SQF Food Safety Audit Edition 9

Corim Industries, Inc.

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
24733 | 410442

AUDIT RATING
96
Excellent

DECISION DATE
06/19/24

AUDIT TYPE
RE-CERTIFICATION

RECERTIFICATION DATE
05/13/25

AUDIT DATES
05/20/24 - 05/21/24

EXPIRATION DATE
07/27/25

ISSUE DATE
07/09/24

Facility & Scope

Corim Industries, Inc.
1112 Industrial Pkwy
Brick NJ 8724
USA

Food Sector Categories:
16, 19

Products:
Chai tea, tea, drink mixes, coffee, cappuccino, hot chocolate mix, instant coffee, gelatin mixes, instant pudding

Scope of Certification:
SQF Food Safety Edition 9

Certification Body & Audit Team

Eurofins
2120 Rittenhouse St., Suite A, Des Moines, IA 50321

CB#: CB-1-Eurofins
Accreditation Body: ANAB
Accreditation Number: 9166

Lead Auditor: Vernon Edwards (202232)
Technical Reviewer: Shashank Sheth (467378)
Other Members:
N/A

Hours Spent on Site: 20
Hours of ICT Activites: 0
Hours Spent Writing Report: 8

Non-Conforming

2.5.3 Corrective and Preventative Action

2.5.3 Corrective Action Policy rev 1/7/2020 describes the responsibility and methods outlining how corrections and corrective actions are determined, implemented and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits, and deviations from food safety requirements. Corrective Actions for internal audits are reviewed during internal management meetings as evidenced by "2024 CA Log". The site's policy and procedures includes the requirements to document all CAPA's in the appropriate program(Food Safety Plus). Records of investigations were maintained, an example of Corrective Action documentation for 24-04, was appropriately filled out when reviewed and found to contain appropriate Corrective Actions and disposition.
Minor: During the review of various inspection records. The site was noted to be missing corrective actions on a couple instances of the site's internal self Inspections noted in March for building 1130 and in November for building 1124 additionally Glass audits were reviewed and corrective actions for damaged glass from 2/2024 was missing corrective actions.

2.5.3.2 Records of all investigation, root cause analysis, and resolution of non-conformities, their corrections, and the implementation of preventative actions shall be maintained.

RESPONSE: MINOR

EVIDENCE: During the review of various inspection records. The site was noted to be missing corrective actions on a couple instances of the site's internal self Inspections noted in March for builing 1130 and in November for building 1124 additionally Glass audits were reviewed and corrective actions for damaged glass from 2/2024 was missing corrective actions.

ROOT CAUSE: There were missing corrective actions from IA reports. Why? The follow up was not documented on form. Why? Lack of standardization for communication. Why? No monthly inspection reporting on form for Administrative review.

CORRECTIVE ACTION: A topic section was included in the adminitrative review form that will review and verify completion of corrective actions from the internal audit reports

VERIFICATION OF CLOSEOUT: An updated meeting form was included as evidence of the new process. The form is HACCP 0117 rev 3 6/11/2024.

COMPLETION DATE: 06/11/2024 **CLOSEOUT DATE**: 06/17/2024

11.1.2 Building Materials

Product contact surfaces are smooth and built with corrosion resistant materials. The food handling areas use Stainless Steel food contact equipment processing equipment. All materials are appropriate for the application. The site has smooth concrete floors covered with or epoxy or painted floors in manufacturing areas. Floors are appropriately sloped to drains. Drains were trench style or circular drains but were clean and accessible. The site has no waste traps. Stairs do not pose a contamination risk. The only stairs were in the processing areas to access sifters and magnets. Minor: Equipment was inspected from various buildings in the plant inspection and it was noted that 1. 2 different Hatches missing sealant on Hopper 2 and 3 Elzan and also some tape was noted in each corner of the interior Hopper box on the Hopper that was adjacent to the far wall in Sugar Drink mix area.

11.1.2.7 Doors, hatches, and windows and their frames in food processing, handling, or storage areas shall be of a material and construction that meets the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction, and windows shall be made of shatterproof glass or similar material.

RESPONSE: MINOR

EVIDENCE: Equipment was inspected from various buildings in the plant inspection and it was noted that 1. 2 different Hatches missing sealant on Hopper 2 and 3 Elzan and also some tape was noted in each corner of the interior Hopper box on the Hopper that was ajacent to the far wall in Sugar Drink mix area.

ROOT CAUSE: Inapropriate repairs were left unfinished. Why? Managers had signed off on repairs that were not sufficient. Why? Managers were not aware that these were not sufficient repairs. Why? Insufficient training of managers to review work orders.

CORRECTIVE ACTION: Managers were provided retraining on what was necessary to sign off on repairs. As well as our policy for maintenance materials and conditions. Screens were repaired and installed. Flashlights were provided to aid in inspections.

VERIFICATION OF CLOSEOUT: Evidence of Updated Training for mechanics was provided, it was dated 6/4/2024. Photo evidence of tape removal, and gasket repairs were provided.

COMPLETION DATE: 06/04/2024 **CLOSEOUT DATE**: 06/17/2024

11.2.5 Cleaning and Sanitation

Methods and responsibilities for cleaning food handling equipment and the environment were documented in 11.2.5 Cleaning and Sanitation rev . A cleaning schedule was maintained on paper. The plant has documented Standard Sanitary Operating Procedures documented in the work instructions for the equipment. Plant uses a combination of cleaning methods including dry cleaning and controlled wet cleaning methods to maintain cleanliness of the equipment and building. Routine cleaning is documented via paper. A preop inspection process is documented and completed; an example of a preop inspection on the Elzan line was witnessed, no issues noted. The site uses pre-dosed chemical detergents and sanitizers for manual cleaning. Titrations are completed by third party (Chemstation). Amenities are cleaned daily. Appropriate chemicals are used per label directions and stored appropriately. Cleaning is verified by visual inspection as well as by ATP per the schedule. Cleaning is validated by microbial and allergen swabbing results from 3 cycle of post cleaning review. The site does not use CIP systems. Minor(s): The site has Preoperational inspections which look at cleanliness and proper functioning of equipment. During the plant inspection, it was noted that there were holes in two screens in 2 out of 3 hoppers in Elzan that are supposed to be checked at preop; there was a hole noted in Sweeco in agglomeration. The preop was completed but no issues with the screen were identified.

11.2.5.7 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities, sanitary facilities, and other essential areas are clean before the start
of production. Pre-operational inspections shall be conducted by qualified personnel.

RESPONSE: MINOR

EVIDENCE: The site has Preoperational inspections which look at cleanliness and proper functioning of equipment. During the plant inspection, it was noted that there were holes in two screens in 2 out of 3 hoppers in Elzan that are supposed to be checked at preop; there was a hole noted in Sweeco in agglomeration. The preop was completed but no issues with the screen were identified.

ROOT CAUSE: Issues were not identified on completed Pre Op inspections. Why? Inspectors had noted these damages on previous inspections and had submitted work orders to have them repaired but were not following up. Why? Inspectors thought that once they had noted it initially they could stop marking the sheet with failing results. Why? Insufficient training of Pre Op for employees.

CORRECTIVE ACTION: Pre Operation retraining was provided for QC/Managers that perform inspections. Emphasis on conditions of equipment to be continuously documented.

VERIFICATION OF CLOSEOUT: Evidence of Updated Training for eemployees conducting preoperational inspections was provided. Training was conducted on 6/4/2024. Photo evidence of screen repairs were documented and provided.

COMPLETION DATE: 06/04/2024 **CLOSEOUT DATE**: 06/17/2024

11.6.5 Loading, Transport, and Unloading Practices

11.6.5 Loading, Transport and Unloading outlines the practices applied during loading, transport and unloading of food. Loading and Unloading operations did not pose a risk to food safety. Trucks were witnessed being loaded, no issues noted. The site receives a small number of ingredients on refrigerated trailers. The trailers temperature is documented on the receiving paperwork before unloading. Raw materials are visually inspected prior to acceptance. External trailers are checked for pest activity, water damage and chemical smells. Non-conforming materials and products and materials are rejected if they do not meet standard. No issues with the trucks monitored on site. Minor: The site will move goods on trucks from company warehouses and with company trucks, however, no intraplant vehicle inspection is documented.

11.6.5.2 Vehicles (e.g., trucks/vans/containers) used for transporting food within the site and from the site shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may impact negatively on the product.

RESPONSE: MINOR

EVIDENCE: The site will move goods on trucks from company warehouses and with company trucks, however, no intraplant vehicle inspection is documented.

ROOT CAUSE: Warehouse staff not filling out truck inspection forms for intraplant vehicles. Why? Staff did not consider the need for in house trucks to be inspected on form. Why? Training was not provided to them to do this. Why? Administrative oversite. We had not considered our own trucks to require aditional documented inspections.

CORRECTIVE ACTION: Warehouse staff were trained on this topic. Warehouse managers from all three locations were trained on this requirement. Truck inspection forms provided with BOL for intraplant vehicles as well in system.

VERIFICATION OF CLOSEOUT: The site provided evidence of complete vehicle inspection forms dated 5/30, 531 and 6/4/2024. Evidence of training on the new vehicle inspection process was documented. 5/22/2024

COMPLETION DATE: 05/22/2024 **CLOSEOUT DATE**: 06/18/2024

Section Responses

Audit Statement	Audit
SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** BENJAMIN KUZMA

SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** BKUZMA@CORIMINDUSTRIES.COM
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** VERNON EDWARDS LEAD AUDITOR, BENJAMIN KUZMA: QA MANAGER, NATAN TEREN PRESIDENT/OWNER, PATRICIA MCDONALD: DIRECTOR OF OPERATIONS
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** 41,000 THE SITE IS A 41,000 SQUARE FEET OF MANUFACTURING AND WAREHOUSING LOCATED IN A LIGHT INDUSTRIAL COMPLEX IN OCEAN COUNTY, NJ. THE SITE EMPLOYS 89 EMPLOYEES WHICH WORK 1 SHIFT 5 DAYS A WEEK, 7-3 PM SPREAD OUT AMONG 6 BUILDINGS(1111, 1111A AND B, 1116, 1130, AND 1124 (1112 EXCLUDES PRODUCTION). THE SITE MANUFACTURERS CAPPUCCINO, SUGAR AND HIGH INTENSITY SWEETENER PACKETS, POWDERED DRINK MIXES, AND K-CUPS. THE SITE HAS 6 HACCP PLANS COVERING ALL PRODUCT TYPES. COFFEE ROASTING IS EXCLUDED.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** VERNON EDWARDS LEAD AUDITOR, BENJAMIN KUZMA: QA MANAGER, NATAN TEREN PRESIDENT/OWNER, PATRICIA MCDONALD: DIRECTOR OF OPERATIONS
Auditor Recommendation	Auditor Recommendation **RESPONSE:** RECERTIFICATION PENDING CORRECTIVE ACTION COMPLETION.

2.1.1 Management Responsibility

SQF 2.1.1.2 Management Responsibility rev 6/8/2022 rev outlines the site's commitment to safe food, methods to comply with regulatory and customer requirements and its commitment to Food Safety. The site has a Food Safety and Quality Policy that is signed by the Owner / President, 2024(1/4/2024) The site is committed has established food safety objectives and a Food Safety Culture that is communicated via training. The objectives are to meet regulatory guidelines and maintain the SQF Certification. Continuous Improvement is measured through the internal audit and CAPA program. The Food Safety Policy is posted in the main entrance. The Policy is written in English. The site has Corim Industries Organization Chart rev 3/5/2024 which identifies the reporting structure. SQF 2.1.1.7 Back up Designee for FS Position identifies the Quality Manager as the SQF practitioner and the Director of Operations as the back-up practitioner. Both individuals have been appropriate training in HACCP. The SQFPs has had Implementing SQF Systems training (SQFP: HACCP Manager, 4/2/2014, Internal Auditor Workshop 3/11/2020, Implementing SQF Cert 4/8/2014 and SQFP BU: HACCP Mgr. 9/14-15/2015, FSPCA PCQI, 5/12/2017, Implementing SQF Systems Practitioner Workshop, 9/16/-17/2015). Job descriptions are available and reviewed (SQF 2.1.2.8 Job Descriptions, Shipping and Receiving, 1/9/2017 and Machine Operator, 9/23/2022, job descriptions sampled). Job descriptions list requirements to report FS/Quality problems. The site conducts appropriate training in Food Safety Systems at hire and annually. The site is adequately resourced, by competent staff to maintain the SQF system. This was a scheduled audit. The site communicates key changes to SQF system through training. Continuous Improvement is measured during the MR meetings by evaluating trends in monthly GMP audit program and annual Systems review as well as the effectiveness of CAPAs. Food safety culture is developed through the use of the training program. Food Safety Culture was assessed through interviews with personnel. No issues noted. The site uses SQF logos on email signatures only. It uses the approved colors and symbols.

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines at a minimum the commitment of all site management to:
i. Supply safe food;
ii.Establish and maintain a food safety culture within the site;
iii. Establish and continually improve the site's food safety management system; and
iv. Comply with customer and regulatory requirements to supply safe food.
The policy statement shall be:
v. Signed by the senior site manager and displayed in prominent positions; and
vi. Effectively communicated to all site personnel in the language(s) understood by all site personnel.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.2 Senior site management shall lead and support a food safety culture within the site that ensures at a minimum:
i. The establishment, documentation, and communication to all relevant staff of food safety objectives and performance measures;
ii. Adequate resources are available to meet food safety objectives;
iii. Food safety practices and all applicable requirements of the SQF System are adopted and maintained;
iv. Employees are informed and held accountable for their food safety and regulatory responsibilities;
v. Employees are positively encouraged and required to notify management about actual or potential food safety issues; and
vi. Employees are empowered to act to resolve food safety issues within their scope of work.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.3 The reporting structure shall identify and describe site personnel with specific responsibilities for tasks within the food safety management system and identify a backup for the absence of key personnel.
Job descriptions for the key personnel shall be documented.
Site management shall ensure departments and operations are appropriately staffed and organizationally aligned to meet food safety objectives.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.4 Senior site management shall designate a primary and substitute SQF practitioner for each site with responsibility and authority to:
i. Oversee the development, implementation, review, and maintenance of the SQF System;
ii. Take appropriate action to ensure the integrity of the SQF System; and
iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.5 The primary and substitute SQF practitioner shall:
i. Be employed by the site;
ii. Hold a position of responsibility related to the management of the site's SQF System;
iii. Have completed a HACCP training course;
iv. Be competent to implement and maintain HACCP based food safety plans; and
v. Have an understanding of the SQF Food Safety Code: Food Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.6 Senior site management shall ensure the training needs of the site are resourced, implemented, and meet the requirements outlined in system elements 2.9 and that site personnel meet the required competencies to carry out those functions affecting the legality and safety of food products.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.7 Senior site management shall ensure the integrity and continued operation of the food safety system in the event of organizational or personnel changes within the company or associated facilities.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.1.8 Senior site management shall designate defined blackout periods that prevent unannounced re-certification audits from occurring out of season or when the site is not operating for legitimate business reasons. The list of blackout dates and their justification shall be submitted to the certification body a minimum of one (1) month before the sixty (60) day re-certification window for the agreed-upon unannounced audit.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.2 Management Review

2.1.3.1 Management Review rev 12/2/2021 outlines the methods for the site uses to conduct monthly meetings with senior management. The site has a monthly review meeting with the key leadership of the site (SQF Practitioner, President, Director of Operations Mgr., Maintenance Mgr.). Management Review meetings included the required topics (Consumer Complaints, GMPs, Corrective Actions, Audit findings, Self Inspection results, and changes to the Food Safety Plan). Key decisions are documented, corrective actions are created as applicable. Management Review notes are summarized monthly and documented. Examples of 10/13/2023 an 1/19/2024 meeting notes reviewed no issues noted. The system is reviewed through the use of the annual internal audit, and is documented via IPRP Year End Summary dated 12/28/2023. There site uses a food culture survey to evaluate the culture performance. The site has identified lowest scores and developed action plans. The site has shown progress in its communication plan. The site is working to free up more time to so that the operations teams it has adequate time to perform its work.

2.1.2.1 The SQF System shall be reviewed by senior site management at least annually and include:
i. Changes to food safety management system documentation (policies, procedures, specifications, food safety plan);
ii. Food safety culture performance;
iii. Food safety objectives and performance measures;
iv. Corrective and preventative actions and trends in findings from internal and external audits, customer complaints, and verification and validation activities;
v. Hazard and risk management system; and
vi. Follow-up action items from previous management reviews.
Records of all management reviews and updates shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.2.2 The SQF practitioner(s) shall update senior site management on at least a monthly basis on matters impacting the implementation and maintenance of the SQF System.
The updates and management responses shall be documented.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.3 Complaint Management

2.1.3 Complaint Management Policy rev 5/6/2019 lists the consumer complaint program. The procedure has methods and responsibilities for handling and investigating the cause and resolution of complaints. The site receives Distributor and Consumer Complaints by phone or by email. Once complaints are received they are documented in in a log and Serious Plant Controllable complaints are investigated. An example of a metal wire brush retail complaint was reviewed from 2/9/2024, the investigation found no plant controllable root cause. Food Safety Complaints require a Corrective Action form to be completed. CAR form 2403 for metal from a wire brush was resolved by replacing and putting an inspection in place to look proactively for the condition of brushes. Records of consumer complaints, 2 year trends and corrective actions are maintained for 2 years. Trending of complaints was done with a pivot table, was reviewed, no issues noted.

2.1.3.1 The methods and responsibility for handling, investigating, and resolving food safety complaints from commercial customers, consumers, and authorities, arising from products manufactured or handled on-site or co-manufactured, shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.3.2 Adverse trends of customer complaint data shall be investigated and analyzed and the root cause established by personnel knowledgeable about the incidents.

RESPONSE: COMPLIANT

EVIDENCE:

2.1.3.3 Corrective and preventative action shall be implemented based on the seriousness of the incident and the root cause analysis as outlined in 2.5.3. Records of customer complaints, their investigation, and resolution shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.1 **Food Safety Management**

SQF Policy Manual rev 11/20/2019 outlines the key food safety programs and products covered under the scope of certification. The document references procedures and documentation to support the food safety system. The summary includes requirements to verify and validate changes to the FS system. The site has a list of products, Food Safety Manual including procedures, prerequisite programs, and a HACCP/Food Safety Plan in place.

2.2.1.1 The methods and procedures the site uses to meet the requirements of the SQF Food Safety Code: Food Manufacturing shall be maintained in electronic and/or hard copy documentation. They will be made available to relevant staff and include:
i. A summary of the organization's food safety policies and the methods it will apply to meet the requirements of this standard;
ii. The food safety policy statement and organization chart;
iii. The processes and products included in the scope of certification;
iv. Food safety regulations that apply to the manufacturing site and the country(ies) of sale (if known);
v. Raw material, ingredient, packaging, and finished product specifications;
vi. Food safety procedures, prerequisite programs, food safety plans;
vii. Process controls that impact product safety; and
viii. Other documentation necessary to support the development, implementation, maintenance, and control of the SQF System.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.1.2 Food safety plans, Good Manufacturing Practices, and all relevant aspects of the SQF System shall be reviewed, updated, and communicated as needed when any changes implemented have an impact on the site's ability to deliver safe food.
All changes to food safety plans, Good Manufacturing Practices, and other aspects of the SQF System shall be validated or justified prior to their implementation. The reasons for the change shall be documented.

RESPONSE: COMPLIANT

EVIDENCE:

2.2.2	**Document Control** The site has Documentation, Record Retention Responsibility, and Good Documentation Practices which outlines the methods for managing version control for documents. The policy is that all electronic (original) copies of controlled documents are maintained in the share drive with access limited to management and the SQF manual. Employees can access pertinent information by requesting a document from management, which will distribute the most recent version of the document or accessing the SQF manual (SQFP offices or Logistics Manager office). All changes of documents are completed by the SQFP and the SQFP is responsible for dissemination of changed documents. The site has a food safety manual that is kept up to date.
2.2.2.1	The methods and responsibility for maintaining document control and ensuring staff have access to current requirements and instructions shall be documented and implemented. Current SQF System documents and amendments to documents shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.2.3	**Records** The site has 2.2.3 Records rev 12/2/2021 which describes the methods and responsibilities for monitoring, verifying and maintaining records. Food Safety Records are to be kept for a minimum of 3 years. Records are securely stored but readily accessible and retrievable found in the cabinet in the department managers or the SQFP's office. Production records are required to be reviewed and signed off by the SQF Practitioner or designee, no issues noted. Records reviewed (11/6-11/10/2023 (Daily Cleaning, Changeover Form, Preop Records, GMP Cleaning Records, Batch Tickets, Label Verification, Allergen / Kosher, CO Inspector Form, (Drink Mix and Single Service)
2.2.3.1	The methods, frequency, and responsibility for verifying, maintaining, and retaining records shall be documented and implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.2.3.2	All records shall be legible and confirmed by those undertaking monitoring activities that demonstrate inspections, analyses, and other essential activities that have been completed. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.2.3.3	Records shall be readily accessible, retrievable, and securely stored to prevent unauthorized access, loss, damage, and deterioration. Retention periods shall be in accordance with customer, legal, and regulatory requirements, at minimum the product shelf-life or established by the site if no shelf-life exists. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.3.1	**Specification, Formulation, and Realization** 2.3.1.1 Spec and Product Development rev 6/7/2023 and 2.3.1.3. Shelf Life/ Microbial Criteria / Storage and Handling rev 3/25/2023 outlines the methods and responsibility for designing, developing and converting product concepts to commercial realization. The site's R&D program is managed by the QA Mgr. and Director of Operations. Any new vendors must be fully approved. An example of a 2.3.1.2 Spec and PD Worksheet rev 0 9/28/18 of 710-6 Soluble Milk and Blackberry Matcha Latte from 4/2024 and 02/2024 was reviewed and it adhered to procedures. Any new products and ingredients are incorporated into the food safety plan. Records are maintained for new products and ingredients. Shelf life studies are completed based on risk, and utilize industry standards. No new products were recently developed. An example of a shelf life extension for French Vanilla Cappuccino single serve from 1/6/2024 was reviewed, no issues noted.
2.3.1.1	The methods and responsibility for designing and developing new product formulations and converting product concepts to commercial realization shall be documented and implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.1.2	New product formulations, manufacturing processes, and the fulfillment of product requirements shall be established, validated, and verified by site trials and product testing as required to ensure product safety. Product formulations shall be developed by authorized persons to ensure that they meet the intended use. Where necessary, shelf life trials shall be conducted to validate and verify a new product's: i. Pre-consumer handling and storage requirements, including the establishment of "use by," "best before dates," or equivalent terminology; ii. Microbiological criteria, where applicable; and iii. Consumer preparation, where applicable, and storage and handling requirements. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.1.3	A food safety plan shall be validated and verified by the site food safety team for each new product and its associated process through conversion to commercial production and distribution or where a change to ingredients, process, or packaging occurs that may impact food safety. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.1.4	Product formulations and manufacturing processes for products included in the scope of certification shall be reviewed when there are changes in materials, ingredients, or equipment. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.1.5	The process flows for all new and existing manufacturing processes shall be designed to ensure that product is manufactured according to approved product formulations and to prevent cross-contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.3.1.6 Records of product design, formulations, label compliance, process flows, shelf life trials, and approvals for all new and existing products shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2 Specifications (Raw Material, Packaging, Finished Product and Services)

2.3.2 Specifications (Raw Material, Packaging, Finished Product and Services) rev 10/7/2019 outlines the methods and responsibilities to maintain specifications for raw and pack materials. The site obtains specifications from each supplier and maintains these as the raw material specifications, if the supplier has none or if special requirements are needed the Quality Mgr. or Director of Operations will develop one. Specifications are compliant to legislation and are reviewed annually. The site obtains LOG or COC's /COAs and relevant supplier approval documentation (Non-fat Dry Milk, LOG, 12/14/2023, TPA Cert, 9/11/2024, COA, 3/8/2024, Spec, 3/13/2022, Peach Flavor, spec, 4/15/20224, LOG, 7/21/2023, TPA, 1/15/2025, COA, 4/15/2024), were reviewed and maintained. The site has "Register of Approved Labels and Specifications". The site reviewed each approved label before first printing(Examples reviewed from 2/13/2024 for Oat Milk Blue Matcha). Labels are checked on the line hourly for accuracy. Additionally the Register of Raw Material Specs, updated 5/5/2022 was sampled and reviewed, no issues noted. The register was sampled for accuracy, no issues noted. 2.3.2.8 Contract Service Providers details procedures for management contractors. The site has "Register of All Contract Service Specifications" which lists several contract services providers and their specifications; the list of CSPs was sampled (Eurofins, Waste Disposal, Pest Control Operator) and found accurate. The site has a register of Finished products which is maintained along with requirements for specifications to be documented per 2.3.2.9 Finished Product Specifications (Oat Milk Blue Matcha Specifications dated, 2/13/2024). Specifications are approved and include physical requirements, allergen information, labeling information, product descriptions and microbial requirements.

2.3.2.1 The methods and responsibility for developing, managing, and approving raw material, finished product, and packaging specifications shall be documented.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.2 Specifications for all raw materials and packaging, including, but not limited to, ingredients, additives, hazardous chemicals, processing aids, and packaging that impact finished product safety shall be documented and kept current.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.3 All raw materials, packaging, and ingredients, including those received from other sites under the same corporate ownership, shall comply with specifications and with the relevant legislation in the country of manufacture and country(ies) of destination if known.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.4 Raw materials, packaging, and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.2.5	Site management shall require approved raw materials suppliers to notify the site of changes in product composition that could have an impact on product formulation (e.g., protein content, moisture, amino acid profiles, contaminant levels, allergens, and/or other parameters that may vary by crop or by season). **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.6	Verification of packaging shall include a certification of all packaging that comes into direct contact with food meets either regulatory acceptance or approval criteria. Documentation shall either be in the form of a declaration of continued guarantee of compliance, a certificate of conformance, or a certificate from the applicable regulatory agency. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.7	Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.8	Description of services for contract service providers that have an impact on product safety shall be documented, current, include a full description of the services to be provided, and detail relevant training requirements of all contract personnel. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.9	Finished product specifications shall be documented, current, approved by the site and its customer, accessible to relevant staff, and shall include, where applicable: i. Microbiological, chemical, and physical limits; ii. Composition to meet label claims; iii. Labeling and packaging requirements; and iv. Storage conditions. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.2.10	Specifications for raw materials and packaging, chemicals, processing aids, contract services, and finished products shall be reviewed as changes occur that impact product safety. Records of reviews shall be maintained. A list of all the above specifications shall be maintained and kept current. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.3.3 Contract Manufacturers

The site does not use contract manufacturers.

2.3.4 Approved Supplier Program

2.3.4 Approved Supplier Program Specification and LOG Policy rev 10/17/2019 describes the methods and responsibilities for approving suppliers. Suppliers approval is based on prior performance and supplier risk. The site has three risk statuses(provisional, approved and probationary). The Policy states that audits will be conducted by individuals knowledgeable of applicable regulatory and food safety requirements risk and trained in auditing techniques; site requires raw material suppliers have a valid third party audit from a GFSI Benchmarked scheme. Packaging suppliers require a third party audit and to provide LOG, spec, NLI, allergen statement, Kosher, and before Supplier Approval. Examples of sample documentation (Non-fat Dry Milk, LOG, 12/14/2023, TPA Cert, 9/11/2024, COA, 3/8/2024, Spec, 3/13/2022, Peach Flavor, spec, 4/15/20224, LOG, 7/21/2023, TPA, 1/15/2025, COA, 4/15/2024) for two suppliers were reviewed onsite. The site requires COAs for all ingredient suppliers. Information is reviewed and approval by the SQF practitioner. Supplier Risk is determined by review of supplied documentation. The site adheres to procedures. The site maintains a register of approved suppliers kept in Register of Approved Suppliers rev; it was sampled and found to be accurate; the register includes email contacts for each supplier. The Supplier Approval Program takes into account emergency approval of suppliers, food defense, and food fraud. All specs are the same for the entire company.

2.3.4.1 The responsibility and procedure for selecting, evaluating, approving, and monitoring an approved supplier shall be documented and implemented.
A current record of approved suppliers, receiving inspections, and supplier audits shall be maintained.

Code Amendment #2
Approved supplier registers shall include supplier contact details. All approved and emergency suppliers shall be registered.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.2 The approved supplier program shall be based on the past performance of a supplier and the risk level of the raw materials, ingredients, processing aids, packaging, and services supplied, and shall contain at a minimum:
i. Agreed specifications (refer to 2.3.2);
ii. Reference to the level of risk applied to raw materials, ingredients, packaging, and services from the approved supplier;
iii. A summary of the food safety controls implemented by the approved supplier;
iv. Methods for granting approved supplier status;
v. Methods and frequency of monitoring approved suppliers;
vi. Details of the certificates of conformance, if required; and
vii. Methods and frequency of reviewing approved supplier performance and status.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.3 Verification of raw materials shall include certificates of conformance, certificates of analysis, or sampling, and testing. The verification frequency shall be identified by the site.

RESPONSE: COMPLIANT

EVIDENCE:

2.3.4.4	The receipt of raw materials, ingredients, processing aids, and packaging from nonapproved suppliers shall be acceptable only in an emergency situation and provided a receiving inspection or analysis is conducted and recorded before use. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.4.5	Raw materials, ingredients, and packaging received from other sites under the same corporate ownership shall be subject to the same specification requirements (refer to 2.3.2), approved supplier requirements, and receiving inspections as all other material providers. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.3.4.6	Supplier audits shall be based on risk (as determined in 2.3.4.2) and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.1	**Food Legislation** 2.4.1.1 Food Legislation and Customer Requirements ver 10/10/18 rev 0 requires the SQFP to stay updated with regulatory requirements. The site is a member of the IFT, attends relevant trainings, and conferences, and obtains updates from the FDA and SQFI. The site maintains Regulatory and Industry Awareness Activity Log, QA 0092 rev 2(6/2023) which maintains updates to regulations and national/international standards. The procedure requires notification within 24 hours in the event of a regulatory warning. Practitioner is responsible for keeping an up to date register of local and national licenses required for business operation. An example of updates (5/17/2024, Sun Noodle Allergy Alert and Cotija Cheese Recall 2/28/2024) was reviewed, no issues noted.
2.4.1.1	The site shall ensure that at the time of delivery to customers finished products shall comply with food safety legislation applicable in the country of manufacture and sale. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen, and additive labeling, labeling of identity preserved foods, any other criteria listed under food legislation, and to relevant established industry codes of practice. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.1.2	The methods and responsibility for ensuring the site is kept informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues, and relevant industry codes of practice shall be documented and implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.1.3	SQFI and the certification body shall be notified in writing within twenty-four (24) hours as a result of a regulatory warning or event. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com. **RESPONSE:** COMPLIANT

EVIDENCE:

2.4.2 Good Production Practices

The site has GMP Policy rev 6/8/2023 which outlines the site's GMP procedures. Procedures address requirements of module 11. Each Procedure or prerequisite program has pertinent information on how to ensure compliance to cGMPs. The site has established PRPs and they are support the food safety management system. GMPs are applicable to the scope of manufacturing.

2.4.2.1 The site shall ensure the applicable Good Manufacturing Practices described in Module 11 of this Food Safety Code are applied or exempted according to a written risk analysis outlining the justification for exemption or evidence of the effectiveness of alternative control measures that ensure food safety is not compromised.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.2.2 The Good Manufacturing Practices applicable to the scope of certification outlining how food safety is controlled and assured shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3 Food Safety Plan

The site has a HACCP Plan based on the 7 Principles of HACCP, and 12 steps. The HACCP/food safety plan includes 6 HACCP plans(cappuccino, sugar and high intensity sweetener packets, powdered drink mixes, agglomeration, and K-Cups) and several products under the scope. The site has a multidisciplined Food Safety committee that includes the: President, QM/SQFP, Ops Mgr., Logistics Mgr., Maintenance Mgr. A product description that references product specifications is included. The Product description lists the target consumer groups. Product descriptions reference food safety water activity. A flow chart(Sugar Packets, Flow Chart) was developed and approved on 5/2/2024, that includes all processes from incoming receiving to packaging; it also includes waste and packaging inputs. The site has completed an ingredient and process hazard analysis. The site's HACCP/Food Safety Plan no CCPs. The HACCP/food safety plan is included on the verification and validation schedule. The plan was reviewed and approved on 5/2024. The HACCP/Food Safety Plan had monitoring and deviation procedures as defined in the HACCP summary table. The site has these PRPs(PRPs Allergen Control(PC), Approved Supplier Program (PC), Chemical Control (PC), Cleaning and Sanitation (PC) , Food Defense (PC), FM Control (PC), Glass and Brittle Plastic Policy, Customer Complaint Management, GMPs, LOG, Microbial Control / EMP, Non-nonconforming Product and Equipment, Pest Management, Regulatory Affairs and Inspections Program, Shipping, Receiving and Storage, Traceability and Training). Process Preventive Controls are Magnets and Sifter screens, CL in place and functioning tested with 2 mm Fe, and the site screens will remove objects greater than 4.6 mm. The Program is validated through complaints and CFR 555.425 documented on 5/2/2024. The HACCP review was conducted and Sucralose was added to the IHA.

2.4.3.1 A food safety plan shall be prepared in accordance with the twelve steps identified in the Codex Alimentarius Commission HACCP guidelines. The food safety plan shall be effectively implemented and maintained and shall outline how the site controls and assures food safety of the products or product groups included in the scope of the SQF certification and their associated processes. More than one HACCP food safety plan may be required to cover all products included in the scope of certification.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.2	The food safety plan or plans shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and engineering knowledge of the relevant raw materials, packaging, processing aids, products, and associated processes. Where the relevant expertise is not available on-site, advice may be obtained from other sources to assist the food safety team. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.3	The scope of each food safety plan shall be developed and documented including the start and endpoints of the processes under consideration and all relevant inputs and outputs. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.4	Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. The descriptions shall reference the finished product specifications (refer to 2.3.2.9) plus any additional information relevant to product safety, such as pH, water activity, composition, and/or storage conditions. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.5	The intended use of each product shall be determined and documented by the food safety team. This shall include target consumer groups, the potential for consumption by vulnerable groups of the population, requirements for further processing if applicable, and potential alternative uses of the product. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.6	The food safety team shall develop and document a flow diagram covering the scope of each food safety plan The flow diagram shall include every step in the process, all raw materials, packaging, service inputs (e.g., water, steam, gasses as applicable), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team to cover all stages and hours of operation. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.7	The food safety team shall identify and document all food safety hazards that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.4.3.8	The food safety team shall conduct a hazard analysis for every identified hazard to determine which hazards are significant, i.e., their elimination or reduction to an acceptable level is necessary to control food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.9	The food safety team shall determine and document the control measures that must be applied to all significant hazards. More than one control measure may be required to control an identified hazard, and more than one significant hazard may be controlled by a specific control measure. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.10	Based on the results of the hazard analysis (refer to 2.4.3.8), the food safety team shall identify the steps in the process where control must be applied to eliminate a significant hazard or reduce it to an acceptable level (i.e., a critical control point or CCP). In instances where a significant hazard has been identified at a step in the process, but no control measure exists, the food safety team shall modify the process to include an appropriate control measure. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.11	For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product (critical limits). The food safety team shall validate all of the critical limits to ensure the level of control of the identified food safety hazard(s) and that all critical limits and control measures individually or in combination effectively provide the level of control required (refer to 2.5.2.1). **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.12	The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.11). Monitoring procedures shall identify the personnel assigned to conduct monitoring, the sampling and test methods, and the test frequency. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.13	The food safety team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CCP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the safety failure. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.14	The documented and approved food safety plan(s) shall be implemented in full. The effective implementation shall be monitored by the food safety team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, inputs, or other changes affecting product safety occur.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.3.15	Procedures shall be in place to verify that critical control points are effectively monitored and appropriate corrective actions are applied. Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5). **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.16	Critical control point monitoring, corrective action, and verification records shall be maintained and appropriately used. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.3.17	Where food safety regulations in the country of production and destination (if known) prescribe a food safety control methodology other than the Codex Alimentarius Commission HACCP guidelines, the food safety team shall implement food safety plans that meet both Codex and food regulatory requirements. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.4	**Product Sampling, Inspection, and Analysis** The site has 2.5.4 Product Sampling, Inspection and Analysis and Incoming Receiving Policy HACCP 0158 rev 0 6/15/2023 which defines the methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work in progress. The site conducts in process tests for sensory, bulk density, pH, and moisture, Finished Product is tested for APC, Coliform, Yeast and Mold, pathogens (Listeria mono, Salmonella). The site sends pathogen testing to an external lab. The site does not conduct microbiological analysis on site. The site uses Siliker Labs which is an A2LA accredited third party lab, the lab has a valid Bio certification #1105.01 that expire 3/31/2026. Lab results are maintained and Proficiency is completed twice per year by comparing Internal Testing vs COA results, Chemical exp 3/31/2026, 1105.15 records reviewed (Saccharin 1101006AC, color, flavor, weight,), no issues noted. Records of all testing results were maintained. No issues noted.
2.4.4.1	The methods, responsibility, and criteria for sampling, inspecting, and/or analyzing raw materials, work-in-progress, and finished product shall be documented and implemented. The methods applied shall ensure that inspections and analyses are completed at regular intervals as required and to agreed specifications and legal requirements. Sampling and testing shall be representative of the process batch and ensure that process controls are maintained to meet specification and formulation. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.4.4.2 Product analyses shall be conducted to nationally recognized methods or company requirements, or alternative methods that are validated as equivalent to the nationally recognized methods.

Where internal laboratories are used to conduct input, environmental, or product analyses, sampling and testing methods shall be in accordance with the applicable requirements of ISO/IEC 17025, including annual proficiency testing for staff conducting analyses.

External laboratories shall be accredited to ISO/IEC 17025, or an equivalent international standard, and included on the site's contract service specifications list (refer to 2.3.2.11).

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.3 On-site laboratories conducting chemical and microbiological analyses that may pose a risk to product safety shall be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.
Signage shall be displayed identifying the laboratory area as a restricted area,
accessible only by authorized personnel.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.4 Provisions shall be made to isolate and contain all hazardous laboratory waste held on the premises and manage it separately from food waste. Laboratory waste outlets shall at a minimum be downstream of drains that service food processing and handling areas.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.5 Retention samples, if required by customers or regulations, shall be stored according to the typical storage conditions for the product and maintained for the stated shelflife of the product.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.5 Non-conforming Materials and Product

The site has 2.4.5 Non-conforming Product or Equipment rev 6/12/2023, which defines the responsibility and methods on handling non-conforming product or equipment. Policy includes provisions to quarantine product that is substandard by placarded it with hold signs. Non conforming equipment is removed from service and a work order for repair is generated or the equipment is disposed of. The site has 2023-2024 Hold Log in Excel. Hold Records were reviewed and sampled(off smell, 2/12/2024, Cappuccino (Return to vendor)) on site and were accurate. The site has a Deviation Report Form that lists the reason for nonconformance and the Final Disposition. The site's food safety holds are disposition by the SQFP as applicable; the site will conduct a corrective action for large holds. Hold records are from Excel and Scanned Hold tags, records including hold reason, full disposal records as well as corrective actions are documented.

2.4.5.1	The responsibility and methods outlining how to handle non-conforming product, raw material, ingredient, work-in-progress, or packaging, which is detected during receipt, storage, processing, handling, or delivery, shall be documented and implemented. The methods applied shall ensure: i. Non-conforming product is quarantined, identified, handled, and/or disposed of in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product; and ii. All relevant personnel are aware of the organization's quarantine and release requirements applicable to product placed under quarantine status. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.5.2	Quarantine records and records of the handling, corrective action, or disposal of nonconforming materials or product shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.6	**Product Rework** The site does not rework any products. However, the site maintains a procedure (Rework of Cappuccino Products rev 1/6/2020) in case needed one day.
2.4.7	**Product Release** The site has Environmental Monitoring & Product Pathogen Sampling Program rev 3/1/2023 which defines the release procedures. The site has a passive release system. Products are checked for sensory, weights, and micro results. All products are deemed acceptable unless placed on hold except for micro, in that case Products are held until results are issued and are deemed in specification. Any hold product may only be released by the SQFP or Director of Operations. Records of product release are maintained.
2.4.7.1	The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released by authorized personnel, and only after all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met. Records of all product releases shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.4.7.2	Product release shall include a procedure to confirm that product labels comply with the food legislation that applies in the country of manufacture and the country(ies) of use or sale if known (refer to 2.4.1.1). If product is packaged and distributed in bulk or unlabeled, product information shall be made available to inform customers and/or consumers of the requirements for its safe use. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.4.7.3 In the event that the site uses positive release based on product pathogen or chemical testing, a procedure shall be in place to ensure that product is not released until acceptable results have been received.
In the event that off-site or contract warehouses are used, these requirements shall be effectively communicated and verified as being followed.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.8 **Environmental Monitoring**

The site has 2.4.8 Environmental Monitoring & Finished Product Pathogen Sampling Program rev 6/6/2019 which details the site's risk based approach to pathogen monitoring. The site tests 9 swabs sites quarterly. The site tests zones 3-4 Listeria spp.(12), Salmonella(12), in each building twice per year. The site tests zone 1 and zone 2 for E. coli (16) for the same analytes. Zone 1+2 has two swab sites each zone for E. coli. The site uses an ISO 17025 accredited lab (Siliker Cert. number 1105.07 expires 6/30/2024). The site has OOS limits which are defined. Corrective actions are taken for positive or presumptive results. 2023 results reviewed. Records were maintained and reviewed, no issues noted. An example of OOS Listeria suspect from 3/25/2024 was reviewed and contained appropriate corrective actions including vector swabs, as documented via CAP 24-04.

2.4.8.1 A risk-based environmental monitoring program shall be in place for all food manufacturing processes and immediate surrounding areas, which impact manufacturing processes.
The responsibility and methods for the environmental monitoring program shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

EVIDENCE:

2.4.8.2 An environmental sampling and testing schedule shall be prepared. It shall at a minimum:
i. Detail the applicable pathogens or indicator organisms to test for in that industry;
ii. List the number of samples to be taken and the frequency of sampling;
iii. Outline the locations in which samples are to be taken and the rotation of locations as needed; and
iv. Describe the methods to handle elevated or undesirable results.

RESPONSE: COMPLIANT

EVIDENCE:

2.4.8.3 Environmental testing results shall be monitored, tracked, and trended, and preventative actions (refer to 2.5.3.1) shall be implemented where unsatisfactory results or trends are observed.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.1 Validation and Effectiveness (Mandatory)

The site ha 2.5.1 Validation and Effectiveness rev which outlines the validation procedures. The site conducts validation of prerequisite programs. Examples of validation information includes trend reviews of complaints, trends of internal and external audit results, customer complaints, Preop results, and micro swab results. CCPs and the HACCP program is a part of the validation procedures. Validation activity completion is documented. A schedule exists for Validation and Verification activities. Validation results are reviewed at the management review meetings as they are completed. Examples of validation summary results were reviewed from 12/28/2023. An Allergen validation for the removal of milk, was reviewed(conducted on 9/26, 10/3 and 10/17/2023), no issues noted.

2.5.1.1 The methods, responsibility, and criteria for ensuring the effectiveness of all applicable elements of the SQF Program shall be documented and implemented. The methods applied shall validate that:
i. Good Manufacturing Practices are confirmed to ensure they achieve the required results;
ii. Critical food safety limits are reviewed annually and re-validated or justified by regulatory standards when changes occur; and
iii. Changes to the processes or procedures are assessed to ensure the controls are still effective.
Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.2 Verification Activities (Mandatory)

2.5 Corim Annual Verification of PRP Programs rev 12/11/2023 outlines the verification process for the food safety management system(Conducted by the SQFP). Procedures include a summary of verification activities and a schedule within the procedure. Verification includes monitoring of prerequisite programs and the HACCP/Food safety plan. The site has a verification schedule (Verification of Monitoring Schedule dated 6/23/2018) that includes all PRPs. Examples of monitoring include Supplier Approval, product testing records, and COA and Specifications, Chemical Control records. Daily Paperwork is reviewed by the SQFP. Records of monitoring activities were reviewed(time frame from 11/6-11/10/2023), no issues noted. Verifications records are maintained for 2 years plus current fiscal year, no issues noted.

2.5.2.1 The methods, responsibility, and criteria for verifying monitoring of Good Manufacturing Practices, critical control points, and other food safety controls, and the legality of certified products shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each verified record.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.2.2 A verification schedule outlining the verification activities, their frequency of completion, and the person responsible for each activity shall be prepared and implemented.
Records of verification of activities shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.3 Corrective and Preventative Action

2.5.3 Corrective Action Policy rev 1/7/2020 describes the responsibility and methods outlining how corrections and corrective actions are determined, implemented and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits, and deviations from food safety requirements. Corrective Actions for internal audits are reviewed during internal management meetings as evidenced by "2024 CA Log". The site's policy and procedures includes the requirements to document all CAPA's in the appropriate program(Food Safety Plus). Records of investigations were maintained, an example of Corrective Action documentation for 24-04, was appropriately filled out when reviewed and found to contain appropriate Corrective Actions and disposition.
Minor: During the review of various inspection records. The site was noted to be missing corrective actions on a couple instances of the site's internal self Inspections noted in March for building 1130 and in November for building 1124 additionally Glass audits were reviewed and corrective actions for damaged glass from 2/2024 was missing corrective actions.

2.5.3.1 The responsibility and methods outlining how corrective and preventative actions are determined, implemented, and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations from food safety requirements, shall be documented and implemented.
Deviations from food safety requirements may include customer complaints, nonconformances raised at internal or external audits and inspections, non-conforming product and equipment, withdrawals and recalls, as appropriate.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.3.2 Records of all investigation, root cause analysis, and resolution of non-conformities, their corrections, and the implementation of preventative actions shall be maintained.

RESPONSE: MINOR

EVIDENCE: During the review of various inspection records. The site was noted to be missing corrective actions on a couple instances of the site's internal self Inspections noted in March for building 1130 and in November for building 1124 additionally Glass audits were reviewed and corrective actions for damaged glass from 2/2024 was missing corrective actions.

ROOT CAUSE: There were missing corrective actions from IA reports. Why? The follow up was not documented on form. Why? Lack of standardization for communication. Why? No monthly inspection reporting on form for Administrative review.

CORRECTIVE ACTION: A topic section was included in the adminitrative review form that will review and verify completion of corrective actions from the internal audit reports

VERIFICATION OF CLOSEOUT: An updated meeting form was included as evidence of the new process. The form is HACCP 0117 rev 3 6/11/2024.

COMPLETION DATE: 06/11/2024 **CLOSEOUT DATE**: 06/17/2024

2.5.4 Internal Audits and Inspections

2.5.7.1 HACCP 0082 Internal Audit Procedure rev 5/10/2016 rev 0 (reviewed 5/15/2023) which defines the methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System. The system is required to be audited annually for compliance. The site conducted the annual system audit as required by policy completed per schedule, last completed on 6/2 and 8/6/2023 completed with the annual systems review. The site's SQF practitioner or designee does internal audits covering the entire facility monthly for GMP audit findings which are documented on the site's corrective action register. Example of GMP audits from 3/2024 and 11/2023 were reviewed, no issues noted. The SQFP has been training in Internal Auditing techniques; the training was completed 3/11/2020. Corrective actions records are maintained. Examples of Corrective Actions were logged from the audit. Internal Audits are retained for 2 years.

2.5.4.1 The methods and responsibility for scheduling and conducting internal audits to verify the effectiveness of the SQF System shall be documented and implemented. Internal audits shall be conducted in full and at least annually. The methods applied shall ensure:
i. All applicable requirements of the SQF Food Safety Code: Food Manufacturing are audited per the SQF audit checklist or a similar tool;
ii. Objective evidence is recorded to verify compliance and/or non-compliance;
iii. Corrective and preventative actions of deficiencies identified during the internal audits are undertaken; and
iv. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective and preventative actions.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4.2 Staff conducting internal audits shall be trained and competent in internal audit procedures. Where practical, staff conducting internal audits shall be independent of the function being audited.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4.3 Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and facility and equipment maintenance are compliant to the SQF Food Safety Code: Food Manufacturing. The site shall:
i. Take corrections or corrective and preventative action; and
ii. Maintain records of inspections and any corrective actions taken.

RESPONSE: COMPLIANT

EVIDENCE:

2.5.4.4 Records of internal audits and inspections and any corrective and preventative actions taken as a result of internal audits shall be recorded as per 2.5.3.
Changes implemented from internal audits that have an impact on the site's ability to deliver safe food shall require a review of applicable aspects of the SQF System (refer to 2.3.1.3).

RESPONSE: COMPLIANT

EVIDENCE:

2.6.1	**Product Identification and Traceability** The site has 2.6.1 Product Identification Policy 10/1/2019 and Lot Coding Standardization rev 12/22/2022 which details the methods and responsibility for identifying raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products during all stages of production and storage. Product Lot numbers are documented on the inbound receiving forms. All product lots are tracked in Batch Master. Lots are recorded at each key step throughout the process. The site has product change overs which require labels to be verified at startup and change over and hourly which is documented on the daily paperwork. Examples of trace summary reports were on file: (Mock Recall Summary Lavender Flow on 5/9/2024 Lot 325851, 100 lbs. produced om 5/3/2024 49.3957 shipped, remaining is still OH 100 % trace in 40 mins. / 1/29/2024). The paperwork also includes label reconciliation for labels used and returned. Amount used and destroyed are documented on the label and attached to the Batch Tickets and CODs maintained. An example of reconciliation from 4/4/2024 for Oat Milk Blue Matcha was reviewed. Investigations are required for significant variances. The site has procedures documented in Label and Packaging Verification Procedures rev 6/12/2023.
2.6.1.1	The methods and responsibility for identifying raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products during all stages of production and storage shall be documented and implemented to ensure: i. Raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products are clearly identified during all stages of receipt, production, storage, and dispatch; and ii. Finished product is labeled to the customer specification and/or regulatory requirements. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.6.1.2	Product start-up, product changeover, and packaging changeover (including label changes) procedures shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label and that the changeover is inspected and approved by an authorized person. Procedures shall be implemented to ensure that label use is reconciled and any inconsistencies investigated and resolved. Product changeover and label reconciliation records shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.6.2	**Product Trace** Products are traceable from the source to the destination and that materials are traceable back to the supplier. Methods used to identify the raw materials; in-progress materials and finished product are outlined in 2.6.2 Product Trace. Incoming material Lot numbers are recorded on the receiving and production logs. Product is traced at least annually as a part of the product recall and withdrawal review (Mock Recall Summary Lavender Flow on 5/9/2024 Lot 325851, 100 lbs. produced on 5/3/2024 49.3957 shipped, remaining is still OH 100 % trace in 40 mins. / Ingredient trace 3/20/2024 for Vanilla Flavor used on 1/29/2024 system. Mock recalls have effectiveness checks included.

2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure:
i. Finished product is traceable at least one step forward to the customer and at least one step back from the process to the manufacturing supplier;
ii. The receipt dates of raw materials, ingredients, food contact packaging and materials, and other inputs are recorded (refer to 2.8.1.8 for traceback of allergen containing food products.);
iii. Traceability is maintained where product is reworked (refer to 2.4.6); and
iv. The effectiveness of the product trace system is reviewed at least annually, as part of the product recall and withdrawal review (refer to 2.6.3.2).
Records of raw and packaging material receipt and use and finished product dispatch and destination shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.3 **Product Withdrawal and Recall (Mandatory)**
The site has 2.6.3 Recall Program rev 1/30/2024 which covers the methods and responsibilities used to withdraw or recall product. The policy includes communication to customers, SQFI, Certification body, and appropriate regulatory bodies. It includes investigation procedures and the requirement for the recall system to be tested. The procedure includes nomination of a Recall team(Food Safety Team: President, Quality Mgr., Director of Operations, and the Maintenance Manager). The VP of Operations is the head of the Recall team. The company president will make the determination to recall product. Provisions are included that require notification of SQFI and certification body in the event of a situation requiring public notification(within 24 hours). The site conducted a Mock recall and traceability exercise on for Nonconforming Product Failed Micro, no issues noted. Effectiveness checks are conducted. The site had 0 recalls in the last year.

2.6.3.1 The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall:
i. Identify those responsible for initiating, managing, and investigating a product withdrawal or recall;
ii. Describe the management procedures to be implemented, including sources of legal, regulatory, and expert advice, and essential traceability information;
iii. Outline a communication plan to inform site personnel, customers, consumers, authorities, and other essential bodies in a timely manner appropriate about the nature of the incident; and
iv. Ensure that SQFI, the certification body, and the appropriate regulatory authority are listed as essential organizations and notified in instances of a food safety incident of a public nature or product recall for any reason.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.3.2 The product withdrawal and recall system shall be reviewed, tested, and verified as effective at least annually. Testing shall include incoming materials (minimum traceability one step back) and finished product (minimum traceability one step forward).
Testing shall be carried out on products from different shifts and for materials (including bulk materials) that are used across a range of products and/or products that are shipped to a wide range of customers.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.3.3 Records shall be maintained of withdrawal and recall tests, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.3.4 SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification. SQFI shall be notified at foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.4 Crisis Management Planning

The site has 2.6.4 Crisis Management Policy rev 12/10/2019 procedures that addresses known hazards and their ability to affect the site's ability to deliver safe food. The Owner is the Sr Mgr. responsible for decision making and oversight for initiating and oversight of the CM team. The team is comprised of the President, Quality Mgr., Director of Operations, and the Maintenance Manager). The procedure includes measures to isolate and identify product, sources of legal advice, and communication responsibilities. The site has a list of phone numbers for each contact. The site is required to review and test the system annually. A crisis management exercise was conducted on 12/22/2023 for a Fire at the facility, product safety is considered in the Crisis Management response.

2.6.4.1 A crisis management plan based on the understanding of known potential dangers (e.g., flood, drought, fire, tsunami, or other severe weather events, warfare or civil unrest, computer outage, pandemic, loss of electricity or refrigeration, ammonia leak, labor strike) that can impact the site's ability to deliver safe food shall be documented by senior management, outlining the methods and responsibility the site shall implement to cope with such a business crisis. The crisis management plan shall include at a minimum:
i. A senior manager responsible for decision making, oversight, and initiating actions arising from a crisis management incident;
ii. The nomination and training of a crisis management team;
iii. The controls implemented to ensure any responses do not compromise product safety;
iv. The measures to isolate and identify product affected by a response to a crisis;
v. The measures taken to verify the acceptability of food prior to release;
vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers;
vii. Sources of legal and expert advice; and
viii. The responsibility for internal communications and communicating with authorities, external organizations, and media.

RESPONSE: COMPLIANT

EVIDENCE:

2.6.4.2 The crisis management plan shall be reviewed, tested, and verified at least annually with gaps and appropriate corrective actions documented. Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

2.7.1	**Food Defense Plan** 2.7.1 SOP Plant Security and Food Defense Plan rev 2 issued on 3/24/2023 which describes the methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident are documented, implemented and maintained. The food defense plan assigns the President as responsible for food defense. The Food Defense team is comprised of the President, QA Mgr., Maintenance Mgr., Director of Operations Mgr. The policy includes details and methods to protect sensitive areas, and to ensure product and raw materials are securely stored. The food defense plan is required to be reviewed and challenged annually(1/120/2024 Allergen Receiving Issue). The system was reviewed(Food Defense Risk Assessment, 2/1/2024 and Food Defense review from 2/1/2024). The facility has self closing locked doors. Employees have badge access. The site has camera access to critical areas inside and outside of the facility which are periodically monitored. The site upgraded the locks to cypher locks on each building.
2.7.1.1	A food defense threat assessment shall be conducted to identify potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.7.1.2	A food defense plan shall be documented, implemented, and maintained based on the threat assessment (refer to 2.7.1.1). The food defense plan shall meet legislative requirements as applicable and shall include at a minimum: i. The methods, responsibility, and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident; ii. The name of the senior site management person responsible for food defense; iii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing, and storage areas through designated access points; iv. The methods implemented to protect sensitive processing points from intentional adulteration; v. The measures taken to ensure the secure receipt and storage of raw materials, ingredients, packaging, equipment, and hazardous chemicals to protect them from deliberate acts of sabotage or terrorist-like incidents; vi. The measures implemented to ensure raw materials, ingredients, packaging (including labels), work-in-progress, process inputs, and finished products are held under secure storage and transportation conditions; and vii. The methods implemented to record and control access to the premises by site personnel, contractors, and visitors. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.7.1.3	Instruction shall be provided to all relevant staff on the effective implementation of the food defense plan (refer to 2.9.2.1). **RESPONSE:** COMPLIANT **EVIDENCE:**
2.7.1.4	The food defense threat assessment and prevention plan shall be reviewed and tested at least annually or when the threat level, as defined in the threat assessment, changes. Records of reviews and tests of the food defense plan shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**

2.7.2	**Food Fraud** Food Fraud Program rev 12/3/2019 outlines the site's Food Fraud procedures, assessment and mitigation plan. The site has prepared a Food Fraud Mitigation Vulnerability assessment utilizing Discernis. The Plan outlines methods, responsibility and criteria for potential motivations and opportunities for committing food fraud. The plan includes a documented Ingredient Vulnerability Assessment (including site, ingredients, costs, countries of origin, and geo political risk, etc.) documented via the plan. The assessment includes a risk rating and mitigation controls primarily through the supplier approval program. The food fraud plan is required to be reviewed and verified annually, last conducted on 2/24/2024 (annual review). An increased risk for Melamine in NFDM was identified and authenticity testing was completed on 2/19/2024.
2.7.2.1	The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud, including susceptibility to raw material or ingredient substitution, finished product mislabeling, dilution, or counterfeiting, shall be documented, implemented, and maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.7.2.2	A food fraud mitigation plan shall be developed and implemented that specifies the methods by which the identified food fraud vulnerabilities shall be controlled, including identified food safety vulnerabilities of ingredients and materials. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.7.2.3	Instruction shall be provided to all relevant staff on the effective implementation of the food fraud mitigation plan (refer to 2.9.2.1). **RESPONSE:** COMPLIANT **EVIDENCE:**
2.7.2.4	The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually with gaps and corrective actions documented. Records of reviews shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1	**Allergen Management** 2.8.1 Allergen Policy rev 1/15/2021 details the responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product and to ensure these policies and procedures are documented and implemented. The site has risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants, that contain food allergens that is contained in the IHA and on separate risk assessment forms. The site list the allergens in the facility are Wheat, Soy and Dairy. Allergen raw materials are isolated upon receipt. The site is controls allergen cross contact through the use of GMPs, cleaning and sanitation, label control and dedicated allergen lines where possible. The site uses color coded tools for handling allergens. The site has preop procedures that verify equipment post clean and requirements to conduct Allergen Validations at least annually by conducted testing after cleaning for 3 straight cycles, samples reviewed from 9/26, 10/3, 10/17/2023 via protein swabs. Relevant staff is trained on allergen handling practices. Site verifies accurate allergen information on Labels at start-up, at change over. All products are traceable.

2.8.1.1	The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include: i. A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors; iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known; iv. A list of allergens that is accessible to relevant staff; v. The control of hazards associated with allergens and incorporated into the food safety plan, and vi. Management plans for control of the identified allergens. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.2	Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in-progress, rework, or finished product on how to identify, handle, store, and segregate raw materials and products containing allergens. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.3	Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.4	Where allergenic material may be intentionally or unintentionally present cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact. Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.5	Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.6	Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact. **RESPONSE:** COMPLIANT

	EVIDENCE:
2.8.1.7	The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements of those products produced on production lines and equipment on which foods containing allergens are manufactured. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.8	The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen-containing foods are manufactured and ensure full traceback of all ingredients and processing aids used. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.9	The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished product as appropriate, and product change over procedures. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.10	Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked product containing allergens shall be clearly identified and traceable. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.8.1.11	Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities. **RESPONSE:** COMPLIANT **EVIDENCE:**
2.9.1	**Training Requirements** 2.9.1 Annual Refresher Training and New Employee Orientation rev 4/5/2019 which details the requirements for establishing and implementing the training needs of the organization. The site uses a customized power point that cover the code elements, HACCP Intro, CCP Overview, Allergens, Biosecurity, Glass, Shipping, Dry Cleaning, Chemical Sanitation, Preop Inspections, BBP, Trace and Recall, Chemical Control, Food Defense, Pest Control, Glove Control, Documentation Practices, and effective implementation of the SQF system. Training covers PRPs and job specific tasks.
2.9.1.1	The responsibility for establishing and implementing the training needs of the organization's personnel to ensure they have the required competencies to carry out those functions affecting products, legality, and safety shall be defined and documented (refer to 2.1.1.6).

RESPONSE: COMPLIANT

EVIDENCE:

2.9.1.2 Appropriate training shall be provided for personnel carrying out the tasks essential to the effective implementation of the SQF System and the maintenance of food safety and regulatory requirements.

RESPONSE: COMPLIANT

EVIDENCE:

2.9.2 Training Program

2.9.1 Annual Refresher Training and New Employee Orientation rev 4/5/2019 addresses the responsibility for establishing and implementing the training needs of the organization. The site's procedures outline the requirements for all employees to be appropriately trained on GMPs, HACCP Intro, CCP Overview, Allergens, Biosecurity, Glass, Shipping, Dry Cleaning, Chemical Sanitation, Preop Inspections, BBP, Trace and Recall, Chemical Control, Food Defense, Pest Control, Glove Control, Documentation Practices, and effective implementation of the SQF system. The site has a custom power point that is reviewed at hire and annually. The Quality Manager has had the required HACCP training. All employees have HACCP training and those monitoring CCPs get OJT and detailed training to confirm they understand the requirements of the job. Competency is measured by written test. Work Instructions, SOP, SSOP's are provided for tasks critical to the maintenance of the food safety program. Training is materials are provided in appropriate language (English). Training is given in English. Refresher training is required to be conducted annually for each employee. The site does a training day. All employees were trained. The site maintains a training skill registers that was complete and includes the required elements. The site has a Master Training List that includes relevant tracking data for all training conducted at the site. Each training is signed off by the SQFP. The training include competency requirements via testing. Examples of training for a Lead Operator, Elzan(2/202/2024) and a Blender Operator(1/9/2024) from Bldg. 1116 from January and February 2024 (Food Defense, GMPs, Allergen) was sampled, and were noted to be appropriately trained.

2.9.2.1 A training program shall be documented and implemented that at a minimum outlines the necessary competencies for specific duties and the training methods to be applied to personnel carrying out tasks associated with:
i. Implementing HACCP for staff involved in developing and maintaining food safety plans;
ii. Monitoring and corrective action procedures for all staff engaged in monitoring critical control points (CCPs);
iii. Personal hygiene for all staff involved in the handling of food products and food contact surfaces;
iv. Good Manufacturing Practices and work instructions for all staff engaged in food handling, food processing, and equipment;
v. Sampling and test methods for all staff involved in sampling and testing of raw materials, packaging, work-in-progress, and finished products;
vi. Environmental monitoring for relevant staff;
vii. Allergen management, food defense, and food fraud for all relevant staff; and
viii. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF code.
The training program shall include provisions for identifying and implementing the refresher training needs of the organization.

RESPONSE: COMPLIANT

EVIDENCE:

2.9.2.2 Training materials, the delivery of training, and procedures on all tasks critical to meeting regulatory compliance and the maintenance of food safety shall be provided in language(s) understood by staff.

RESPONSE: COMPLIANT

EVIDENCE:

2.9.2.3	Training records shall be maintained and include: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Verification that the trainee is competent to complete the required tasks.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.1	**Premises Location and Approval** The property is licensed and located in a light industrial area within Ocean NJ(Brick). The facility was established in Building 1112 and keeps expanding into other buildings on the campus. The site has an up to date State of NJ Business License that expires 5/31/2024, 7/31/2024 . The Site is registered with the FDA, its registration expires 12/31/2024.
11.1.1.1	The site shall assess local activities and the site environment to identify any risks that may have an adverse impact on product safety and implement controls for any identified risks. The assessment shall be reviewed in response to any changes in the local environment or activities. The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2	**Building Materials** Product contact surfaces are smooth and built with corrosion resistant materials. The food handling areas use Stainless Steel food contact equipment processing equipment. All materials are appropriate for the application. The site has smooth concrete floors covered with or epoxy or painted floors in manufacturing areas. Floors are appropriately sloped to drains. Drains were trench style or circular drains but were clean and accessible. The site has no waste traps. Stairs do not pose a contamination risk. The only stairs were in the processing areas to access sifters and magnets. Minor: Equipment was inspected from various buildings in the plant inspection and it was noted that 1. 2 different Hatches missing sealant on Hopper 2 and 3 Elzan and also some tape was noted in each corner of the interior Hopper box on the Hopper that was adjacent to the far wall in Sugar Drink mix area.
11.1.2.1	Floors shall be constructed of smooth, dense, impact-resistant material that can be effectively graded, drained, impervious to liquid, and easily cleaned. Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions. Where floor drainage is not available, plumbed options to handle overflow or wastewater shall be in place.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.2	Drains shall be constructed and located so they can be easily cleaned and not present a hazard.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.3 Waste trap system shall be located away from any food handling areas or entrances to the premises.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.4 Walls, partitions, ceilings, and doors shall be of durable construction. Internal surfaces shall have an even and regular surface and be impervious with a light-colored finish and shall be kept clean (refer to 11.2.5). Wall-to-wall and wall-to-floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.5 Ducting, conduit, and pipes that convey ingredients, products, or services, such as steam or water, shall be designed and constructed to prevent the contamination of food, ingredients, and food contact surfaces and allow ease of cleaning.
A risk analysis shall be conducted to ensure food contamination risks are mitigated.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.6 Pipes carrying sanitary waste or wastewater that are located directly over product lines or storage areas shall be designed and constructed to prevent the contamination of food, materials, ingredients, and food contact surfaces and shall allow ease of cleaning.
A risk analysis shall be conducted to ensure food contamination risks are mitigated.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.7 Doors, hatches, and windows and their frames in food processing, handling, or storage areas shall be of a material and construction that meets the same functional requirements as for internal walls and partitions. Doors and hatches shall be of solid construction, and windows shall be made of shatterproof glass or similar material.

RESPONSE: MINOR

EVIDENCE: Equipment was inspected from various buildings in the plant inspection and it was noted that 1. 2 different Hatches missing sealant on Hopper 2 and 3 Elzan and also some tape was noted in each corner of the interior Hopper box on the Hopper that was adjacent to the far wall in Sugar Drink mix area.

ROOT CAUSE: Inapropriate repairs were left unfinished. Why? Managers had signed off on repairs that were not sufficient. Why? Managers were not aware that these were not sufficient repairs. Why? Insufficient training of managers to review work orders.

CORRECTIVE ACTION: Managers were provided retraining on what was necessary to sign off on repairs. As well as our policy for maintenance materials and conditions. Screens were repaired and installed. Flashlights were provided to aid in inspections.

VERIFICATION OF CLOSEOUT: Evidence of Updated Training for mechanics was provided, it was dated 6/4/2024. Photo evidence of tape removal, and gasket repairs were provided.

COMPLETION DATE: 06/04/2024 **CLOSEOUT DATE**: 06/17/2024

11.1.2.8 Product shall be processed and handled in areas that are fitted with a ceiling or other acceptable structure that is constructed and maintained to prevent the contamination of products. Drop ceilings, where present, shall be constructed to enable monitoring for pest activity, facilitate cleaning, and provide access to utilities.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.2.9 Stairs, catwalks, and platforms in food processing and handling areas shall be designed and constructed so they do not present a product-contamination risk and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.5).

RESPONSE: COMPLIANT

EVIDENCE:

11.1.3 Lightings and Light Fittings

Lighting is a combination of LED. Lighting was maintained to not present a contamination risk. Lighting is listed on the Glass and Brittle Plastic Register and Monitored.

11.1.3.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively and shall comply with local light-intensity regulations or industry standards.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.3.2 Light fixtures in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers, and recessed into or fitted flush with the ceiling.

Where fixtures cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials, and addressed in the cleaning and sanitation program.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.3.3 Light fixtures in the warehouse or other areas where product is covered or otherwise protected shall be designed to prevent breakage and product contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.4	**Inspection/ Quality Control Area** The site conducts visual product inspections of raw materials on the floor. The site has a Quality lab where more detailed inspections take place if applicable. The area has access to hand washing, appropriate waste handling, and is kept neat and tidy.
11.1.4.1	If online inspection is required, a suitable area close to the processing line shall be provided for the inspection of product (refer to 2.4.4). The inspection/quality control area shall be provided with facilities that are suitable for examination and testing of the type of product being handled/processed. The inspection area shall: i. Have easy access to handwashing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.5	**Dust, Insect, and Pest Proofing** The site's windows and doors were self closing and well sealed. Doors and windows were insect proofed. The site employed pest control devices, but the locations did not put product at risk. Rodenticide was only used in exterior bait stations. Their were no insect light traps or pheromones in use. Locations of mechanical rodent traps did not put product at risk.
11.1.5.1	All external windows, ventilation openings, doors, and other openings shall be effectively sealed when closed, and proofed against dust, vermin, and other pests. External personnel access doors shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against entry of dust, vermin, and other pests. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.5.2	External doors, including overhead dock doors in food handling areas used for product, pedestrian, or truck access, shall be designed and maintained to prevent pest ingress by at least one or a combination of the following methods: i. A self-closing device; ii. An effective air curtain; iii. A pest-proof screen; iv. A pest-proof annex; and v. Adequate sealing around trucks in docking areas. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.5.3	Electric insect control devices, pheromone, or other traps and baits shall be located and operated so they do not present a contamination risk to the product, packaging, containers, or processing equipment. Poison rodenticide bait shall not be used inside ingredients or product storage areas or processing areas where ingredients, packaging, and products are handled, processed, or exposed. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.1.6	**Ventilation** The site has adequate ventilation. Four high speed Ventilation fans were present was in the fudge kitchen. The ventilation system had lights above kettles, condition of exhaust ducts and lights were checked at preop. The ventilation system is noted on the PM schedule.
11.1.6.1	Adequate ventilation shall be provided in enclosed processing and food handling areas. Where appropriate, positive air-pressure systems shall be installed to prevent airborne contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.6.2	All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.5 to prevent unsanitary conditions. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.6.3	Extractor fans and canopies shall be provided in areas where open cooking operations are carried out or a large amount of steam is generated. Capture velocities shall be sufficient to prevent condensation build-up and to evacuate all heat, fumes, and other aerosols to the exterior via an exhaust hood positioned over the cooker(s). **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.6.4	Fans and exhaust vents shall be insect-proofed and located so they do not pose a contamination risk and shall be kept clean. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.1.7	**Equipment and Utensils** Building and Facility Policy rev 11/20/2016 rev 1, 11.1.7. New Equipment Procedure rev 12/4/2018 and Equipment, Utensils and Protective Clothing procedures which details the specifications for equipment, utensils and protective clothing. Equipment and utensil surfaces were smooth, free from cracks and crevices. Product containers are clearly identified. Conveyor belts, plastic totes, and packaging equipment were hygienically designed and made of appropriate materials. Waste was properly discarded. The site is responsible to wear clean clothes and laundered uniforms when handling open food. The facility had requirements to clean equipment, utensils and clothing at a frequency to prevent contamination. The site has established a color code procedure, that defines where equipment can be used. The site requires the Sanitary Design to be evaluated for any new or used equipment(11.2 Premises and Equipment Maintenance Product Protection Risk Assessment).
11.1.7.1	Specifications for equipment and utensils and procedures for purchasing equipment shall be documented and implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.1.7.2 Equipment and utensils shall be designed, constructed, installed, operated, and maintained to meet any applicable regulatory requirements and to not pose a contamination threat to products.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.3 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers. Where possible, food contact equipment shall be segregated from non-food contact equipment.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.4 Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging storage, and cold storage areas shall be constructed of materials that will not contribute to a food safety risk.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.5 Benches, tables, conveyors, mixers, mincers, graders, and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious, and free from cracks or crevices.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.6 Product containers, tubs, and bins used for edible and inedible material shall be constructed of materials that are non-toxic, smooth, impervious, and readily cleaned as per 11.2.5.1. Bins used for inedible material shall be clearly identified.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.7 All equipment and utensils shall be cleaned after use (refer to 11.2.5.1) or at a set and validated frequency to control contamination and be stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.8 Vehicles used in food contact, handling, or processing zones or cold storage rooms shall be designed and operated so as not to present a food safety hazard.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.7.9 Non-conforming equipment shall be identified, tagged, and/or segregated for repair or disposal in a manner that minimizes the risk of inadvertent use, improper use, or risk to the integrity of finished product. Records of the handling, corrective action, and/or
disposal of non-conforming equipment shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.8 **Grounds and Roadways**
The site has well maintained exterior grounds , roadways, and docks. Exterior grounds are neat and tidy. No standing water or vegetation near the building was noted during grounds walk. Paths are effectively sealed. Inspections are done monthly and documented on the audit checklist.

11.1.8.1 A suitable external environment shall be established, and the effectiveness of the measures shall be monitored and periodically reviewed. The premises, its surrounding areas, storage facilities, machinery, and equipment shall be kept free of waste or accumulated debris, and vegetation shall be controlled so as not to attract pests and vermin or present a food safety hazard to the sanitary operation of the site.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.8.2 Paths, roadways, and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operations of the premises. They shall be adequately drained to prevent the pooling of water. Drains shall be separate from the site drainage system and regularly cleared of debris.

RESPONSE: COMPLIANT

EVIDENCE:

11.1.8.3 Paths from amenities leading to site entrances shall be effectively sealed.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.1 **Repairs and Maintenance**
11.2.10 Facility and Plant Maintenance Program rev 6/25/2018 which lists procedures and policies to prevent product contamination by plant equipment and the building. The site has documented weekly, monthly, and semi annual PM's. Corrective Maintenance is tracked in the morning meeting minutes. PM Work Orders are completed on paper and given to the SQFP for documenting in Excel; equipment failures are reviewed and incorporated into the maintenance control schedule. Examples of Work Orders from 1/23/2024 thermostat not working, 2/23/2024 Mixer weld repair needs fixing, and 4/22/2024 Broken Sink work order examples were reviewed, no issues noted. Maintenance staff and contractors are required to adhere to GMP and Hygiene policies and escorted while at the site. Visitors are trained on GMP's upon entry. Site supervision is notified when maintenance repairs are needed verbally or by filling out a work request. Employees were trained to report maintenance issues as confirmed via interview. Tool reconciliation and cleaning of tools is assessed. PMs were reviewed for the Bag Feeder Monthly PM from 4/5 and 5/9/2024 were sampled and adhere to established schedule. The site has established temporary repair procedures. The site performs a temporary repair audit and logs needed repairs, an example of a temporary repair on the log from 4/22/2024 for a rubber coupling was reviewed, no issues noted. The site uses food grade lubricants. Paint in not used on food contact surfaces. Food grade lubricants are only used in the maintenance repair process. Records for Preventive Maintenance are documented in Food Safety Plus.

11.2.1.1	The methods and responsibility for the maintenance and repair of plant, equipment, and buildings shall be documented, planned, and implemented in a manner that minimizes the risk of product, packaging, or equipment contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.1.2	Routine maintenance of plant and equipment in any food processing, handling, or storage areas shall be performed according to a maintenance control schedule and recorded. The maintenance schedule shall be prepared to include buildings, equipment, and other areas of the premises critical to the maintenance of product safety. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.1.3	Failures of plant and equipment in any food processing, handling, or storage areas shall be documented and reviewed, and their repair(s) incorporated into the maintenance control schedule. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.1.4	Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling, or storage areas. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.1.5	The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance activities pose a potential threat to product safety (e.g., pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside operating times. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.1.6	Temporary repairs, where required, shall not pose a food safety risk and shall be included in routine inspections (refer to 2.5.4.3) and the cleaning program. There shall be a plan in place to address the completion of temporary repairs to ensure they do not become permanent solutions. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.1.7	Food contact equipment and equipment located over food contact equipment shall be lubricated with food-grade lubricant, and its use shall be controlled to minimize the contamination of the product. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.2.1.8 Paint used in a food handling or processing area shall be suitable for use, in good condition, and not be used on any product contact surfaces.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.2 Maintenance Staff and Contractors

The site's contractors are required to follow established GMPs. Maintenance contractors are trained prior to entering the facility. The site has return to service procedures post completion of work. The site requires the area to be inspected prior to contractor repairs and restarting operations.

11.2.2.1 Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 11.3).

RESPONSE: COMPLIANT

EVIDENCE:

11.2.2.2 All maintenance and other engineering contractors required to work on-site shall be trained in the site's food safety and hygiene procedures or shall be escorted at all times until their work is completed.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.2.3 Maintenance staff and contractors shall remove all tools and debris from any maintenance activity once it has been completed, and inform the area supervisor and maintenance supervisor, so appropriate hygiene and sanitation can be conducted and a pre-operational inspection completed prior to the restarting of site operations.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.3 Calibration

Calibration procedures are established and maintained for each respective piece of equipment. The procedure includes disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration. Equipment is calibrated against national standards and performed according to regulatory requirements. The site has register of equipment to be calibrated(Master Calibration Log, 4/21/2022). The site conducts annual scale calibration of scales via a third party (Scale Calibration Report 4/2025). The site has documented calibration records for thermometers, NIST cooler thermometers, 11/2024. Calibration records were maintained. Magnets are tested for pull strength, last completed, 11/2024 as per procedure. The ATP unit is to be calibrated monthly. pH meters are calibrated daily an example from 2024 was reviewed. No issues with calibration noted.

11.2.3.1 The methods and responsibility for calibration and re-calibration of measuring, testing, and inspection equipment used for monitoring activities outlined in prerequisite programs, food safety plans, and other process controls, or to demonstrate compliance with customer specifications, shall be documented and implemented. Software used for such activities shall be validated as appropriate.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.3.2	Equipment shall be calibrated against national or international reference standards and methods or to an accuracy appropriate to its use. In cases where standards are not available, the site shall provide evidence to support the calibration reference method applied. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.3.3	Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers' recommended schedule. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.3.4	Procedures shall be documented and implemented to address the resolution of potentially affected products when measuring, testing, or inspection equipment is found to be out of calibration. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.3.5	Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment or use. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.3.6	A directory of measuring, testing, and inspection equipment that require calibration and records of the calibration tests shall be maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.4	**Pest Prevention** The methods and responsibilities for pest prevention are documented in the Pest Control Manual. The site has a third party pest control service that monitors the facility for targeted pests. The site has a signed service agreement in place. ILTs are checked bi-monthly. Bait stations are checked monthly. Interior tin cats are checked bi-monthly. A couple Tin cats from each building were reviewed for compliance. There is a manual maintained by the third party and one that found online. The manual contains an up to date map of traps (2/2/2023), SDS sheets for chemicals used, business license (expires 10/31/2024) and liability insurance (expires 1/1/2025). The site includes an approved chemical register (Talstar), and a list of chemicals used and dosages. The site is serviced by trained technician (applicator license 10/31/2024). Examples of Service reports were reviewed. The site has a procedures on how the site will interact with the Pest control Company denoting responsibilities of the site and those of the third party. Pesticides are removed from the site after use. Food products, raw materials or packaging that are found to be contaminated by pest activity are isolated and dispositioned accordingly, and the source of pest infestation is investigated and resolved by issuing a corrective action.

11.2.4.1 A documented pest prevention program shall be effectively implemented. It shall:
i. Describe the methods and responsibility for the development, implementation, and maintenance of the pest prevention program;
ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications;
iii. Outline the methods used to prevent pest problems;
iv. Outline the pest elimination methods and the appropriate documentation for each inspection;
v. Outline the frequency with which pest status is to be checked;
vi. Include the identification, location, number, and type of applied pest control/monitoring devices on a site map;
vii. List the chemicals used. The chemicals are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available;
viii. Outline the methods used to make staff aware of the bait control program and the measures to take when they come into contact with a bait station;
ix. Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and
x. Measure the effectiveness of the program to verify the elimination of applicable pests and to identify trends.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.2 Pest contractors and/or internal pest controllers shall:
i. Be licensed and approved by the local relevant authority;
ii. Use only trained and qualified operators, who comply with regulatory requirements;
iii. Use only approved chemicals;
iv. Provide a pest prevention plan (refer to 2.3.2.8), which includes a site map, indicating the location of bait stations traps and other applicable pest control/monitoring devices;
v. Report to a responsible authorized person on entering the premises and after the completion of inspections or treatments;
vi. Provide regular inspections for pest activity with appropriate action taken if pests are present, and
vii. Provide a written report of their findings and the inspections and treatments applied.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.3 Pest activity risks shall be analyzed and recorded. Inspections for pest activity shall be conducted on a regular basis by trained site personnel and the appropriate action taken if pests are present. Identified pest activity shall not present a risk of contamination to food products, raw materials, or packaging.
Records of all pest control inspections and applications shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.4 Food products, raw materials, or packaging that are found to be contaminated by pest activity shall be effectively disposed of, and the source of pest infestation shall be investigated and resolved. Records shall be kept of the disposal, investigation, and resolution.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.5 Pesticides shall be clearly labeled and stored per 11.6.4 if kept on-site.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.4.6 No animals shall be permitted on-site in food handling and storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5 Cleaning and Sanitation

Methods and responsibilities for cleaning food handling equipment and the environment were documented in 11.2.5 Cleaning and Sanitation rev . A cleaning schedule was maintained on paper. The plant has documented Standard Sanitary Operating Procedures documented in the work instructions for the equipment. Plant uses a combination of cleaning methods including dry cleaning and controlled wet cleaning methods to maintain cleanliness of the equipment and building. Routine cleaning is documented via paper. A preop inspection process is documented and completed; an example of a preop inspection on the Elzan line was witnessed, no issues noted. The site uses pre-dosed chemical detergents and sanitizers for manual cleaning. Titrations are completed by third party (Chemstation). Amenities are cleaned daily. Appropriate chemicals are used per label directions and stored appropriately. Cleaning is verified by visual inspection as well as by ATP per the schedule. Cleaning is validated by microbial and allergen swabbing results from 3 cycle of post cleaning review. The site does not use CIP systems. Minor(s): The site has Preoperational inspections which look at cleanliness and proper functioning of equipment. During the plant inspection, it was noted that there were holes in two screens in 2 out of 3 hoppers in Elzan that are supposed to be checked at preop; there was a hole noted in Sweeco in agglomeration. The preop was completed but no issues with the screen were identified.

11.2.5.1 The methods and responsibility for the effective cleaning of the food handling and processing equipment and environment and storage areas shall be documented and implemented. Consideration shall be given to:
i. What is to be cleaned;
ii. How it is to be cleaned;
iii. When it is to be cleaned;
iv. Who is responsible for the cleaning;
v. Validation of the cleaning procedures for food contact surfaces (including CIP);
vi. Methods used to confirm the correct concentrations of detergents and sanitizers; and
vii. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.2 Detergents and sanitizers shall be suitable for use in a food manufacturing environment, labeled according to regulatory requirements, and purchased in accordance with applicable legislation. The organization shall ensure:
i. The site maintains a list of chemicals approved for use;
ii. An inventory of all purchased and used chemicals is maintained;
iii. Detergents and sanitizers are stored as outlined in element 11.6.4;
iv. Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and
v. Only trained staff handle sanitizers and detergents.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.3	Detergents and sanitizers that have been mixed for use shall be correctly mixed according to the manufacturers' instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.5.4	Cleaning-in-place (CIP) systems, where used, shall not pose a chemical contamination risk to raw materials, ingredients, or product. CIP parameters critical to assuring effective cleaning shall be defined, monitored, and recorded (e.g., chemical and concentration used, contact time, and temperature). CIP equipment, including spray balls, shall be maintained, and any modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.5.5	Cleaning equipment, tools, racks, and other items used in support of the cleaning and sanitizing program shall be clearly identified, stored, and maintained in a manner that prevents contamination of processing areas, product handling equipment, and storage areas as well as the tools themselves. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.5.6	Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards, and other utensils used by staff. The areas for these cleaning operations shall be controlled so they do not interfere with manufacturing operations, equipment, or product. Racks and containers for storing cleaned utensils shall be provided as required. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.2.5.7	Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities, sanitary facilities, and other essential areas are clean before the start of production. Pre-operational inspections shall be conducted by qualified personnel. **RESPONSE:** MINOR **EVIDENCE:** The site has Preoperational inspections which look at cleanliness and proper functioning of equipment. During the plant inspection, it was noted that there were holes in two screens in 2 out of 3 hoppers in Elzan that are supposed to be checked at preop; there was a hole noted in Sweeco in agglomeration. The preop was completed but no issues with the screen were identified. **ROOT CAUSE:** Issues were not identified on completed Pre Op inspections. Why? Inspectors had noted these damages on previous inspections and had submitted work orders to have them repaired but were not following up. Why? Inspectors thought that once they had noted it initially they could stop marking the sheet with failing results. Why? Insufficient training of Pre Op for employees. **CORRECTIVE ACTION:** Pre Operation retraining was provided for QC/Managers that perform inspections. Emphasis on conditions of equipment to be continuously documented.

VERIFICATION OF CLOSEOUT: Evidence of Updated Training for eemployees conducting preoperational inspections was provided. Training was conducted on 6/4/2024. Photo evidence of screen repairs were documented and provided.

COMPLETION DATE: 06/04/2024 **CLOSEOUT DATE**: 06/17/2024

11.2.5.8 Staff amenities, sanitary facilities, and other essential areas shall be inspected by qualified personnel at a defined frequency to ensure the areas are clean.

RESPONSE: COMPLIANT

EVIDENCE:

11.2.5.9 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.
A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.1 Personnel Welfare

The site has GMP Policy rev 1/14/2022 which details employee and personal hygiene standards. The policy requires personnel who have communicable diseases to not work while infected. The procedure details the bloodborne pathogen management procedures. Personnel who have exposed cuts are not allowed to work without proper protective dressings. Smoking and eating is restricted to designated areas. Water is consumed in designated areas off the production floor. Medical Screening is done through daily Temperature Monitoring. (COVID-19 8/17/2021).

11.3.1.1 Personnel who are known to be carriers of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food or enter storage areas where food is exposed.

Code Amendment #1
A medical screening procedure shall be in place for all employees, visitors and contractors who handle exposed product or food contact surfaces.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.1.2 The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids, open wounds, coughing, sneezing, spitting, or any other means.
In the event of an injury that causes the spillage of bodily fluid, a properly trained staff member shall ensure that all affected areas, including handling and processing areas, have been adequately cleaned, and that all materials and products have been quarantined and/or disposed of.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.1.3	Personnel with exposed cuts, sores, or lesions shall not engage in handling or processing exposed products or handling primary (food contact) packaging or touching food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored, metal-detectable bandage or an alternative suitable waterproof and colored dressing. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.2	**Handwashing** The site has 11.3.2 Hand Washing procedures which discusses the requirements around hand washing. Hand wash stations have paper towels, storage for waste, and adequate hot water. Hand wash stations are hands free. Adequate signage exists reminding employees to wash their hands. Personnel followed handwash procedures. Personnel were noted to be complaint to handwash procedures.
11.3.2.1	All personnel shall have clean hands, and hands shall be washed by all staff, contractors, and visitors: i. On entering food handling or processing areas; ii. After each visit to a toilet; iii. After using a handkerchief; iv. After smoking, eating, or drinking; and v. After handling wash down hoses, cleaning materials, dropped product, or contaminated material. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.2.2	Handwashing stations shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.2.3	Handwashing stations shall be constructed of stainless steel or similar non-corrosive material and at a minimum supplied with: i. A potable water supply at an appropriate temperature; ii. Liquid soap contained within a fixed dispenser; iii. Paper towels in a hands-free cleanable dispenser; and iv. A means of containing used paper towels. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.2.4	The following additional facilities shall be provided in high-risk areas: i. Hands-free operated taps; and ii. Hand sanitizers. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.2.5	Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in break rooms, at break room exits, toilet rooms, and in outside eating areas, as applicable.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.2.6 When gloves are used, personnel shall maintain the handwashing practices outlined above.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3 Clothing and Personal Effects

The site has 11.3.3 Clothing which outlines clothing requirements. The site employs the use of laundered Uniforms supplied by Cintas. The site uses hair nets or head coverings for GMP purposes. Coverings must be in good condition and changed when soiled. Excessively soiled smocks will be promptly addressed by the leadership and are appropriately removed when dirty. The site has cleaning procedures to remove any potential micro contamination. Gloves were in use at the site for handling open product. The site has 11.3.3 Jewelry policy that prevents the use of jewelry in the production area. Only plain wedding bands are permissible. The jewelry policy is appropriate and complies with 21 CFR part 117.

11.3.3.1 The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food, and food contact surfaces from unintentional microbiological or physical contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.2 Clothing worn by staff engaged in handling food shall be maintained, stored, laundered, and worn so it does not present a contamination risk to products.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.3 Clothing, including shoes, shall be clean at the start of each shift and maintained in a serviceable condition.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.4 Excessively soiled uniforms shall be changed or replaced when they present a product contamination risk.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.5 Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area, and when damaged.
Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or in designated sealed containers in personnel lockers. They should not be placed or stored on packaging, ingredients, product, or equipment.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.3.6	Protective clothing shall be manufactured from material that will not pose a food safety threat and is easily cleaned. All protective clothing shall be cleaned after use, or at a frequency to control contamination, and stored in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.3.7	Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided nearby or adjacent to the personnel access doorways and handwashing facilities. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.3.8	Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or into any area where food is exposed. Wearing plain bands with no stones, prescribed medical alert bracelets, or jewelry accepted for religious or cultural reasons can be permitted, provided these items are properly covered and do not pose a food safety risk. All exceptions shall meet regulatory and customer requirements and shall be subject to a risk assessment and evidence of ongoing risk management. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.4	**Visitors** 11.3.4 Visitors rev 4/13/2020 describes clothing standards. Guest must wear suitable clothing. The policy states that visitors are required to remove jewelry except wedding bands without stones. Guests are required to be escorted at all times and are trained in GMP's before entering the site. Visitors exhibiting visible signs of illness, will not be admitted into the site.
11.3.4.1	All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing and handling areas or shall be escorted at all times in food processing, handling, and storage areas. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.4.2	All visitors, including management staff, shall be required to remove jewelry and other loose objects in accordance with the facilities Good Manufacturing Practices and 11.3.3.8. All visitors shall wear suitable clothing and footwear when entering any food processing and handling area. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.4.3	Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled and processed. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.3.4.4 Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all handwashing and personnel practice requirements.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5 Staff Amenities (change rooms, toilet, break rooms)

The site has amenities that are well lit and ventilated for persons engaged in handling and processing of food. Staff has lockers and change rooms they are well maintained and do not pose a risk of contamination to food. Locker rooms are located off the production floor in the bath rooms. Showers are not provided or required. There are no high risk areas. Toilets room are designed and constructed separately from the production areas. There is sufficient number and location based on the staff. Toilet rooms are clean and tidy. The site has a drain map showing the separation of sanitary and process drains. Lunch room are separated from food handling zones, they are ventilated and well lit. They have adequate access to handwash sinks; garbage does not attract pests. Hand wash signs are in appropriate languages are posted at prominent positions to remind people to wash hands before returning to work. There are no outside eating areas.

11.3.5.1 Staff amenities shall have documented cleaning procedures, be supplied with appropriate lighting and ventilation, and shall be made available for use by all persons engaged in the handling and processing of product.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.2 Change rooms shall be provided to enable staff and visitors to change into and out of protective clothing as required. Change rooms shall be kept clean.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.4 Provision shall be made for staff to store their street clothing and personal items separate from clean uniforms, food contact zones, food, and packaging storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.6 Toilet rooms shall be:
i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations;
ii. Accessed from the processing area via an airlock vented to the exterior or through an adjoining room;
iii. Sufficient in number for the maximum number of staff;
iv. Constructed so that they can be easily cleaned and maintained;
v. Located inside or nearby areas for storing protective clothing, outer garments, and other items while using the facilities; and
vi. Kept clean and tidy.
Tools/equipment used for cleaning toilet rooms shall not be used to clean processing areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.3.5.7	Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system in accordance with regulations. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.5.8	Handwashing basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.3. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.3.5.9	Separate break rooms shall be provided away from food contact/handling zones. Break rooms shall be: i. Ventilated and well lit; ii. Provided with adequate tables and seating to cater for the maximum number of staff at one sitting; iii. Equipped with a sink serviced with hot and cold potable water for washing utensils; iv. Equipped with refrigeration and heating facilities, enabling staff to store or heat food and to prepare non-alcoholic beverages if required; and v. Kept clean and free from waste materials and pests. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.4.1	**Staff Engaged in Food Handling and Processing Operations** All personnel engaged in food handling were using appropriate GMP's. Sensory is performed in designated Quality office areas. Packaging materials and ingredients were stored appropriately off the floor in racks for that intended purpose. Hoses are stored appropriately.
11.4.1.1	All personnel engaged in any food handling, preparation, or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices: i. Personnel entry to processing areas shall be through the personnel access doors only; ii. All doors are to be kept closed. Doors shall not be open for extended periods when access is required for waste removal or receiving of product/ingredient/packaging; iii. Packaging, product, and ingredients shall be kept in appropriate containers as required and off the floor; iv. Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate; and v. All wash down and compressed air hoses shall be stored on hose racks after use and not left on the floor. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.4.1.2 Personnel working in or visiting food handling or processing operations shall ensure that:
i. Staff shall not eat or taste any product being processed in the food handling/contact zones, except as noted in element 11.4.1.4;
ii. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails, or fingernail polish is not permitted when handling exposed food;
iii. Hair restraints and beard covers, where applicable, shall be used in areas where product is exposed.
iv. Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed.
v. Drinking water is permissible only under conditions that prevent contamination or other food safety risks from occurring. Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging, tools, or equipment storage.

RESPONSE: COMPLIANT

EVIDENCE:

11.4.1.3 The flow of personnel in food processing and handling areas shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

EVIDENCE:

11.4.1.4 In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone, the site shall implement controls and procedures to ensure:
i. Food safety is not compromised;
ii. Sensory evaluations are conducted by authorized personnel only;
iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations;
iv. Sensory evaluations are conducted in areas equipped for the purpose; and
v. Equipment used for sensory evaluations is sanitized, maintained, and stored separately from processing equipment.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.1 **Water Supply**
The site as adequate potable water supply as supplied by the city (Ocean Township NJ). Water is tested at least annually. Water is tested for Total Coliform, APC and E. coli. A full panel on the water content is completed annually . The site employs the use of a backflow preventers and they are tested annually, last conducted 3/7/2024. Each was tested and passed for the year of 2024. Water is not stored on site. Testing complies to 11.5.1 Water, Ice and Air Supply. Contingency plans for non potable water use exists, primarily by bringing in a bulk water source.

11.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for water used as an ingredient during processing operations and for cleaning the premises and equipment. The source of potable water shall be identified as well as on-site storage (if applicable) and reticulation within the facility.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.1.2 Contingency plans shall be in place for instances when the potable water supply is deemed to be contaminated or otherwise inappropriate for use.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.1.3 Supplies of hot and cold water shall be provided, as required, to enable the effective cleaning of the premises and equipment.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.1.4 The delivery of water within the premises shall ensure potable water is not contaminated. Testing of the backflow system, where possible, shall be conducted at least annually and records shall be maintained.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.1.5 The use of non-potable water shall be controlled such that:
i. There is no cross-contamination between potable and non-potable water lines;
ii. Non-potable water piping and outlets are clearly identified; and
iii. Hoses, taps, and other similar sources of possible contamination are designed to prevent backflow or back-siphonage.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.1.6 Where water is stored on-site, storage facilities shall be adequately designed, constructed, and routinely cleaned to prevent contamination.

RESPONSE: COMPLIANT

EVIDENCE:

11.5.2 Water Treatment

The site does not treat water.

11.5.3 Water Quality

Water complies to water potability standards. The site tests water for Total Coliform and E. coli annually, last tested on 2/9/2024, no issues noted. The test site is the main production sinks. A full panel was completed each year; results from 2023 were available. The site sends samples for analysis to an accredited third party lab using appropriate AOAC approved methods.

11.5.3.1	Water shall comply with local, national, or internationally recognized potable water microbiological and quality standards, as required when used for: i. Washing, thawing, and treating food; ii. Handwashing; iii. Conveying food; iv. An ingredient or food processing aid; v. Cleaning food contact surfaces and equipment; vi. The manufacture of ice; or vii. The manufacture of steam that will come into contact with food or be used to heat water that will come into contact with food. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.3.2	Microbiological analysis of the water and ice supply shall be conducted to verify the cleanliness of the supply, the monitoring activities, and the effectiveness of the treatment measures implemented. Samples for analysis shall be taken at sources supplying water for the process or cleaning or from within the site. The frequency of analysis shall be risk-based and at a minimum annually. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.3.3	Water and ice shall be analyzed using reference standards and methods. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.4	**Ice Supply** The site does not use ice in the process
11.5.5	**Air and Other Gasses** The site uses compressed air and Nitrogen for cleaning. It is filtered at the source, and air sampled and tested for Yeast and Mold and Coliforms monthly, last completed on 5/30/2023.
11.5.5.1	Compressed air or other gases (e.g., nitrogen or carbon dioxide) that contact food or food contact surfaces shall be clean and present no risk to food safety. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.5.5.2	Compressed air systems and systems used to store or dispense other gases that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards. The frequency of analysis shall be risk-based and at a minimum annually. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.6.1	**Receipt, Storage and Handling of Goods** The site has 11.6 Storage and Transport which describes the site's policy for storing raw materials (i.e. frozen, chilled, and ambient), ingredients, packaging materials, equipment, and chemicals. The site uses FIFO for storage practices. Products are shipped out FEFO. There is no overflow or alternate storage. Ingredients are stored off the floor on pallets in the main dry storage areas. Inventory Management is done by hand.
11.6.1.1	The site shall document and implement an effective storage plan that allows for the safe, hygienic receipt and storage of raw materials (i.e., frozen, chilled, and ambient), ingredients, packaging, equipment, and chemicals. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.1.2	Controls shall be in place to ensure all ingredients, raw materials, processing aids, and packaging are received and stored properly to prevent cross-contamination risks. Unprocessed raw materials shall be received and stored separately from processed raw materials to avoid cross-contamination risk. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.1.3	The responsibility and methods for ensuring effective stock rotation principles shall be documented and implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.1.4	Procedures shall be in place to ensure that all ingredients, materials, work- in-progress, rework, and finished product are utilized within their designated shelf-life. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.2	**Cold Storage, Freezing and Chilling of Foods** The site has no coolers or refrigerators.
11.6.3	**Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods** The site stored ingredients off the floor on pallets and ingredient racking. The storage areas were dry and constructed of appropriate materials. Storage areas were clean and free of harborage points. Packaging is appropriately covered. Vehicles used to transport ingredients were clean and well maintained.
11.6.3.1	Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration and prevent packaging from becoming a harborage for pests or vermin. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.6.3.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning and inspection of the floors and behind the racks. Storage areas shall be cleaned at a pre-determined frequency.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

The site has few bulk chemicals which are secured in job boxes near production lines. Access is restricted to only trained personnel. Training is conducted annually. Chemical Control rev 3/4/2016 procedures are documented. Pine Kleen was listed on the Approved Chemical List rev 5/12/2023 and SDS, dated, 6/6/2022. All SDS's for chemicals were maintained at the sight. Water is treated by the municipality. Chemicals are used per label instructions and comply with regulations. Sanitizer is stored adjacent to lines and is appropriately labeled. Utensils are stored in each department and cleaned appropriately. Pest Control chemicals are not stored on site. The site has a couple of chemical cabinets in the areas where chemicals are used, they were locked. Chemicals are appropriately labeled. The site stores bulk chemicals on spill proof pallets.

11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be:
i. Clearly labeled, identifying and matching the contents of their containers;
ii. Included in a current register of all hazardous chemicals and toxic substances that are stored on-site; and
iii. Supplemented with current Safety Data Sheets (SDS) made available to all staff.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4.2 Storage of hazardous chemicals and toxic substances shall be:
i. Located in an area with appropriate signage indicating that the area is for hazardous storage;
ii. Controlled, lockable, and accessible only by personnel trained in the storage and use of chemicals;
iii. Adequately ventilated;
iv. Stored where intended and not comingled (e.g., food versus non-food grade);
v. Designed such that pesticides, rodenticides, fumigants, and insecticides are stored separately from sanitizers and detergents; and
vi. Stored in a manner that prevents a hazard to finished product or product contact surfaces.
Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4.3 Hazardous chemicals and toxic substances shall be correctly labeled and:
i. Used only according to manufacturers' instructions;
ii. Controlled to prevent contamination or a hazard to raw and packaging material, work-inprogress, finished product, or product contact surfaces;
iii. Returned to the appropriate storage areas after use; and
iv. Be compliant with national and local legislation.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.4.4	Daily supplies of chemicals used for continuous sanitizing of water, as a processing aid, or for emergency cleaning of food processing equipment and surfaces in food contact zones may be stored within or in close proximity to a processing area, provided that access to the chemical storage facility is restricted to only authorized personnel. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.4.5	Personnel who handle hazardous chemicals and toxic substances, including pesticides and cleaning chemicals,: i. Shall be fully trained in the purpose of the hazardous chemicals and toxic substances, their storage, handling, and use; ii. Be provided first aid equipment and personnel protective equipment (PPE); and iii. Ensure compliance with the proper identification, storage, usage, disposal, and clean-up requirements. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.4.6	The site shall dispose of empty, obsolete, and unused chemicals, pesticides, toxic substances, and containers in accordance with requirements and ensure that primary containers are: i. Not reused; ii. Segregated and securely stored prior to collection; and iii. Disposed through an approved vendor. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.4.7	In the event of a hazardous spill, the site shall: i. Have spillage clean-up instructions to ensure that the spill is properly contained; and ii. Be equipped with PPE, spillage kits, and cleaning equipment. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.6.5	**Loading, Transport, and Unloading Practices** 11.6.5 Loading, Transport and Unloading outlines the practices applied during loading, transport and unloading of food. Loading and Unloading operations did not pose a risk to food safety. Trucks were witnessed being loaded, no issues noted. The site receives a small number of ingredients on refrigerated trailers. The trailers temperature is documented on the receiving paperwork before unloading. Raw materials are visually inspected prior to acceptance. External trailers are checked for pest activity, water damage and chemical smells. Non-conforming materials and products and materials are rejected if they do not meet standard. No issues with the trucks monitored on site. Minor: The site will move goods on trucks from company warehouses and with company trucks, however, no intraplant vehicle inspection is documented.
11.6.5.1	The practices applied during loading, transport, and unloading of food shall be documented, implemented, and designed to maintain appropriate storage conditions and product integrity. Foods shall be loaded, transported, and unloaded under conditions suitable to prevent cross-contamination. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.6.5.2 Vehicles (e.g., trucks/vans/containers) used for transporting food within the site and from the site shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose, and free from odors or other conditions that may impact negatively on the product.

RESPONSE: MINOR

EVIDENCE: The site will move goods on trucks from company warehouses and with company trucks, however, no intraplant vehicle inspection is documented.

ROOT CAUSE: Warehouse staff not filling out truck inspection forms for intraplant vehicles. Why? Staff did not consider the need for in house trucks to be inspected on form. Why? Training was not provided to them to do this. Why? Administrative oversite. We had not considered our own trucks to require aditional documented inspections.

CORRECTIVE ACTION: Warehouse staff were trained on this topic. Warehouse managers from all three locations were trained on this requirement. Truck inspection forms provided with BOL for intraplant vehicles as well in system.

VERIFICATION OF CLOSEOUT: The site provided evidence of complete vehicle inspection forms dated 5/30, 531 and 6/4/2024. Evidence of training on the new vehicle inspection process was documented. 5/22/2024

COMPLETION DATE: 05/22/2024 **CLOSEOUT DATE**: 06/18/2024

11.6.5.3 Vehicles (e.g., trucks/vans/containers) shall be secured from tampering using seals or other agreed-upon and acceptable devices or systems.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.5.4 Loading and unloading docks shall be designed to protect the product during loading and unloading. Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity during loading and transport.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.5.6 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals, and the storage temperature at regular intervals during transit.

RESPONSE: COMPLIANT

EVIDENCE:

11.6.5.8 Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining product and package integrity.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.1 **High-Risk Processes**
The site has no high risk processes.

11.7.2	**Thawing of Food** The site does not thaw any food.
11.7.3	**Control of Foreign Matter Contamination** Methods and Responsibilities for foreign material control are documented in the facility HACCP Plan, and in 11.7 Detection and Prevention of FM Contamination rev 4/18/2019. The facility has an up to date glass registry, it was sampled and found to be accurate. GMP inspections are performed monthly, completed on 3/5/2024. Glass and Brittle audits are conducted monthly. The site has glass clean-up procedures that includes the isolation, cleaning, and release of potentially affected products. Wooden pallets are inspected as a part of the unloading procedure and poor pallets are rejected or culled from the system at that point. There was no loose metal seen. Foreign Metal inspection is part of the daily preop procedures. The facility has defined knife control procedures. The site has Managing Foreign Matter Incidents which covers the FM containment procedures. The site will isolate, inspect and dispose of potentially contaminated products. Glass follows the same procedures as other FM contamination, the area is cleaned and released by authorized personnel. The site conducts glass and brittle audits monthly. A glass audits for the month of 3/25/2024 were reviewed and no issues were noted. (Glass /Brittle Plastic Breakage Form 1/2/2016 completed on 3/5-3/19/2024)
11.7.3.1	The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented, and communicated to all staff. Inspections shall be performed (refer to 2.5.4.3) to ensure plant and equipment remain in good condition and equipment has not become detached or deteriorated and is free from potential contaminants. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.7.3.2	Containers, equipment, and other utensils made of glass, porcelain, ceramics, laboratory glassware, or other similar materials shall not be permitted in food processing /contact zones (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers are used, or MIG thermometers are required under regulation). Where glass objects or similar material are required in food handling/contact zones, they shall be listed in a glass inventory, including details of their location and condition. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.7.3.3	Regular inspections of food handling/contact zones shall be conducted (refer to 2.5.4.3) to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass inventory. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.7.3.4	Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.7.3.5 In circumstances where glass or similar material breakage occurs, the affected area shall be isolated, cleaned, thoroughly inspected (including cleaning equipment and footwear), and cleared by a suitably responsible person prior to the start of operations.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.6 Wooden pallets and other wooden utensils used in food processing and handling areas shall be dedicated for that purpose, clean, and maintained in good order. Their condition shall be subject to regular inspection.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.7 Loose metal objects on equipment, equipment covers, and overhead structures shall be removed or tightly fixed so as not to present a hazard.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.8 Knives and cutting instruments used in processing and packaging operations shall be controlled, kept clean, and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.3.9 Gaskets, rubber impellers, and other equipment made of materials that can wear or deteriorate over time shall be inspected on a regular frequency (refer to 2.5.4.3).

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4 Detection of Foreign Objects

The facility has appropriate preop procedures to inspect for foreign matter. The site uses magnets and sifters as product protection. The equipment is monitored at startup and as specified based on the product run. Magnets are checked for pull strength annually, last conducted on 11/2023. Site personnel were interviewed on the corrective action procedures. The site personnel was knowledgeable oof the corrective action procedures and monitored the devices appropriately. Records of monitoring were reviewed no issues noted.

11.7.4.1 The responsibility, methods, and frequency for monitoring, maintaining, calibrating, and using screens, sieves, filters, or other technologies to remove or detect foreign matter shall be documented and implemented.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4.2 Where detection and/or removal systems are used, the site shall establish limits for detection, based on a risk assessment of the product and its packaging, and identify the location(s) of the detector(s) in the process.

RESPONSE: COMPLIANT

EVIDENCE:

11.7.4.3	Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated, and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.7.4.4	Records shall be maintained of the inspection of foreign object detection devices, of any products rejected or removed by them, and of corrective and preventative actions resulting from the inspections. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.7.4.5	In all cases of foreign matter contamination, the affected batch or item shall be isolated, inspected, reworked, or disposed of. Records shall be maintained of the disposition. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1	**Waste Disposal** Waste storage areas are neat and organized. Waste is removed daily from the production areas and stored in rodent proofed dumpsters and removed weekly as documented in 11.8.1 Waste Management rev 4/20/2021. Vehicles and waste transport containers are cleaned as needed. Liquid wastes do not present a hazard. Plant does not have an animal feed waste stream. The site disposes of its trade marked materials appropriately, by crushing or cutting before disposal. Certificates of Destruction are maintained.
11.8.1.1	The responsibility and methods used to collect and handle dry, wet, and liquid waste and how to store it prior to removal from the premises shall be documented and implemented. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.2	Waste shall be removed on a regular basis and not allowed to build up in food handling or processing areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until external waste collection is undertaken. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.3	Waste and overflow water from tubs, tanks, and other equipment shall be discharged directly to the floor drainage system or by an alternative method that meets local regulatory requirements. **RESPONSE:** COMPLIANT **EVIDENCE:**

11.8.1.4	Trolleys, vehicle waste disposal equipment, collection bins, and storage areas shall be maintained in a serviceable condition, cleaned, and sanitized regularly to prevent the attraction of pests and other vermin. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.5	Adequate provision shall be made for the disposal of all solid processing waste, including trimmings, inedible material, and used packaging. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.6	Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials waste considered high-risk for handling or other reasons. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.7	Inedible waste designated for animal feed shall be stored and handled so that it will not cause a risk to the animal or further processing. If denaturant is used to identify inedible waste, it shall be demonstrated that it does not pose a risk to animal health. **RESPONSE:** COMPLIANT **EVIDENCE:** **EVIDENCE:**
11.8.1.8	Waste held on-site prior to disposal shall be stored in a separate storage facility that is suitably insect proofed and located where it does not present any hazards. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.9	Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall either be removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal where it does not present any hazards. **RESPONSE:** COMPLIANT **EVIDENCE:**
11.8.1.10	Reviews of the effectiveness of waste management shall form part of regular site inspections (refer to 2.5.4.3), and the results of these inspections shall be included in the relevant inspection reports. **RESPONSE:** COMPLIANT **EVIDENCE:**