes product safety, traceability, HACCP review and Good Manufacturing Practices.

The site did know their last known identity of the last known processor, packer, or consolidator for their agents and brokers. The site requires the agents and brokers to give them all of the approval supplier information. The following ingredients from agents and brokers reviewed: Granulated Salt (Item number: 16005), Palm oil (Item number: 16225), and Organic Cain Sugar (Item number: 25060). The site stores the approval supplier documentation for all ingredients with their third-party system.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Documented procedure Storage and Transport dated 2022-03-10 and Receipt Instruction dated 2022-10-25 controls for acceptance of raw materials and packaging materials. A list of raw materials and requirements to be met for acceptance was available and observed to be followed. During the audit were sampled materials to ensure compliance with the defined requirements the results of the sample were as follows:

Material description: White Wafer (Item number: 17065/Lot number: H6095556/1/1/2)
Defined means of control: Trailer Inspection stamp, Packing Slip, BOL, and COA
Evidence provided: Trailer Inspection stamp, Packing Slip, BOL, and COA
Comments: None

Material description: Pure Cane Sugar (Item number: 12010/Lot number: H610177/1/1/1)
Defined means of control: Trailer Inspection stamp, Shipment Pack list, BOL, and COA
Evidence provided: Trailer Inspection stamp, Shipment Pack list, BOL, and COA
Comments: None

Packaging:
Material description: Metallize Packaging Film (Item number: 35275C/Lot number: H609307/3/1/1)
Defined means of control: Trailer Inspection stamp, BOL, and COA
Evidence provided: Trailer Inspection stamp, BOL, and COA
Comments: The site receives an approved packaging samples with a part number that is visually checked at receipt to ensure that the packaging materials are correct.

Documented procedure Supplier and Raw Materials Approval and Performance Monitor dated 2022-05-03 describes the approved changes to raw materials which includes primary packaging. The procedure details how changes are communicated to personnel to ensure that the correct raw materials and primary packaging is accepted and avoiding accidental releasing of the materials into production.

The site does not receive live animals.

3.5.3 Management of suppliers of services

Procedure Supplier and Raw Materials Approval and Performance Monitor dated 2022-05-03 describes the means to approve and monitor service suppliers which includes Pest Control, Laundry Services, Contracted Cleaning, Contracted Servicing and Maintenance of equipment, Transport and Distribution, off-site storage of ingredients, packaging or products, Laboratory Testing, Catering/Vending Services, Waste Management,

and Product Safety consultants. Contracts reviewed during the audit included Transport and Distribution, Pest Control, and Laundry Services. This includes service expectations.

3.5.4 Management of Out sourced processing

Section considered not applicable. There are no process steps conducted by external organizations.

3.6 Specifications

Specifications are in place for raw materials including packaging and finished product. When required specifications are formally agreed with customers/suppliers. Procedure includes the requirement to review specifications when product/materials change or at least every 3 years.

Sampling of specifications was conducted as part of the site inspection and traceability with following results:
Type of Specification: Final Product
Description: Drizzled Popcorn (Item number: 350070)
Specification: Drizzled Popcorn (Item number: 350070)
Last review date: 2021-03-17
Comments: None

Type of Specification: Raw material
Description: White Wafer (Item number: 17065)
Specification: White Wafer (Item number: 17065)
Last review date: 2022-05-06
Comments: None

Type of Specification: Raw material
Description: Pure Cane Sugar (Item number: 12010)
Specification: Pure Cane Sugar (Item number: 12010)
Last review date: 2022-04-27
Comments: None

Type of Specification: Packaging material
Description: Metallize Packaging Film (Item number: 35275C)
Specification: Metallize Packaging Film (Item number: 35275C)
Last review date: 2022-09-29
Comments: None

All six ingredients within the finished product (Drizzled Popcorn- item number: 350070) recipe specifications were reviewed and compliant.

3.7 Corrective and preventive actions

The organization provided evidence of documented procedure Corrective and Preventative Action dated 2022-03-29 (rev.12) The company demonstrated that they use information from identified failures in the food safety, legality, or quality of the products to make necessary corrections and prevent recurrence. The organization manages existing corrective and preventive actions via browser-based collaboration database.

Example seen during audit is listed below, which showed that root cause analysis was effective.
Internal audits, Customer Complaint, BRCGS NC's

Trend analysis showed:

Trend Analysis: BRCGS NC's
Year/Complaint Amount: 2022 (3)
Year/Complaint Amount: 2021 (4)
Status: decrease

Trend Analysis: Customer Complaint
Year/Complaint Amount: 2022 (2)
Year/Complaint Amount: 2021 (0)
Status: increase

Trend Analysis: Internal Audits
Year/Complaint Amount: 2022 (0)
Year/Complaint Amount: 2021 (1)
Status: decrease

3.8 Control of non-conforming product

A non-conforming product procedure is in place and dated 2022-11-18 which includes controls and responsibilities for out-of-specification products, avoided use of materials, and prevents unauthorized release.

Non-conforming materials and products were mostly identified by e.g., direct labelling, block in IT-systems and placed on hold to avoid accidental release. Three ingredients which was placed on automatic hold within the site's electronic management warehouse system did not have hold tags on the ingredients. The site's non-conforming process was not followed which requires hold tags to be placed on them.

A sample was conducted to verify that physically segregated materials/products matched with the ones reported in existing records. Results demonstrate that controls are effective.

Hold product(s) Customer brand film (Item number: 35609) and Customer brand film (Item number: 35277C) on the floor was compared to the (log, computer system) and demonstrated compliance/non-compliance.

Minor Non-Conformance raised against 3.8.1- Three ingredients which was placed on automatic hold within the site's electronic management warehouse system did not have hold tags on the ingredients. The site's non-conforming process was not followed which requires hold tags to be placed on them.

3.9 Traceability

A system is in place which allows the organization to trace all raw material product lots including primary packaging from their suppliers through all stages of their process until one step out of their responsibility and vice versa. The procedure Traceability dated 2022-07-26 (rev.14) describes how items may be traced.

The organization provided evidence of internal traceability exercises across a range of products which included a review of the pertinent documentation and records as follows:

Backward trace:
Date: 2022-11-28
Product- Sweet and Salty Popcorn (Item number: 300245/lot number: 583179)
Date of Production- 2022-02-14
Amount Produced- 802 cases
Amount Traced- 802 cases
Time Required / Comments- 39 minutes/100%

Forward trace
Date: 2022-04-26
Product- Metalized resealable pouch (item number: 39963/lot number: 125411)
Date of Production- lot number: 125411
Amount Produced- 22,000 impressions
Amount Traced- 22,000 impressions
Time Required / Comments- 31 minutes/100%

An onsite traceability test was successfully conducted on:

Forward trace
Product- White Wafer (Item number: 17065/Lot number: H6095556/1/1/2)
Date Produced- Lot number: H6095556/1/1/2
BB Date- 2024-07-09
Mass Balance- 810,400 oz.
Time Required- One hour and ½ /100%

Backward trace
Product- Drizzled Popcorn (Item number: 350070/Lot number: 594088)
Date Produced- 2022-09-26 and 2022-09-27
BB Date- 2023-05-24
Mass Balance- 3,000 cases
Time Required- One hour and 54 minutes/100%

The site's rework is fully traced through the site's electronic warehouse management system. The site repacks product for rework.

3.10 Complaint-handling

There is a fully documented complaint handling procedure issued on dated 2021-08-04.

All complaints are recorded, and an investigation is conducted by the management test. The organization demonstrates the means to analyses and trend complaints and in case of significant increase or serious complaint root cause is determined as part of the action plan.

Main cause of complaints is listed below.

During this year 366 complaints have been reported compared to 639 last year. The decrease of the complaints was due to the site being able to better control their new product for staling.

Type of Complaint: Stale product
Year of Complaints: 2021 (379)
Year of Complaints: 2022 (98)

Type of Complaint: Foreign material
Year of Complaints: 2021 (83)
Year of Complaints: 2022 (45)

During the audit records were reviewed of existing complaints which demonstrates a proper documented and implemented system.

3.11 Management of incidents, product withdrawal and product recall

There is a documented crisis management (Incident) procedure dated 2022-05-03 (rev.19).

The crisis management team includes COO, General Manager (3), Food Safety Coordinator, Safety Director, President, Legal counsel, and Legal Representative.

There is also a recall procedure dated 2022-02-21.

The recall procedure is tested at least annually to ensure effective operation at both facility and company level. The test showed that the site's responsibilities were properly understood and capable of being promptly enacted.

Last test
Date: 2022-10-17
Product: Supplement Gummy (Item number: S760027)
Batch Traceability: lot number: 591405*2
Key Timings: One hour and nine minutes/100%
Corrective Actions: None

The company has confidence in its out of hours protocol as evidenced through training/an after-hours phone list.

There have been no withdrawals / recalls in the last 12 months however the procedure states that in the event of a product recall the certification body should be informed within 3 working days of the decision to issue a recall.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
3.5.2.3	The site does not receive live animals.
3.5.4	There is no outsourced processing/packing
3.9.4	There is no rework undertaken

4. Site standards

4.1 External standards

The production site is situated in a rural area in Perham, Minnesota. A plant tour around the perimeter was conducted and no activities were observed which may have an adverse impact on the site's product from local activities.

Building number one was made of concrete with some sheet metal walls, located next to a neighbourhood and a couple of manufacturing facilities. They are also located next to a railroad track. Building number two was also made of concrete but their walls were mostly made of sheet metal in the production areas. The site had a corporate building, an admin. building, and two facilities. The site was located on the edge/west side of town.

External areas were observed to be well maintained. All areas surrounding the building were observed with sufficiently clear/clean areas to discourage rodents from burrowing. Roads around the plant were observed to be paved and in good condition. Waste containers are maintained far from the plant entrance and kept closed to prevent pest harborage.

Building fabric was in good condition. Dock doors were observed to be properly closed, covered, and without evidence of bird roosting sites. Walls and floors were in good condition; pipes, vents etc. were also adequately proofed.

4.2 Site security and food defence

Security systems are in place. A documented risk/threat assessment has been conducted and dated 2022-08-03.

The system requires annual review and was last conducted on 2022-08-03. The individual areas within the site's food Defense plans were reviewed, compliant, and dated 2022-07-27 (Licorice), 2022-09-07 (Gummies), 2022-12-01 (Panning, Popcorn, enrobed, supplement, and extruded snacks), and 2022-nuts (coated nuts).

There were not issues identified issue during the last review of the threat assessment plan.

The facility did not have raw materials or products identified as a risk within the threat assessment plan. Raw materials or products were controlled through monitoring. The site deemed that through the concentration level were low and that it would not put the customer at risk.

The site's policy and system ensure that only authorized person has access into production and storage areas, and those employees have access to the site.

Staff shall be trained in site security procedures and Food Defense. The site's staff was trained on the site security procedure and Food Dense. See clause 7.1 for security procedures and Food Defense training.

Security procedures are part of the training program and personnel interviewed explained their responsibilities.

A visitor reporting system is in place which consisted of visitors reporting the to the administration building and/or at the facility within the main office area.

External storage tanks / silos were properly controlled. The site's silos, intake ports for production, raw ingredients and packaging materials were properly controlled. The site's silos were located internally.
The site's used electronic locks to secure access loading ports on their bulk ingredient storage silos. The codes for the lock changes for each load and are only available for authorized employees.

The site is registered with FDA, the registration number is confidential, and the issue date was dated 2022-10-03.

4.3 Layout, product flow and segregation

The factory layout, process flow and movement of personnel appeared acceptable. Contractors and visitors are made aware of company procedures by Company Visitor Agreement policy dated 2018-10-23. Contractors are under the supervision of management.

The site tour demonstrated that the plant has sufficient workspace and storage capacity to enable proper hygienic conditions.

Temporary structures are managed through the site's Facility Site Standards Program dated 2022-03-29. There were no temporary structures.

Map provided by the plant and assessed by the auditor demonstrate the following areas:

Areas Low risk
Location: All production areas.
Level of control: Physical segregated which includes equipment, personnel, and waste flow. Air flow and utilities were on site schematic.

Areas: Enclosed product
Location: The processing areas have enclosed processes.
Level of control: Physical segregated which includes equipment, personnel, and waste flow. Air flow and utilities were on site schematic.

Areas: Non-product
Location: Support Areas
Level of control: Physical segregated which includes equipment, personnel, and waste flow.

Contractors and visitors were made aware of all access restrictions and procedures related to them via Company Visitor Agreement policy dated 2018-10-23 (v13). Contractors working in production or storage areas are the responsibility of a designate manager.

The facility's site map and process flow diagram were used to identify the movement of personnel, raw materials, packaging, rework, and waste.

The site's storage and workspace were sufficient enough in size to provide operation's to be carried out in a safe and hygienic condition.

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

Fabrication of site, buildings and facilities observed to be suitable for intended purpose:

Walls- Walls were mostly observed to be maintained and in good condition, with no accumulation of dirt, condensation and/or mold. Walls are included in the cleaning program. The site's walls were made of mostly of sheet metal and/or concrete.

Floors- The floors were observed to be maintained and in good condition, without cracks or evidence that does not resist process needs and observed in good cleaning conditions. The site's floors were made of concrete.

Drainage- Included in the cleaning program, properly covered to avoid pest entrance.

Back flow prevention devices are installed and reported to be in good condition according to the site's last report dated 2022-09-06 to 2023-09-06.

Ceilings and overheads- Generally maintained in good condition, included in the cleaning program.

There were no suspended ceilings within the production or support areas.

Ceiling and overheads were maintained, in good condition, and included in the cleaning program. Elevated walkways are well controlled.

Windows, roof glazing and ventilation. Observed to be in good condition. Windows which open to the outside are properly screened to prevent the ingress of pests. Glass near production areas was observed to be protected against breakage. Natural / mechanical ventilation system were installed. No condensation or excessive dust observed.

Doors- All doors provided evidence that plants are properly sealed; no gaps between walls and/or floor were noted.

Docking area doors were observed in good conditions, close fitting.

Lights- Lighting was adequate for process needs. Process areas were observed properly protected and shatter proofed. Inspection areas observed with adequate light for proper performance of their operations.

4.5 Utilities – water, ice, air and other gases

The water distribution schematic diagram dated 2022-11-17 was used as a basis for water sampling. All water is potable and provided by Perham 2021 Drinking Water Bacterial Test and monthly City testing dated 2022-10-04. A testing sample schedule is in place and requires quarterly microbiological and chemical quality tests was conducted by a third-party lab. Satisfactory results for Coliform, E. coli, Chlorine Residuals, yeast, and mold dated 2022- 10-27 (building one) and 2022-10-04 (building two) was seen.

Non-potable water is not used.

Compressed air is generated by oil compressors. The organization has identified the steps in the process were compressed air is in contact with product or primary packaging at point of use. The oil is filtered at point of such with a 0.01 microns filter which is replaced every two weeks. The filter was last replaced on 2022-11-27.

The organization does not use CO2 / N2 for their production process.

The site's steam was in contact with their product, Control of boiler chemicals and tests were conducted to ensure purity. The following supplier documentation for the use of the boiler water treatment were reviewed and compliant: BWT 4391, OXY 42523, and RLT 4730 (issued 2011-05-17). The compliance profile is compliant with USDA regulations (G-6) and FDA for the treatment of boilers producing steam which contact food, including milk and milk products, in accordance with items of the Code of Federal regulations, CFR 21, Section 173.310, boiler water additives. The boiler log records were reviewed and compliant. Reviewed records were dated September 02, 2022 through December 02-2022. The site third-party boiler inspection was dated 2022-11-23.

4.6 Equipment

Food processing equipment observed to be industry standard. Key pieces of equipment include Corn Popping, slurry mixer, kettle, and packaging line. Equipment selection is based on Sanitary Design and industrial standards in compliance with FDA's 21 CFR. Equipment in direct contact with food including stainless steel mixers, stainless steel screw conveyors, stainless-steel product scales, and stainless-steel bins is food grade.

Minor Non-Conformance raised against 4.6.1- a. Four stainless steel product zone scoops used for popcorn and the sifting mesh screen drum was cracked and/or missing pieces on-line A.
b. The rubber sleeve around the conduit pipe (5) on the popper kettles were missing small pieces of the rubber.

4.7 Maintenance

The organization plans, tracks and record their maintenance program based on a software system. The system has controls in place to provide corrective/preventive/deductive maintenance based on defined routines.

Temporary repairs are controlled through the site's Maintenance Policy dated 2022-03-23 (rev.7).

Maintenance work is followed by documented hygiene/sanitation clearance Maintenance Repairs and Post Work Inspection Policy dated 2022-11-21 (rev.7) and a hand-over process to production is in place, evidence of compliance seen was documented on the Maintenance Repairs and Post Work Order form dated 2022-07-15, 2022-07-20, 2022-08-11, 2022-09-14, 2022-10-17, and 2022-11-10. The Preventative Maintenance

and Pre-op programs ensure that foreign materials contamination is removed before the line starts up. Work orders, P.M.'s and Pre-op's help to minimize and prevent the risk of foreign materials contamination to the site's product through equipment management. These methods help to limit the chances of worn and/or damaged equipment through assigned intervals.

Documented start-up checks are completed by production to ensure that the equipment will not put the site's product at risk. Appropriate actions are taken and documented if inspections are not compliant.
There are twenty maintenance team members and supported by contractors as appropriate.

Food grade lubricants including allergen status were listed on the site's maintenance shop within designated food grade specific cabinets. Location, identification, and clear determination on where permissible for use were evaluated and considered to be satisfactory.

Engineering workshop is situated near the boiler room and next to the warehouse (building two) and was observed to be well controlled with swarf mats in place to control contamination into other areas.

During the audit were assessed maintenance routines for the following equipment: corn popping, slurry mixer, and packaging line.

Equipment- Corn Popping
Routines verified- monthly
Period Reviewed- 2022-09-01, 2022-08-02, 2022-07-06, and 2022-06-09
Comments- The PMs were properly documented within the electric copies

Equipment- Kettle
Routines verified- monthly
Period Reviewed- 2022-08-23, 2022-07-18, 2022-06-20, and 2022-05-19
Comments- The PMs were properly documented within the electric copies

Equipment- Slurry mixer
Routines verified- monthly
Period Reviewed- 2022-09-09, 2022-08-10, 2022-07-14, and 2022-06-18
Comments- The PMs were properly documented within the electric copies

Equipment- Packaging line
Routines verified- monthly
Period Reviewed- 2022-09-14, 2022-08-18, 2022-07-20, and 2022-06-22
Comments- The PMs were properly documented within the electric copies

4.8 Staff facilities

Suitable staff facilities are provided. Changing rooms are adequate for number of staffs. Lockers allow for the segregation of personal items and production clothing. Clean and dirty production clothing are properly segregated.

Suitable handwashing facilities are in place. Toilets are segregated.

Adequate smoking facilities provided externally and include policies with respect to the use of electronic cigarettes.

Catering facilities is provided. The site used a third-party vending machine service.

The site's rest rooms were adequately segregated, provided appropriate handwash stations, and were in suitable hygienic conditions.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

Cleaning chemicals and lubricants are properly identified in the existing list of approved chemicals, properly contained, and segregated with non-food grade chemicals in specified lockers located in the maintenance shop and inside of locked chemical cages in both buildings.

Confirmation of suitability is conducted by management.

When in use chemicals are properly identified and employees are aware and trained on their proper use.

Safety Data Sheets are made available and used as part of existing training programs. The site uses an online web-based system for their SDSs, which is also available to employees through their computers within production through a link. The interviewed employees during the walk-through were able to explain where to locate the SDS's.

When strongly scented or taint forming materials are used the site has procedures are in place to reduce the risk of contamination.

4.9.2 Metal control

Sharp metal implements are controlled according to policy Foreign Body Detection & Physical Contamination Control dated 2022-03-29 (rev.19). This requires that they be inspected, records from 2021-10-14 to 2022-11-17 were seen. Snap-off-blade knives were not observed and reported to be forbidden.

The policy also confirms that packaging/ingredients which use staples is not permitted. Policies are in place to avoid the use of staples, paper clips etc.

4.9.3 Glass, brittle plastic, ceramics and similar materials

Glass breakage procedure dated 2019-02-13 (rev.7) was in place. Instructions for staff clothing were included and breakages are recorded on the Glass or Brittle Plastic Breakage Incident report document.

Glass and other transparent brittle materials have been excluded wherever possible from open product areas.

The glass and hard plastic register were up to date. Checks are conducted on a quarterly frequency and records for the check conducted on 2022-09-26 (building one) and 2022-09-25 (building two) were reviewed.

4.9.4 Products packed into glass or other brittle containers

The organization does not pack products in glass or brittle containers

4.9.5 Wood

Wood is used in production areas.

Wood is only used in pallets. In such cases there are inspections of conditions to reduce risk of product contamination.

Wooden pallets were checked for structural integrity upon receipt and through the use in production and within the warehouse. Wood within the site included pallets. They were noted to be in good condition during the site tour.

4.9.6 Other physical contaminants

When unpacking raw materials / ingredients care is taken to prevent cross contamination via the Foreign Body Detection & Physical Contamination Control policy dated 2022-03-29 (rev.19).

Writing implements comply with the standard – pens are controlled and managed through the Good Manufacturing Practices policy dated 2022-11-03 and within the Foreign Body Detection & Physical Contamination Control policy dated 2022-03-29 (rev.19).

4.10 Foreign-body detection and removal equipment

4.10.1 Selection and operation of foreign-body detection and removal equipment

A documented assessment dated 2022-07-22 and 2022-11-30 has been carried out to identify the potential use of equipment to detect or remove foreign body contamination. The site identifies their investigation process within their individual program such as magnet checks, metal detection process/program. The site's findings are tracked through their CAPA program.

4.10.2 Filters and sieves

Filters / sieves are located in the following areas: after bulk dry storage, after the scaled weigh hopper, and after the bulk liquid silo. The mesh/gauge is 30 mesh (flour and 16 mesh for sugar) and the oil straining was .125 (18") - adequate to reduce of further contamination. Filters/sieves are inspected/tested daily based on available risk assessment. Records from 2022-09-02 through 2022-09-28 (bulk sugar and flour) were reviewed. The strainer check was dated 2022-10-21 through 2022-11-22, reviewed and compliant.

4.10.3 Metal detectors and X-ray equipment

Metal detectors include an automatic rejection device / a belt stop system with an alarm where the product cannot be automatically rejected and an in-line detectors which identify the location of the contaminant to allow effective segregation of the affected product. Rejected items are isolated in a secure location. Metal detectors are calibrated by a third-party. The electronic metal detectors are password protected, and monitored checks are recorded after adjustments are made. Metal detector checks were reviewed, compliant, and dated 2022-09-26, 2022-11-14 and 2022-11-15 (supplements) and 2022-09-23 and 2022-09-26 (panning). The site metal checks are record in a third-party electronic database for all line except supplements and panning.

The site's metal detectors were located at the bagger, after the polishing pan (panning), prior to bulk filling.

Documented procedure Foreign Body Detection & Physical Contamination Control dated 2022-03-29 (rev.19) and Metal Detection Testing/Monitoring dated 2022-12-01 details controls for testing of the equipment including responsibilities, operating conditions including sensitivity; methods and frequency of checks and requirement to document the obtained results.

Process Step: Metal detection
Type and size of test pieces 1.5 FE, 1.5 Brass/NF, and 2.0 SS
Frequency of verifications- Start of each shift, at a minimum of every four hours, and at the end of weekly production.

Method used: Place the test card inside the center sample and run the package with the test card underneath the center of the metal detector. The rejection device kicks the product off the line, the line stops, and an alarm goes off.

Vertical lines: Insert the test wand into the testing metal opening/product flow. The rejection device kicks the product off the line, the line stops, and an alarm goes off.

Action plans when failures in the equipment- shut down the line, notify the supervisor, determine the root cause/investigate the source and/or reason, and hold product back to the last good check of the metal detector. The held product was required to be passed through a functioning metal detector.

Test observed during site tour and conducted correctly.

4.10.4 Magnets

Magnets are located after the holding tank, after the bulk sifter, and after the mixing buffer. Inspection of the magnets is conducted via Foreign Body Detection & Physical Contamination Control policy dated 2022-03-29 (rev.19). This is required to be done annual for building one. There are no magnets at building two. The pull test was last conducted on 2022-10-24. Records reviewed on site provided details of test results. Weekly magnet check was dated 2022-11-12, reviewed, and compliant.

If the magnet shows 15% difference from the baseline reading, the defective magnet must be replaced per the site's Magnetic inspection form dated 2022-06-19.

4.10.5 Optical sorting equipment

Optical sorting equipment is used for color and shape. The optical sorter is not used for foreign materials.

The optical sorter conducts daily verifications within the site's electronic database system, records for 2022-12-05 was reviewed and compliant.

4.10.6 Container cleanliness – glass jars, cans and other rigid containers

Tins, PVC/PET tubes are used. The containers are inverted, covered, shrink wrapped on a skid. The product is packaged and the tins, PVC/PET tubes are inspected during the packaging process. There is no cleaning process.

4.11 Housekeeping and hygiene

A team of production employees, sanitation employees, a cleaning crew clean the facility during the daily, during the week and during the weekend. Prestart checks and equipment cleanliness were verified during the audit. Site was maintained in appropriate level of cleanliness.

Written cleaning methods/instructions are in place. The cleaning methods/instructions for corn popping, slurry mixer, kettle, and packaging line were checked during the audit.

Cleaning records are analysed, and trend analysis are available to instigate improvements where required.

Cleaning is verified via ATP swabs and pre-start visual inspections. Records for 2022-09-24 were reviewed. Out of specification results have been defined and the corrective action is described in the procedure.

The site's utensils, tools, and equipment used for cleaning was suitable for its intended use/purposes. The equipment was clearly identified through color coding and was clean. The tools were stored on equipment shadow boards and equipment hooks for the separation of food-contact and non-food contact equipment. The utensil, tools, and equipment were also stored in a hygienic manner.

4.11.7 Cleaning in place (CIP)

There is no CIP in use.

4.11.8 Environmental monitoring

The facility has developed a program which requires ATP, Coliform, Salmonella, Listeria spp. testing based on the areas. (e.g., zone 1- random testing for Coliform- food contact surfaces, zone 2-non-product zone contact zones- Salmonella testing monthly, zone 3- Salmonella testing monthly and random Listeria spp. twice per year, and zone 4 Salmonella testing monthly).

Acceptable limits have been defined within the Microbiological Testing procedure and dated 2021-10-28 requires that the following actions be taken when these limits are exceeded recleaned and sanitized then retested.

The last review of the program was triggered by an annual review.

Environmental test results were reviewed from July through September 2022. The results were mostly negative/not detected per swab and was in compliance. On 2022-08-04 (swabbed)/test date 2022-08-09 a floor drain tested positive for Salmonella. The site conducted vector swabs on 2022-08-11, the results were negative for Salmonella. The site took three consecutive sample swabs of the floor drain on 2022-08-15, 2022-08-16, and 2022-08-17. The drain came back positive for the 2022-08-15 swab sampling. The other two were negative. A total of ten samples were taken for each sampling date. The site cleaned and swabbed on a routine swab test on 2022-08-24 which came back positive. The site kept getting positive hits on the floor drain, the drain was replaced on 2022-11-23 through 2022-11-28. After the replacement of the drain, deep cleaning was completed within the room dated 2022-11-23, and the three consecutive swabs 2022-11-29, 2022-11-30, and 2022-12-01 came back negative. All other reviewed testing results for the months of July through September was negative except for the floor drain.

The site's CAPA was started on 2022-08-09 and is currently still open await more testing results/trending results.

4.12 Waste

Waste was observed to be well managed. All waste is removed from production on a regular basis.

External waste collection containers/rooms housing waste are well managed. Containers are properly covered.

Waste is removed by licensed contractor. Unsafe product or trademarked waste is disposed of by a third-party waste management company and records retained.

4.13 Management of surplus food and products for animal feed

There are no surplus foods.

Waste for animal feed is popcorn. The recipient is properly registered with the relevant local authority.

4.14 Pest management

The organization has a preventive control program in place to minimize risk of infestation which includes external service provided by a licensed third-party pest control company.

The following is a description of the existing program

Contract or document that describe service- 2022-01-19.
License or permit- Minnesota Department of Agriculture valid until 2022-12-31.
Pest covered- rodents, crawling, birds, and flying insects
No. of routine visits- 52
Station map- 2022-12-06 (building one) and 2022-12-05 (building two) which matches with existing numbered pest control devices.
Type of used pest control devices- Interior Rodent Traps, External Bait Stations, Pheromone traps, Dome, and Tent, and ILT.
In-depth pest control surveys- The frequency is annual and lasted conducted on 2022-01-19 (building one) and 2022-01-19 (building two) through their licensed third-party pest control company.

Controls in case of infestation- Through inspection with treatment as needed.

Birds control was addressed as a part of the site's IPM program to prevent the birds from entering the building of roosting above the loading and unloading dock areas. Doors were also kept closed and the outside grounds were monitored. The PCO actively look for signs of birds while servicing the exterior monitoring devices.

The organization has a list of approved pest control products used which include MSDS's. Bait stations are robust and secured in place. Toxic rodent baits are not used in open product areas. EFKs and pheromone traps are correctly sited.

Inspection reports provide details of the inspections conducted, if any activity is reported inside or outside the facility, recommendations are provided, and actions are taken over such recommendations.

Reports are assessed every quarterly for trending which includes catch analysis existing information to provide evidence to support that in the last 12 months there has not been infestation.

Interviewed employees understand the signs of pest activity and are aware of the steps to be followed to inform of pest activity to designated functions.

4.15 Storage facilities

Storage facilities was observed to be satisfactory. This included raw materials, packaging materials, and finished products. Packaging was stored away from raw materials, finished products, and properly covered to prevent contamination. Allergens were segregated by like over like or stored within a floor location. The site's allergens were wheat, soy, eggs, milk, tree nuts, and peanuts. The site's tree nuts and peanuts are pasteurized and in nut form, coatings, and/or within candy pieces.

The site received bulk liquid corn syrup, cane syrup, fructose (building one) and sunflower oil (building two). Dry bulk ingredients are granulated beet sugar and flour for building one. The dry ingredient bulk tanks/silos are located on the outside. All other silo's were located inside (liquid ingredients).

The site's used electronic locks to secure access loading ports on their bulk ingredient storage silos. The codes for the locks changes for each load and are only available for authorized employees.
There are temperature controls for quality purposes only. The site has a cooler and a freezer in building number one and a cooler in building number two. The site's coolers and freezer are for quality purposes only. Building one cooler stored colors, flavor, and juice concentrate and building two cooler stored butter and candy pieces. Building one freezer stored juice concentrate.

The system is alarmed and set at 37-degree Fahrenheit for the coolers and 16-degree Fahrenheit for the freezer. The site did not store product for food safety.

The temperature management system is manual and is monitored daily, this allows sufficient time to take action before the product exceeds defined limits. Documentation was reviewed and dated 2022-09-04 through 2022-09-22 (cooler/building two) 2022-09-20 through 2022-09-28 (Freezer/building One) and 2022-09-22 through 2022-09-17 (Cooler/building One).

The following dates were also reviewed and compliant the freezer temperature log dated 2022-10-27 through 2022-11-03, cooler (B1) temperature log dated 2022-10-24 through 2022-11-02, and cooler (B2) temperature log dated 2022-09-04 through 2022-09-12.
Controlled atmosphere storage is not applicable.

Outside storage is not conducted.

Stock rotation is controlled by FEFO (ingredients) and FIFO (finished products). Program was observed properly followed.

4.16 Dispatch and transport

Dispatch observed to be satisfactory. Loads are inspected prior to dispatch which includes documented verification of seals, odors, visual conditions, debris, container conditions, and compatible materials.

Vehicles are provided by mix of customers and third-party contractors.

Containers are not required to control temperature.

The site's Maintenance systems had documented cleaning procedures available for all vehicles and equipment used for loading/unloading. The site had records of the measures.

Vehicles used such as forklifts, trucks, pallet trucks were observed in good condition during the audit documented on the site's SOP- Storage and Transportation (Forklift Operation and Maintenance) dated 2022-03-10.
The documented procedures for transportation include restrictions in the loads, security measures during transit, and instructions in case of breakdowns or accidents.

Approved third party contractors are BRCGS S&D / GFSI certified or meet requirements which are described in contracts. Examples seen include third-party transportation company contract. The contract/Storage, Transportation, and Security policy. The policy/contract was signed on 2022-03-03.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
4.4.5	There were no suspended ceilings within the production or support areas
4.9.4	There are no products packed in glass or brittle containers
4.10.5	There is no optical sorting equipment
4.11.7	There is no CIP in use
4.13.1, 4.13.2	The site does not sell/donate surplus customer branded product
4.14.3	The site does not undertake its own pest control
4.15.4	There is no controlled atmosphere storage
4.15.5	There is no outside storage
4.16.3	There is no temperature control required for transport

5. Product control

5.1 Product design/development

Product development and design procedure is in place dated 2021-12-01. Procedure is applicable for new, modified products and includes HACCP review and production trials.

Shelf-life tests are conducted following documented protocols which demonstrates compliance with relevant microbiological, chemical, and organoleptic criteria.

Records for the following shelf-life products were reviewed:

Product Description: Drizzle coated popcorn (item number: 300125)
Start Date: 2021-10-13
End Date: 2022-05-11
Product Description: licorice (item number: 120184)

Start Date: 2021-05-21
End Date: 2022-05-21

5.2 Product labelling

The company ensures that labels are legal for the country of use by inspecting and reviewing the labels for accuracy. Process is followed also in case of changes to recipe, raw materials and supplier or country of origin legislation. The R&D regulatory, Quality Assurance Manager, and food technologist I and/or II are responsible for the site labels/preprint bags and specifications. The site only used pre-printed bags.

Evidence seen during the audit included Metallize Packaging Film (Item number: 35275C/Lot number: H609307/3/1/1)
All ingredients specification listed within the Drizzled Popcorn (Item number: 350070) recipe was reviewed and compared to the finished product specification and label to ensure that the finished product label was correct/had no missing ingredients. Reviewed documentation for ingredients were complaint.

Where claims are made these are verified through certification. See selection 5.4 for claim certifications.

The site's product was RTE and did not include cooking instruction.
The site produced RTE gummy dietary supplements, the extrusion of snack products, the popping and coating of popcorn and coating of pre-made snacks and nuts which does not need further processing.

5.3 Management of allergens

The company have an allergen control procedure in place and dated 2022-11-18 which includes assessment of raw materials to establish the presence and likelihood of contamination by allergens.

The sites allergen(s) were wheat, soy, eggs, milk, tree nuts, and peanuts.

A risk assessment dated 2022-07-22 (licorice, gummies, supplements), 2022-08-25 (panning), 2022-11-30 (popcorn), 2022-12-01 (enrobed), and 2022-07-28 (extruder) has been conducted to identify routes of contamination.

Procedure Allergen dated 2022-11-18 have a list of the site's allergens containing materials which included raw materials, processing aides, intermediate and finished products.

Allergen rework is controlled by Allergen procedure dated 2022-11-18 and through an electronic warehouse management system to avoid cross contamination.

Warnings are in place on labelling as appropriate.

Claims made regarding suitability of a food for allergy or food sensitivity sufferers is fully validated Documented Gluten Free Certification Organization valid to 2023-11-30. Claims were made due to raw material status and/or the status of every batch (Gluten free). Examples of the Gluten testing results were seen for 2022-10-24 through 2022-11-07 (popcorn) and 2022-01-02 through 2022-09-01 licorice and raw materials/rice flour, rainbow sprinkles, and finished product) testing and were compliant.

Cleaning methods have been validated:

Allergen- Wheat
Protein Specific Swab Neogen Reveal 3D (wheat)
Date- 2022-11-19

Allergen- Soy
Protein Specific Swab Neogen Reveal 3D (soy)
Date- 2022-11-19

Allergen- Dairy
Protein Specific Swab Neogen Reveal 3D (Total Milk)
Date- 2022-11-19

Allergen- Eggs
Protein Specific Swab Neogen Reveal 3D (Eggs)
Date- 2022-11-19

Allergen- Peanuts
Protein Specific Swab Neogen 3D Reveal (peanuts)
Date- 2022-11-19

Allergen- Tree nuts
Protein Specific Swab Neogen Reveal 3D (tree nuts)
Date- 2022-03-10

The site had allergens cleaning instruction on file. Allergen cleaning Instructions dated 2022-08-05 (popcorn), 2022-07-21(licorice), and 2020-11-18 (extruder) were seen.

Line start-up checks are in place for product change over and changes in batches of packaging to ensure labels applied are correct for products packed. Records for 2022-09-26 checked.

5.4 Product authenticity, claims and chain of custody

Company has access information on risks of adulteration or substitution of raw materials via trade associations / government sources/ private resource centers.

A vulnerability risk assessment dated 2022-11-21 was made available to assess the potential of adulteration or substitution. Due to the assessment the organization identified certain raw materials as being affected.

The following examples were noted:

Ingredient- Hemp Extract w/coconut MCT

History of Food Fraud- Historical evidence
Evidence- Dilution of substitution with an alternative ingredient, misrepresentation of botanical origin

Ingredient- Butter and Milk fat
History of Food Fraud- Historical evidence
Evidence- Replacement with margin or other vegetable oils

Ingredient- Chocolate, compound coating, cocoa butter, coco powder, diary free compounds, peanut butter chips
History of Food Fraud- Historical evidence
Evidence- replacement with cocoa butter substitute or lard, powder nuts, grains, spices, sugars, or carob. Unapproved colors and flavor

Ingredient- Corn meal
History of Food Fraud- Historical evidence
Evidence- Replacement with cheaper ingredients or with substances to make protein content appear higher

Ingredient- Color
History of Food Fraud- Historical evidence
Evidence- Replacement with pigments from less expensive sources if sourced outside the US.

The controls in place are the following: An annual review of the risk assessment, incoming inspection of raw ingredients, and continuous monitoring of FDA throughout the year and other industry sources for potential misuse and cases of EMA.

Product claims are in place. The status of each batch of raw materials is verified by quality assurance and records maintained. Evidence of the certificates are listed below.

The organization provided copy of the documented process flow for production of products with claims which identify potential areas for contamination or loss of identity identified and controls established.

The auditor/rabbi comes yearly. They review documentation and conducts inspections only. No trace exercises are conducted for the Kosher, NSF Dietary Supplement certification, and RSPO.

Certificates valid to:

Product Claim Types: Kosher
Documented: Orthodox Union- Letter of Kosher Certification valid to 2023-06-30.

Product Claim Types: Organic
Documented: National Organic Program Certification of Compliance- Certified Organic valid 2023-06-21

Product Claim Types: RSPO
Documented: RSPO Supply Chain Certification (Sustainable Palm Oil) valid to 2023-10-23.

Product Claim Types: Gluten Free
Documented Gluten Free Certification Organization valid to 2023-11-30.

Product Claim Types: Non-GMO
Documented: Non-GMO Project Verified Certification, valid to 2023-08-29.

The site also has an NSF Dietary Supplement certification (NSF Certificate of Conformity. The expiration date was 2023-11-09.

These claims are labelled onto finished products: Drizzled Popcorn (Item number: 350070/Non-GMO) and Item Number: S760027 (Gummy Supplement/Organic), and Popcorn (Item number: 125411/Gluten Free).

The last traceability exercise to confirm this status was conducted 2022-03-16 and 2022-11-28 with satisfactory results, these are conducted every 6 months.

A trace exercise is only required for the site's Organic (2022-03-16 and 2022-10- 17) & Gluten Free and Non-GMO (2022-11-28 and 2022-0407).

5.5 Product packaging

Purchasing of food contact packaging includes the need to provide particular characteristics of the food to ensure the provided material is suitable for the intended use. Evidence seen during the audit included Metallize Packaging Film (Item number: 35275C/Lot number: H609307/3/1/1) specifications.
Obsolete packaging is managed via Product Packaging procedure dated 2021-11-18 and through a designated storage area.

Bags / liners for work in progress were robust and blue color.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Test critical to confirm product safety, legality and quality are performed by the organization laboratories.

Tests include salt, bulk density, moisture, color, flavor, P.H., water activity, brix, solids, starches, piece size, piece weight. The regime does properly consider risk. Results are recorded and reviewed regularly to identify trends.

Test results are compared against product specifications or acceptability criteria to identify compliance and relevance of reported determinations, when deviations are identified the organization treat product as non-conformity/re-evaluate test results before actions are taken. The site's shelf-life records and results matched the shelf-life for their product. The shelf-life records and ongoing study is documented within clause 5.1.

Pistachios is the only tree nut received in whole nut form. The COAs are received prior to the use of the site's product/at receiving. The COA were reviewed, compliant, and dated 2022-05-15 (Pistachios), 2022-05-09 (candy pieces that contained eggs and peanuts), 2022-10-11 (milk-chocolate coating), and 2022-09-01 (soy lecithin-liquid). The site's allergens are RTE coatings, toppings, pasteurized nut form, oils and used within the site's licorice cooking process minimum of 215 Fahrenheit. The site also uses liquid and solid fats.

Product inspection and testing results for 2022-09-26 seen during audit.

5.6.2 Laboratory testing

Laboratory testing is carried out by in-house laboratory for analytical / external accredited laboratory which follows the principles of ISO 17025 this applies if pathogen test is conducted by a third-party laboratory for which the scope of services matches the tests conducted.

The third-party laboratory accreditation was valid until 2024-03-31.

The site does not conduct pathogen testing onsite within their lab. Environmental pathogen testing is conducted through an external lab. The test results for all third-party tests for July through September 2022 were seen and were compliant. The site does not test finished product for pathogens.

The reliability of in-house laboratory results includes recognized documented test methods, qualification of laboratory staff, and implementation of ring/proficiency tests, inclusion of laboratory equipment in calibration and maintenance programs.

The site's testing is carried out with acceptable and action limits is established so that the results of the tests can be understood. The staff receiving and reviewing the test results was able to explain the process, which also included unsatisfactory results. The trace records reviewed were satisfactory results.

A schedule of testing is in place, satisfactory results were seen for:

Test- color, flavor, length, water activity, P.H., brix, solids, starches, moisture, and diameter.
Frequency- hourly.

Test- color, water activity, P.H., and brix, solids.
Frequency- once per batch.

5.7 Product release

Product is released on meeting the specification requirements which demonstrate criteria have been met. Product release is conducted by the Quality Assurance Department.

The site's finished products are delivered to the shipping dock and receives a final inspection prior to loading.

5.8 Pet Food

The factory does not make pet food.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
5.2.5	There are no cooking instructions.
5.8	The facility does not make pet food

6. Process control

6.1 Control of operations

Process observed to be well controlled.

Documented process specifications / work instructions are available for key processes in production. Process specifications were assessed during the audit as well as part of the traceability study. Documents reviewed demonstrated that process specifications meet final product specifications.

Key process monitoring includes water activity, P.H., brix, solids, starches, and diameter, cooling, and humidity in the tunnels, cook temperatures, starch temperatures, coil temperatures, electronic metal detectors, magnet checks which are controlled by manual / in-line monitoring devices. Records were seen

for 2022-09-26, 2022-11-12, and 2022-09-29 (2). Process monitoring is documented within the site's quality assurance internal database system.

The site's testing is carried out with acceptable and action limits is established so that the results of the tests can be understood. The staff receiving and reviewing the test results was able to explain the process, which also included unsatisfactory results. The trace records reviewed were satisfactory results.

Process conditions are critical safety and quality parameters of the product. The site's cook processes have in-line control which is validated by a third-party company and monitored by production employees. The monitoring of the quality in-processing controls is monitored by the operator and validated by a third-party company. The sites in line controls were as followed: cook processing, sieves/filters (CP), electronic metal detectors (CCP), and magnets (CP).

In the event of issues with foreign material control devices (magnets/sifters/metal detectors), corrective actions were in place and would default to Non-Conforming and Hold programs.
Equipment failure is covered by non-conformance procedure.

Access to key pieces of equipment such as the Electronic Metal Detector is controlled via a quality assurance internal database system and equipment storage area.

The site's maintenance department is authorized to change and set their metal detector. The maintenance team is conducted training prior to coming to work and it is a part of the job tasks/description.

6.2 Labelling and pack control

The company ensures that the correct labelling / packaging is available on the line through regular monitoring, by inventory and verification packer/operator. Label monitoring/checks are documented within the site's quality assurance internal database system which are documented hourly.

Packaging controls consisted of poly film (pre-printed), metalized film (pre-printed), resealable pouches (pre-printed), form and fill bags (pre-printed), bulk containers (jet printed or sticker applied to the corrugated boxes), tins (sticker applied and/or pre-printed sticker), and PVC/PET tubs (pre-printed sticker). The labels consisted of the following data: Product name, item code, lot code, expiration date, ingredients, net weight, plant name & address, etc.

A documented label procedure to determine that checks are carried out to minimize errors is available. The frequency for checks were predetermined and based on risk within the policy. The policy was on file.

Documented procedures are in place to ensure that products are packed into the correct packaging and correctly labelled.

These checks included: Date, time, int., line, code date, that the correct label is applied, correct film, correct cases, listed allergens, correct UPC, correct bag size, and correct jet printed applied.

Documented checks are conducted at the beginning, during and at the end of production. Records for 2022-09-26 and 2022-12-06 was seen during the audit.

Due to production runs / scheduling no changeover observed during the audit.

On-line vision is used.

On-line vision was with the site's QA Packaging procedures dated 202-03-02 were in place to ensure that the system is correctly set up and able to alert and/or reject product when packaging information is out of specification/in correct.

6.3 Quantity, weight, volume and number control

Products are checked for quantity/weight. Controls are done using product scale and in-line scale.

The site does not produce product for bulk.
Online checkweighers are managed through Scale Verification procedure dated 2022-08-01.
Weights are monitored:

Product- Piece weight
Frequency- daily
Method of weight checks- Manually checked and records the weights with a quality assurance third-party internal database system.

Product- bag weight
Frequency- hourly
Method of weight checks- Manually checked/product passes through the in-line scale and records the weights with a quality assurance third-party internal database system.

Product- bulk boxes
Frequency- hourly
Method of weight checks- Manually checked and records the weights with a quality assurance internal third-party database system.

6.4 Calibration and control of measuring and monitoring devices

A list of equipment requiring calibration is documented within the Calibration Master List and Schedule Excel Spreadsheet.

Equipment used to monitor CCP's, product safety or legality includes:

Item- Weight
Frequency- Annual
Valid until- 2023-09-30 and 2023-11-30

Item- Scales
Frequency- Annual
Valid until- 2023-02-20 (building one) and 2023-02-28 (building two)

Item- Metal detector
Frequency- Annual
Valid until- 2023-10-22 and 2023-10-11

Item- P.H. Meter
Frequency- Daily
Valid until- 2022-12-07

Item- Moisture meter
Frequency- Annual
Valid until- 2023-02-28

Item- Refract Meter
Frequency- Daily
Done- 2022-12-07

Item- Water Meter
Frequency- Daily
Done- 2022-12-07

Item- Checkweigher
Frequency- Annual
Valid until- 2023-02-28

Reference equipment is stored in the quality assurance lab.
Procedures for control of out of specification equipment are available which include documentation of actions taken.

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
6.3.2	There is no product where quantity is not governed by legislation e.g., dispatched in bulk

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

Relevant personnel, including agency-supplied staff, temporary staff and contractors are trained prior to coming to work, this also included allergen, labelling and packaging process training which is based on the task and/or job function. New employees are supervised for 90 days plus an additional time period to evaluate adherence and compliance to defined rules.

All visitor which includes agency-supplied staff, temporary staff and contractors receives training through the site's Visitor policy.

Training records for labelling and packing was dated 2022-05-13, 2022-05-03, 2022-06-16, 2022-07-13, 2022-05-14, and 2022-05-10.

Training records for Security/Food Defense was dated 2022-04-30.

Training records for Quality Assurance Product Testing's was dated 2022-10-27 and 2022-11-21.

Training records for sifter checks was dated 2022-10-27

Training records for Allergens was dated 2022-05-14.

Training records for EMD checks was dated 2022-05-13, 2022-05-03, 2022-06-16, 2022-07-13, 2022-05-14, and 2022-05-10.

Employees engaged in activities relating to critical control points are assessed for competency and training requirements. The assessment for competency is conducted through (e.g., internal audits, job training matrix, etc.) Records for EN/Packaging Operator, DR/Packaging Operator, JF/Packaging Operator, LB/Packaging Operator, and VL/Packaging Operator were seen.

Training records assessed provide the name of the trainee, date and duration, title of the course, the training provided, and results of training effectiveness. Training is provided in a language that is understood by employees – English and Spanish.

During the audit the training and competency requirements were assessed for the employees in the below table which demonstrate compliance with the program requirements and expectations.

The following employees were interviewed:
Employee Initial/Title- JF/Packaging Operator
Location- GMP, Pest Control, Confidentiality, Non-conformance, Allergens, and Food Defense/Security, SDS, Metal detector checks and reject process, packaging verification, and code date.

Employee Initial/Title- JT/Packaging Operator
Location- GMP, Pest Control, Confidentiality, Non-conformance, Allergens, and Food Defense/Security, SDS, Metal detector checks and reject process, packaging verification, and code date.

Employee Initial/Title- VL/Packaging Operator
Location- GMP, Pest Control, Confidentiality, Non-conformance, Allergens, and Food Defense/Security, SDS, Metal detector checks and reject process, packaging verification, and code date.

Employee Initial/Title- LB/Packaging Operator
Location- Metal detector checks (false reject, non-metal rejects, and metal rejects) and reject process packaging verification, and code date.

Employee Initial/Title- LL/Packaging Operator
Location- Metal detector checks (false reject, non-metal rejects, and metal rejects) and reject process packaging verification, and code date.

Employee Initial/Title- EN/Packaging Operator (second shift)
Location- Metal detector checks (false reject, non-metal rejects, and metal rejects) and reject process packaging verification, packaging change-over process, documentation process, and code date.

Employee Initial/Title- DR/Packaging Operator (second shift)
Location- Metal detector checks (false reject, non-metal rejects, and metal rejects) and reject process packaging verification, packaging change-over process, documentation process, and code date.

Minor Non-Conformance raised against 7.1.1- One employee was using cornmeal which is an ingredient as an absorbent to clean-up cheese slurry that had spilled on the floor.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

Personal hygiene rules are documented within the Good Manufacturing Practices policy dated 2022-11-03 and compliance is checked by the management team. During the audit these were observed to be properly followed.

Hand cleaning observed to be performed appropriately. Entry to production and at a frequency as appropriate.

Cuts and grazes on exposed skin are covered through the use of an appropriately colored plaster/band-aid. metal detectable plasters. Where appropriate in addition to the plaster, a glove is worn. Blue metal detectable plasters/band-aides are used; a sample of each batch of plasters is checked through metal detectors recorded on 2022-11-01 through 2022-11-29. The site uses metal detectable band aides, ear plus, and pens.

Use and storage of medicines are described in Good Manufacturing Practices policy dated 2022-11-03.

7.3 Medical screening

Employees are made aware of and know who to notify in the case of symptoms of infection, disease or condition which would prevent a person from working with open food through the Good Manufacturing Practices policy dated 2022-11-03.

Visitors and contractors are aware of conditions that prevents visiting areas with open food through the Company Visitor Agreement policy dated 2018-10-23 requires them to inform the organization if suffers of any identified conditions by informing a member of the management team.

Procedure Company Visitor Agreement dated 2018-10-23 describe actions to be taken in case of been in contact with an infectious disease.

7.4 Protective clothing: employees or visitors to production areas

The use of protective clothing is defined and documented in the Good Manufacturing Practices policy dated 2022-11-03.

Protective clothing includes shirts, pants, disposable plastic aprons, hairnets, beard nets, cloth gloves, and safety glasses. Uniforms are not provided. Lab coats are provided in key areas. The site's risk assessment for clothing was dated 2022-11-17. The employees are able to wear their personal clothing. Cleaning instructions are located in the site's Good Manufacturing Practices policy dated 2022-11-03 under the clothing section (3).

Laundering services for the site is completed by a third-party laundering service for their lab coats.

Gloves are controlled through a vending machine (cloth) and plastic disposal gloves are on the lines where employee have access to them. The site has a storage area in both buildings for the storage of their gloves within vending machines (cloth) and locked storage (plastic gloves).

The site used disposable gloves both plastic for product zone areas and cloth gloves at the end of the packaging lines. Plastic gloves are used within the product zone areas.

Details of non-applicable clauses with justification

Clause/Section Ref	Justification
N/A	

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones

8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones

The site does not have High Risk, High Care, or Ambient High-Care production risk zones.

8.2 Building fabric in high-risk and high-care zones

N/A

8.3 Maintenance in high-risk and high-care zones
N/A
8.4 Staff facilities for high-risk and high-care zones
N/A
8.5 Housekeeping and hygiene in the high-risk high-care zones
N/A
8.6 Waste/Waste disposal in high risk, high care zones
N/A
8.7 Protective clothing in the high-risk high-care zones
N/A

Details of non-applicable clauses with justification	
Clause/Section Ref	Justification
8	The site does not have High Risk, High Care, or Ambient High-Care production risk zones.

9 - Traded Products
9.1 Approval and performance monitoring of manufacturers/packers of traded food products
Not applicable
9.2 Specifications
Not applicable
9.3 Product inspection and laboratory testing
Not applicable
9.4 Product legality
Not applicable
9.5 Traceability
Not applicable

Module 11: Meat supply chain assurance	
Scope	Not applicable

11.1 Traceability
Not applicable
11.2 Approval of meat supply chain
Not applicable
11.3 Raw material receipt and inspection
Not applicable
11.4 Management of cross-contamination between species
Not applicable
11.5 Product testing
Not applicable
11.6 Training
Not applicable

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018			
Clause	Module item	Conforms Y/N	Comments
13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.		
13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.		
13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth		

	of microorganisms and allergen cross-contact.		
13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.		
13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.		
13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety		
13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).		

13.1.8	Establish one or more preventive control(s) for each identified “hazard requiring a preventive control” (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product		
13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRCGS section 2.10.		
13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements		

	of BRCGS sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).		
13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.		
13.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
13.1.14	Where product testing for a pathogen (or indicator organism) or		

	other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		
13.1.16	Devices used to verify preventive controls must be calibrated.		
13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls,		

	review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.		
13.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.		
13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		
13.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific		

	supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.		
13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.		
13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.		
13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against contamination, including the following: - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that identifies the product by the common or usual name must be		

	affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		
13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.		
13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying		

	significant vulnerabilities and actionable process steps • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum): • Scale and severity of threat if a contaminant is added to product • Degree of physical access to the product • Ability of an attacker to successfully contaminate product—including consideration of an inside attacker A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.		
13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the		

	vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.		
13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.		
13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions		
13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to		

	verify implementation of mitigation strategies. Verification procedures shall include: • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities		
13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence		
13.3.9	All records required by 21 CFR § 121 must include:		

	• Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable		
13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.		
13.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.		
13.4.1	Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or containers are not in a clean condition, they shall not be used.		

	A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.		
13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.		
13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be		

	communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.		
13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.		
13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.		
13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety		

	• Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper		
13.4.7	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems • Responsibilities of the carrier		
13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite records shall be retrievable within 24 hours.		
13.4.9	The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.		
13.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional		

	training on the following: • Principles of food hygiene and food safety Produce safety standards applicable to an individual's job		
13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment		
13.5.3	One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.		
13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be		

	identified on the site's organizational chart.		
13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.		
13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.		
13.5.7	Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable		

	generic Escherichia coli (E. coli) in 100mL.		
13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.		
13.5.9	Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria. Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.		
13.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency		

	(EPA), "Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007)," December, 2009 or equivalent method.		
13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.		
13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.		
13.5.13	Sewage disposal and septic systems shall be controlled and		

	appropriate for the site to prevent the contamination of produce and food contact surfaces.		
13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.		
13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.		
13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes used by the site for analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts. Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria:		

	• Target test (i.e., Listeria spp. or L. mono) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) The plan shall describe aseptic methods for sample collection and testing according to FDA's "Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples," Version 1, October 2015 (or equivalent).		
13.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts. The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono. If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process: • Resample positive surfaces and the		

	surrounding area to determine the extent of contamination • Clean and sanitize the affected and surrounding areas • Resample and re-test to confirm the elimination of Listeria spp. or L. mono • Conduct finished product testing as appropriate • Take additional action to prevent recurrence and to prevent adulterated food from entering commerce		

14.1 Additional Specifier requirements

14.1 Traceability

The site tested the traceability system twice during the year by conducting separate traceability exercises using Sweet and Salty Popcorn (Item number: 300245/lot number: 583179) conducted on 2022-11-28, 100% was located in 39 minutes; and Metalized resealable pouch (item number: 39963/lot number: 125411), conducted on 2022-04-26, 31 minutes/100%. The on-site trace exercise was conducted using Drizzled Popcorn (Item number: 350070/Lot number: 594088)100% was located One hour and 54 minutes.

The site only produces popcorn and licorice candy for the customer requesting this addendum.

14.2 Environmental Monitoring

The site does not produce high risk as defined by the customer.

The site produces include Licorice, Gummy, Panning, Extruded snacks, Supplements, Enrobed products, popcorn, and Coated nuts which are low risk products. However, the site only produces low risk RTE products such as licorice and popcorn for the customer who is requesting this addendum.

A documented environmental sampling monitoring program was used to detect organisms of concern are listed below. The program was based on a risk assessment of the operation and its effectiveness was re-evaluated when deficiencies were identified or at least annually. On-going review and analysis of data from routine monitoring programs was performed to detect trends.

The facility has developed a program which requires ATP, Coliform, Salmonella, Listeria spp. testing based on the areas. (e.g., zone 1- random testing for Coliform- food contact surfaces, zone 2-non-product zone contact zones- Salmonella testing monthly, zone 3- Salmonella testing monthly and random Listeria spp. twice per year, and zone 4 Salmonella testing monthly).

Acceptable limits have been defined within the Microbiological Testing procedure and dated 2021-10-28 requires that the following actions be taken when these limits are exceeded recleaned and sanitized then retested.

14.3 Product inspection and laboratory testing

The site does not produce high-risk products. The site's ready-to-eat products is low risk. The site products include Licorice, Gummy, Panning, Extruded snacks, Supplements, Enrobed products, popcorn, and Coated nuts. The site only produces popcorn and licorice candy for the customer requesting this addendum. The site does not conduct pathogen testing on their finished products. The site also only uses pasteurized nuts.

The site does not test their finished products for pathogen testing. Raw ingredients are tested such as: testing consisted of Salmonella/pathogen, yeast, salt level, moisture (Pistachios), Salmonella/pathogen, Yeast and mold, APC (candy pieces that contained eggs and peanuts), and Salmonella/pathogen, Listeria, E. coli, Yeast and mold, Coliform, APC, and Coagulases positive staph (milk-chocolate coating), Salmonella/pathogen, Listeria, E. coli, Yeast, and mold (soy lecithin-liquid). The site placing the raw ingredient on hold which is described within their non-conforming product procedure dated 2022-11-18.

14.4 Protective clothing: Employees or visitors to production areas

The site had a "No Bare Hands" policy and written procedure on using and handling gloves where there was direct hand contact with ready-to-eat products of all risk levels. Reusable gloves were washed and sanitized frequently. Fabric gloves were covered with an outer disposable glove. All disposable gloves were latex and powder free.