SQF Food Safety Audit Edition 9

Steuben Foods, Inc - Steuben Foods, Inc

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
8279 | 152336

AUDIT RATING
96
Excellent

DECISION DATE
05/10/2022

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
03/31/2023

AUDIT DATES
03/29/2022 - 04/01/2022

EXPIRATION DATE
06/14/2023

ISSUE DATE
05/11/2022

Facility & Scope

Steuben Foods, Inc (44428)
Steuben Foods, Inc
1150 Maple Street
Elma, NY 14059
United States

Food Sector Categories:
15. Canning, UHT, and Aseptic Operations
19. Food Ingredient Manufacturing

Products:
Milk, Flavored Milk, Broth, Gravy, Beverages, Fruit Beverages, Plant Based beverages, Nutritional beverages, Soups, Grain and Seed Powders; Exclusons: None

Scope of Certification:
The manufacture and UHT processing of Milk, Flavored Milk, Broth, Gravy, Beverages, Fruit Beverages, Plant Based beverages, Nutritional beverages, Soups, Grain and Seed Powders

Certification Body & Audit Team

AIBI Certification Services
1213 Bakers Way
PO Box 3999
Manhattan, KS 66502
United States

Email: GFSI@aibinternational.com

CB#: CB-1-AIBI
Accreditation Body: ANSI
Accreditation Number: 0835

Lead Auditor: Tharwala, Jatin (206670)
Technical Reviewer: Sodhi, Gurpreet (205005)

Hours Spent on Site: 28
Hours of ICT Activities: 0
Hours Spent Writing Report: 8

Non-Conforming

2.4.3 Food Safety Plan (Mandatory)

The site has documented and implemented six HACCP/ food safety plans prepared in accordance with Codex Alimentarius Commission HACCP guidelines and FSMA requirements. Food safety plans were developed and maintained by site's multi-disciplinary team that included representatives from Quality Assurance, Technical, Maintenance, Production, Warehousing, and Engineering. Products and processes in the scope were covered by site's food safety plan which included; product descriptions, intended use, process flow charts, and hazard analysis of raw materials and processing steps. Process flow was verified by food safety team on May 24, 2021. (1) Raw dairy plan dated May 19, 2021 with CCP-1 (Pasteurization Time/ Temperature) with CCP limit set as 163 deg F at maximum flow rate of 120 gallon per minute (GPM) for minimum of 15 seconds hold time. (2) Extended Shelf Life (ESL) plan dated May 19, 2021 with CCP1 (Ultra-Pasteurization) critical limit set as 280 deg F at maximum flow rate of 85 GPM for minimum of 2 seconds. (3) Tetra Pack Aseptic plan dated May 24, 2021 with CCP1 Ultra high treatment critical limit set as 288 deg F at maximum flow rate of 88 GPM for minimum of 4 seconds for cocoa products and critical limit set as 284 deg F at maximum flow rate of 88 GPM for minimum of 4 seconds for non-cocoa products. CCP-2 Filling critical limit set as Sterile air temperature 330 deg C, Hydrogen peroxide (H_2O_2) concentration 30%, H_2O_2 temperature 79 deg C, Drying air temperature 135 deg C for a contact time of 4.8 seconds. (4) Bottle line dated Jun 4, 2021 with CCP1 Process time temperature critical limit set as 286 deg F for cocoa products and 282 deg F for non-cocoa products at maximum flow rate of 40 GPM. CCP-2 Filling critical limit set as Hydrogen peroxide (H_2O_2) temperature 265 deg F and flow of 3.20 g/s, air flow maximum 60 SCFM, H_2O_2 concentration 32%, Drying air temperature 349 deg F and drying air flow 0.525 PSI for 12 Oz bottle, and preheat temperature of 150 deg F. (5) Combi bloc plan dated May 24, 2021 with CCP1 Indirect heating, Process time temperature critical limit set as (i) for broth product 282 deg F at maximum flow rate of 62 GPM for minimum of 5.32 seconds (ii) for non-dairy cocoa beverage products 287 deg F at maximum flow rate of 27 GPM for minimum of 4.85 seconds. CCP1 Direct heating, Process time temperature for direct heating of dairy and non-dairy beverage product critical limit set as (i) for cocoa containing products 285 deg F at maximum flow rate of 60 GPM for minimum of 5.93 seconds (ii) for non-cocoa containing products 281 deg F at maximum flow rate of 60 GPM for minimum of 5.95 seconds. CCP-2 Filling critical limit preheating temperature 125 deg C; Hydrogen peroxide (H_2O_2) temperature 250 deg F, concentration of 33%, and dosing of 490 micro liter per second; drying air temperature 115 deg C and H_2O_2 transport air flow 180 liter per minute. GNS (Grain, Nuts, and Seeds) plan dated May 18, 2021 with No CCP identified. CCP monitoring, corrective actions, verification, deviation, and record keeping were identified. Food safety plan was last reviewed on Jun 4, 2021. CCP records were reviewed dated Jan 6, 2022; Jan 11, 2022; Feb 10, 2022; Mar 16, 2022; and Mar 17, 2022. Minor: Dry ingredient staging and ingredient hopper/ ingredient feed were not identified on GNS flow diagram. Enzyme receiving and enzyme storage were also not identified on GNS flow diagram.

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: MINOR

EVIDENCE: Dry ingredient staging and ingredient hopper/ ingredient feed were not identified on GNS flow diagram. Enzyme receiving and enzyme storage were also not identified on GNS flow diagram.

ROOT CAUSE: HACCP team member that walked through process missed steps due to lack of understanding of the process.

CORRECTIVE ACTION: Corrective: Process flow was walked through by two additional people familiar with process to update the flow chart. The additional steps identified were worked though the processing evaluation for hazard analysis. The plan was reviewed in full for accuracy. Preventive: process walkthroughs will be completed as a team including the manager of the area who is deemed knowledgeable of the process in detail while the operation is in the process.

VERIFICATION OF CLOSEOUT: Reviewed updated HACCP flow chart submitted by the site.

COMPLETION DATE: 04/22/2022 **CLOSEOUT DATE:** 04/26/2022

11.1.5 Dust, Insect, and Pest Proofing

External windows, doors, and other openings were observed to be properly sealed to prevent pest infestations. Overhead dock doors were provided with adequate sealing around trucks. Fly lights, interior traps, and exterior bait station locations appeared to not pose contamination risk to products. Rodenticide bait was not used or stored inside facility. Minor: External door in Silo Hall 1 was observed without a functioning self-closing device.

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: MINOR

EVIDENCE: External door in Silo Hall 1 was observed without a functioning self-closing device.

ROOT CAUSE: Self-closing device was installed. Upon inspection the self closing device appeared to be damaged making it inoperable. The damage was not reported to maintenance to be repaired.

CORRECTIVE ACTION: Corrective: self-closing device was repaired by maintenance staff and is fully functional (see pictures). Preventive: Master sanitation program forms include reporting any damaged, unsanitary, or misplaced items to the area supervisor. An addendum was created and shared with production departments to outline specific items that should be inspected, including damage to exterior doors (see Master Sanitation Addendum).

VERIFICATION OF CLOSEOUT: Reviewed pictures and updated document submitted by the site.

COMPLETION DATE: 04/25/2022 **CLOSEOUT DATE:** 04/25/2022

11.1.6 Ventilation

Adequate ventilation was observed in processing and food handling areas. Positive air pressure was maintained in airlock room at the entrance of segreagated GNS area. Ventilation equipment, fans, and exhaust pipes were insect-proofed and located to not pose contamination risks. Extractor fans were provided and there was no observation of condensation buildup during site tours. Minor: Ventilation opening near boiler room in the hallway and near supervisor offices near ESL lines were observed inadequately cleaned.

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: MINOR

EVIDENCE: Ventilation opening near boiler room in the hallway and near supervisor offices near ESL lines were observed inadequately cleaned.

ROOT CAUSE: The fan and A/C unit noted as unsanitary was overlooked during cleaning by facility personnel and contracted service dedicated to ventilation cleaning.

CORRECTIVE ACTION: Corrective: The A/C unit was cleaned by sanitation personnel (see pictures). The fan was discarded and replaced due to the cleanliness issue and damage to the protective screen. Preventive: Master sanitation program forms include reporting any damaged, unsanitary, or misplaced items to the area supervisor. An addendum was created and shared with production departments to outline specific items that should be inspected, including ventilation (see Master Sanitation Addendum).

VERIFICATION OF CLOSEOUT: Reviewed pictures and updated document submitted by the site.

COMPLETION DATE: 04/25/2022 **CLOSEOUT DATE:** 04/25/2022

11.1.7 Equipment and Utensils

Sanitary Design Policy dt. Dec 8, 2021 documented requirement for construction and fabrication of equipment and purchasing requirement. Equipment product contact surfaces conditions appeared crack free and made of impervious materials. There were no observations of processing equipment that may be pose a potential food safety risks. Containers for edible and inedible materials were constructed from appropriate materials and properly identified. Product containers and bins used were appeared of materials that are suitable for food contact. Waste bins were clearly identified. There were no excessively soiled or unclean equipment or utensils. There were no issues noted with vehicles used in the handling areas. Equipment, utensils, and containers were constructed from stainless steel or food- grade synthetic materials. Non-conforming equipment segregation and disposal was covered under site's nonconformance procedure. Equipment destined for disposal were properly identified and tagged. Minor: Plastic straps curtains at the pallet conveyor to cold storage were observed broken and in unsanitary condition.

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: MINOR

EVIDENCE: Plastic straps curtains at the pallet conveyor to cold storage were observed broken and in unsanitary condition.

ROOT CAUSE: The curtain was planned to be replaced but materials had not yet arrived.

CORRECTIVE ACTION: Corrective: The new curtain was installed (see pictures). Preventive: Master sanitation program forms include reporting any damaged, unsanitary, or misplaced items to the area supervisor. An addendum was created and shared with production departments to outline specific items that should be inspected, including conveyors (see Master Sanitation Addendum).

VERIFICATION OF CLOSEOUT: Reviewed pictures and updated document submitted by the site.

COMPLETION DATE: 04/25/2022 **CLOSEOUT DATE:** 04/25/2022

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Alyssa Cook
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** acook@steubenfoods.com
Opening Meeting	People Present at the Opening Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Nicholas Eisensmith: Quality Assurance Manager, Leonard Carruthers: Vice President Engineering, Steve Crescente: Vice President Quality Assurance, Jeff Trujillo: General Manager, Jack Lockwood: Quality Assurance Director, Kenneth J. Stanley: Vice President Operations, Alyssa Cook: Compliance Coordinator SQF Practitioner, Andrea Scanzuso: Human Resources Director, Sara Owczarzak: Training Manager, Julie Senko: President, Jatin Tharwala: AIBICS SQF Auditor
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** The site is located on outskirts of Elma, NY. Company is operating at the current location since 1985 and was expanded several times over years. Most recent expansion was in 2018-2019 while a new warehouse-3 was added to the existing building. The site is USDA and FDA registered and current document were available. Site has implemented 06 FSMA compliant HACCP/ food safety plans and 03 food quality plans. Site produces Milk, Flavored Milk, Broth, Gravy, Beverages, Fruit Beverages, Plant Based beverages, Nutritional beverages, Soups, Grain and Seed Powders. Products manufactured were company owned brand as well as private label brands. Facility structures were built of appropriate solid metal frame and safe materials. The facility operates 24 hour 07 days a week and employed 650 employees.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Nicholas Eisensmith: Quality Assurance Manager, Leonard Carruthers: Vice President Engineering, Steve Crescente: Vice President Quality Assurance, Jeff Trujillo: General Manager, Jack Lockwood: Quality Assurance Director, Kenneth J. Stanley: Vice President Operations, Alyssa Cook: Compliance Coordinator SQF Practitioner, Andrea Scanzuso: Human Resources Director, Sara Owczarzak: Training Manager, Jatin Tharwala: AIBICS SQF Auditor
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Certificate may be issued upon satisfactory completion of non-conformances observed during audit.

Section Responses

2.1.1 Management Responsibility (Mandatory)

Food Safety and Quality Policy Statement dt. Apr 29, 2021 was signed by CEO. Policy included commitment to safe quality food, customer and regulatory requirement, customer specifications, continuous improvement, food safety culture, resource allocation, and employee communication. Policy was communicated by posting at all entrances and during onboarding and refresher training. Site established and communicated food safety and quality objectives and performance measures with KPI which were tracked on monthly basis and shared with site management. KPI included 93% first pass (without food safety or quality related hold); Less than 6 failed aseptic runs (in a month); and >95% compliance to micro testing of finished product. Food safety culture improvements and employee encouragement was achieved by monthly plant meetings, employee surveys, see something - say something program, and weight control SPC data collection and analysis. Site used electronic and physical communication boards to communicate food safety and quality performance, KPI status, and food safety spot lights. Organization chart dt. Feb 22, 2022 was created that listed key positions with responsibilities related to food safety and quality and communicated to employees by posting at plant entrance. The chart also identified reporting relationship and back-ups for each position. Job descriptions for QA Manager, Compliance Coordinator, Sanitation Manager, Maintenance Manager, and Shipping/ Receving personnel were documented. Compliance Coordinator was designated as Primary SQF practitioner and QA Manager was designated substitute SQF practitioner who were responsible and authorized for maintenance of SQF Food Safety and Quality System. SQFP HACCP training record from May 2021 and substitute SQFP HACCP training record from Mar 2008 were reviewed. Site management ensured training needs were resourced to ensure integrity and continued operation of food safety and quality system. This was an announced audit and accordingly blackout periods were not applicable for this cycle.

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

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

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

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

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

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

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

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

2.1.2 Management Review (Mandatory)

Management commitment procedure dt. Dec 14, 2021 outlined site's management review requirements. Annual management review meeting dt. Feb 11, 2022 covered updates to food safety and quality management systems, Quality manufacturing procedures, internal audits, hazard and risk management, food safety and quality plans, food safety culture, food safety and quality objectives, non-conformances from internal and external audits, customer complaints, and follow-up action items from previous management reviews. Monthly team meetings were held between SQFP, food safety team, and plant management on matters impacting implementation and maintenance of SQF system and records from dated Jan 7, 2022; Feb 21, 2022; and Mar 3, 2022 were available.

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

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

2.1.3 Complaint Management (Mandatory)

Complaint handling procedure dt. Jan 21, 2022 outlined methods for handling and investigation of food safety and quality complaints for product manufactured by the site. Complaints are received by regulatory coordinator who log each complaint in complaint database and assign complaint codes and initiate investigation by and forwarding to relevant personnel at the site for further investigation and corrective action and all records were maintained. A compliant log is maintained electronically in shared drive. 13 complaints year to date were logged in 2022. Records of investigation and resolution were maintained. Trend analysis was completed on monthly basis and record dt. Feb 11, 2022 was reviewed. Complaints did not reveal any adverse trending. Records reviewed dated Jan 18, 2022 for watery texture; dt. Mar 3, 2022 for a foreign material; and dt. Mar 4, 2022 for off flavored product.

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

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

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

2.2.1 Food Safety Management System (Mandatory)

Food safety and quality system documents were maintained electronically by SQFP on site's shared drive. Food safety and quality system included food safety plans, quality plans, preventive controls, CCPS/ process preventive controls, CQPs, specifications and formulations, standard operating procedures, policies and procedures, and training plans. Site's program and procedures were reviewed at least on annual basis. All changes to program documents were reviewed, logged at the end of each document with details of changes prior to implementation.

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

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

2.2.2 Document Control (Mandatory)

Change control and document management procedure dt. Jan 21, 2022 outlined methods and responsibilities for maintaining site's document control system. All changes to program documents were reviewed, logged at the end of each document with details of changes prior to implementation. Documents are electronically stored on shared drive and access was granted to relevant employees using a secured password. A paper copy was maintained by SQFP as a hard copy binder in QA office.

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

2.2.3 Records (Mandatory)

Records storage and retention procedure dt. Jan 21, 2022 outlined records management and retention requirements followed by the site. In-process monitoring records were maintained in paper copy format by QS Manager. Preventive control records were reviewed by Quality Systems group. During audit various production and in-line checks, HACCP, and SQF systems records were randomly reviewed and were found to be readily accessible, legible, dated, and duly signed. Records dated Sept 3, 2021; Dec 7, 2021; Jan 6, 2022; Jan 12, 2022; Feb 10, 2022; and Mar 17, 2022 were reviewed.

2.2.3.1 The methods, frequency, and responsibility for verifying, maintaining, and retaining records shall be documented and implemented.

RESPONSE: COMPLIANT

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

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

2.3.1 Specification, Formulation and Realization

New product development and commercialization program dated Jan 28, 2022 was documented methods and responsibilities for commercialization of new products. Business Development, Marketing, or Product development group initiates new product idea and a product road map is maintained. New Product Development (NPD) Project brief is completed with scope of the project for visibility of objectives of new product project. Brief contained objectives, product type, product characteristics, labeling and regulatory requirement, and packaging type and size. Site uses formulation software to track project progress. Formulation scientist is assigned and bench top samples were prepared in NPD lab. Internal cutting/ sensory is completed by PD group and Sales and Marketing and customers. Once the team identify two sample then a pilot plant product run is being scheduled and samples created for internal and customer team. Site uses accelerated shelf life studies. HACCP review was completed by QA group prior to plant trials or approval of new product or changes in ingredient or product formulations. NPD and QA group was responsible for new products specifications approval. Finished product specifications included product description; ingredient, nutritional, and allergen declarations; analytical and microbiological limits; packaging information; storage and shelf life; sensory information; and lot coding information. Food safety plan was reviewed for each new product. There was no issues observed in process flow. New products development records dated Feb 5, 2022 for Pistachio Milk NSA reviewed indicated documented procedures were followed.

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

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

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

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

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

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

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

Supplier approval procedure dated Sept 14, 2021 outlined requirement for development, maintenance, and approval of raw materials, finished products, and packaging specifications. Ingredients, packaging materials, and finished product specifications were maintained and site ensured those are meeting applicable legislations. There was no other site under the same corporate ownership. CoA were required from suppliers of ingredients. Certificate of analysis for cocoa powder; 30% beef stock concentrate; and for strawberry flavor were reviewed. Verification of packaging included continuing letter of guarantee (LoG) from approved primary packaging suppliers and records dt. Mar 21, 2022 from 12 Oz HDPE bottle supplier and dt. Mar 15, 2022 from gable top printed flat carton supplier were reviewed. Register of contract service provider dt. Jan 4, 2022 outlined contract service providers and included description of services provided and applicable training requirements. Contractor register listed flooring contractor, dock maintenance contractor, conveyor repair contractor, cleaning chemicals contractor, uniform laundering contractor, pest control service provider, HVAC service provider, and calibration service provider. Details of service provided and training requirements was listed for each contract service provider. Finished product specifications were maintained. Rice powder specification dt. Oct 10, 2019 included product description; ingredient, nutritional, and allergen declarations; analytical and microbiological limits; packaging information; storage and shelf life; sensory information; and lot coding information. Specifications for raw materials and packaging, chemicals, contract services, and finished products were reviewed whenever changes occur that impact product safety and site required supplier to notify prior to making changes in specifications. All specifications were maintained electronically and readily accessible. Specification for ingredients were maintained and reviewed for 30% beef stock concentrate; strawberry flavor; cocoa powder; 12 Oz HDPE bottle; and gable top printed carton. Finished product labels were approved by QA and NPD and all approved and current labels were maintained. FSSC 22000 audit dt. Sept 6, 2021 from 12 Oz. HDPE bottle supplier; SQF audit dt. Apr 28, 2021 from gable top caton supplier; BRCGS audit dt. Nov 16, 2021 from cocoa powder supplier; and SQF audit dt. Aug 13, 2021 from 38% beef stock supplier were reviewed.

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

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

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

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

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

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

2.3.2.7 Finished product labels shall be accurate, comply with the relevant legislation, and be approved by qualified company personnel.

RESPONSE: COMPLIANT

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

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

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

2.3.3 Contract Manufacturers

Contract manufacturers program dt. Sept 1, 2021 included methods and responsibility for compliance from co-manufacturers of products. Site uses one contract manufacturer for drying of whole grain oat milk powder and rice powder. Site do not outsource any other contract manufacturing or part of the processing steps. The program outlined risk based evaluation of contract manufacturer and GFSI certification requirement; co-manufacturing facility assessment; co-man approval; and re-approval requirements. A singed contract dated Jan 30, 2020 was in place. SQF audit exp date Feb 2, 2023 was reviewed.

2.3.3.1 The methods and responsibility for ensuring all agreements with contract manufacturers relating to food safety, customer product requirements, their realization, and delivery shall be documented and implemented.

RESPONSE: COMPLIANT

2.3.3.2 The site shall establish a method to determine the food safety risk level of contract manufactured product and shall document the risk. The site shall ensure that: i. Products and processes of co-manufacturers that are considered high-risk have undergone an audit by the site or third-party agency to confirm compliance with the SQF Food Safety Code: Food Manufacturing and regulatory and customer requirements; ii. Products and processes of co-manufacturers that are considered low-risk meet the requirements of the SQF Food Safety Code: Food Manufacturing, or other GFSI benchmarked certification programs, and regulatory and customer requirements; and iii. Changes to contractual agreements are approved by both parties and communicated to relevant personnel.

RESPONSE: COMPLIANT

2.3.3.3 Contractual agreements with third party storage and distribution businesses shall include requirements relating to customer product requirements and compliance with clause 2.3.3.2 of the SQF Food Safety Code: Food Manufacturing. Contractual agreements shall be approved by both parties and communicated to relevant personnel. The site shall verify compliance with the SQF Code and ensure that customer and regulatory requirements are being met at all times.

RESPONSE: COMPLIANT

2.3.3.4 Records of audits, contracts, and changes to contractual agreements and their approvals shall be maintained.

RESPONSE: COMPLIANT

2.3.4 Approved Supplier Program (Mandatory)

Approved Supplier Program dt. Sept 14, 2021 outlined responsibility and procedure for selecting, evaluating, approving, and monitoring of suppliers. The HACCP team, Ingredient Specialist, R&D department, and Brands Specialist share responsibility for selecting, evaluating, approving, and monitoring an approved supplier. Supplier risk assessment and supplier monitoring was maintained by Ingredient Specialist. Supplier approval was based on risk assessment process to determine quality control points and food safety risks. Criteria included audit reports, supplier history, specifications, formulations, Certificate of Analysis, identity preserved certifications, and Letter of Guarantee. Approved supplier registers included supplier contact details. Current records of approved suppliers, receiving inspections, and supplier audits were maintained. Supplier records were reviewed for 38% beef stock, strawberry flavor, cocoa powder, gable top paperboard carton, and 12 Oz HDPE bottle. CoA was required from supplier of ingredient and a certificate of conformance was required from primary packaging suppliers. CoA was required for each lot of ingredient received by the site. Emergency purchases form non approved supplier required prior approval, current GFSI audit certification, and COA for the raw material lot supplied and material was inspected prior to use. There was no other sites under same corporate ownership. Site do not conduct supplier audits, instead site accepts third party audit results from approved suppliers. Letter of Guarantee dt. Mar 15, 2022 from 12 Oz HDPE bottle supplier and dt.

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

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

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

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

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

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

2.4.1 Food Legislation (Mandatory)

Food legislation dt. Nov 23, 2021 outlined requirements to ensure finished products manufactured at the site complied with applicable food safety legislations. Products produced at the site were sold in Canada and USA. The regulatory compliance was achieved by Food safety and Regulatory program implementation, product testing, regulatory reviews, FDA and USDA registration, COAs, LoG, product testing, and employee training. No regulatory violation was observed during the audit. QA Manager was designated as Process Plant Superintendent who was responsible for industry code of practice and obtaining guidance from onsite regulatory personnel and share changes to current legislation throughout organization. QA Manager subscribed to FDA and SQFI updates. VP of Quality and QA Director reviewed latest trend in industry and scientific developments and kept site informed of changes to relevant legislation, scientific and technical developments, emerging food safety issues. Requirement for notification to SQFI (foodsafetycrisis@sqfi.com) and the certification body within 24 hors in case of food safety event was described in site's crisis plan. FSMA compliant food safety plans were combined with HACCP plans.

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

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

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

2.4.2 Good Manufacturing Practices (Mandatory)

The site implemented Good Manufacturing Practices as described in Module 11 of current SQF Code. Programs reviewed during on-site audit indicated that Module 11 was implemented by the site. The effectiveness of pre-requisite programs were verified through daily plant floor supervision, weekly and monthly facility inspections, internal audits, and daily pre-operation checks.

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

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

2.4.3 Food Safety Plan (Mandatory)

The site has documented and implemented six HACCP/ food safety plans prepared in accordance with Codex Alimentarius Commission HACCP guidelines and FSMA requirements. Food safety plans were developed and maintained by site's multi-disciplinary team that included representatives from Quality Assurance, Technical, Maintenance, Production, Warehousing, and Engineering. Products and processes in the scope were covered by site's food safety plan which included; product descriptions, intended use, process flow charts, and hazard analysis of raw materials and processing steps. Process flow was verified by food safety team on May 24, 2021. (1) Raw dairy plan dated May 19, 2021 with CCP-1 (Pasteurization Time/ Temperature) with CCP limit set as 163 deg F at maximum flow rate of 120 gallon per minute (GPM) for minimum of 15 seconds hold time. (2) Extended Shelf Life (ESL) plan dated May 19, 2021 with CCP1 (Ultra-Pasteurization) critical limit set as 280 deg F at maximum flow rate of 85 GPM for minimum of 2 seconds. (3) Tetra Pack Aseptic plan dated May 24, 2021 with CCP1 Ultra high treatment critical limit set as 288 deg F at maximum flow rate of 88 GPM for minimum of 4 seconds for cocoa products and critical limit set as 284 deg F at maximum flow rate of 88 GPM for minimum of 4 seconds for non-cocoa products. CCP-2 Filling critical limit set as Sterile air temperature 330 deg C, Hydrogen peroxide (H_2O_2) concentration 30%, H_2O_2 temperature 79 deg C, Drying air temperature 135 deg C for a contact time of 4.8 seconds. (4) Bottle line dated Jun 4, 2021 with CCP1 Process time temperature critical limit set as 286 deg F for cocoa products and 282 deg F for non-cocoa products at maximum flow rate of 40 GPM. CCP-2 Filling critical limit set as Hydrogen peroxide (H_2O_2) temperature 265 deg F and flow of 3.20 g/s, air flow maximum 60 SCFM, H_2O_2 concentration 32%, Drying air temperature 349 deg F and drying air flow 0.525 PSI for 12 Oz bottle, and preheat temperature of 150 deg F. (5) Combi bloc plan dated May 24, 2021 with CCP1 Indirect heating, Process time temperature critical limit set as (i) for broth product 282 deg F at maximum flow rate of 62 GPM for minimum of 5.32 seconds (ii) for non-dairy cocoa beverage products 287 deg F at maximum flow rate of 27 GPM for minimum of 4.85 seconds. CCP1 Direct heating, Process time temperature for direct heating of dairy and non-dairy beverage product critical limit set as (i) for cocoa containing products 285 deg F at maximum flow rate of 60 GPM for minimum of 5.93 seconds (ii) for non-cocoa containing products 281 deg F at maximum flow rate of 60 GPM for minimum of 5.95 seconds. CCP-2 Filling critical limit preheating temperature 125 deg C; Hydrogen peroxide (H_2O_2) temperature 250 deg F, concentration of 33%, and dosing of 490 micro liter per second; drying air temperature 115 deg C and H_2O_2 transport air flow 180 liter per minute. GNS (Grain, Nuts, and Seeds) plan dated May 18, 2021 with No CCP identified. CCP monitoring, corrective actions, verification, deviation, and record keeping were identified. Food safety plan was last reviewed on Jun 4, 2021. CCP records were reviewed dated Jan 6, 2022; Jan 11, 2022; Feb 10, 2022; Mar 16, 2022; and Mar 17, 2022. Minor: Dry ingredient staging and ingredient hopper/ ingredient feed were not identified on GNS flow diagram. Enzyme receiving and enzyme storage were also not identified on GNS flow diagram.

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

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

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

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

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

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: MINOR

EVIDENCE: Dry ingredient staging and ingredient hopper/ ingredient feed were not identified on GNS flow diagram. Enzyme receiving and enzyme storage were also not identified on GNS flow diagram.

ROOT CAUSE: HACCP team member that walked through process missed steps due to lack of understanding of the process.

CORRECTIVE ACTION: Corrective: Process flow was walked through by two additional people familiar with process to update the flow chart. The additional steps identified were worked though the processing evaluation for hazard analysis. The plan was reviewed in full for accuracy. Preventive: process walkthroughs will be completed as a team including the manager of the area who is deemed knowledgeable of the process in detail while the operation is in the process.

VERIFICATION OF CLOSEOUT: Reviewed updated HACCP flow chart submitted by the site.

COMPLETION DATE: 04/22/2022 **CLOSEOUT DATE:** 04/26/2022

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

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

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

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

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

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

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

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

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

2.4.3.16 Critical control point monitoring, corrective action, and verification records shall be maintained and appropriately used.

RESPONSE: COMPLIANT

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

2.4.4 Product Sampling, Inspection and Analysis

Post production inspection program dated Sept 17, 2021; Sensory evaluation program Jun 14, 2021; Ingredient receiving and Packaging Receipt Program dated July 16, 2021; and Quality Monitoring Program dated Mar 24, 2022 outlined site's procedure for sampling, inspecting, and analysis of raw materials, work-in-progress, and finished products. Visual inspection was conducted on receiving and samples were drawn as per raw documented program. Visual inspections and physical checks were conducted on in-process materials. Time-temperature monitoring, dye test, leak test, seal and packaging integrity, product and package condition, lot codes, label, and net weight were monitored throughout shift. Internal laboratory conducts; pH, weight, protein, viscosity, total solids, milk fat, milk protein, lactose, acidity, microbiological analysis for indicator organism, environmental pathogen testing laboratory (salmonella and listeria spp.) Pathogen testing was conduced in environmental laboratory located in separate building. Annual proficiency testing for laboratory staff conducting analyses was on file from Feb 10, 2021. Site uses external accredited laboratory for microbiological analysis including water testing and ISO 17025 certificate with expiry date Dec 31, 2022 was on file. On-site laboratories was conducting chemical and microbiological analyses and was located away from food processing or handling activities. Access to the laboratory was restricted to authorized personnel using secured electronic swipe cards. Laboratory conducting environmental pathogen testing was located in a separate building away from food processing and handling areas to isolate hazardous waste from food waste. Each production run, samples from start-middle-end of run were retained based on customer and company requirements. Retained samples were stored in accordance with typical storage conditions. Records reviewed for Jan 6, 2022; Jan 11, 2022; Feb 10, 2022; Mar 16, 2022; and Mar 17, 2022.

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

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

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

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

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

2.4.4.6 Records of all inspections and analyses shall be maintained.

RESPONSE: COMPLIANT

2.4.5 Non-conforming Materials and Product

Product Hold Program dt. Nov 5, 2021 outlined methods for handling of non-conforming products. Employees inform production supervisor who will initiate product hold by identifying affected product and placing hold tags (yellow). Quality Systems (QS) group will log hold detail on a hold log and initiates investigation and root cause analysis and determined disposition of hold. Only QS Manager is authorized to determine product disposition. All records are maintained. Hold records dated Jan 4, 2022 for package quality issue due to a equipment failure; dt. Feb 7, 2022 for burnt marks through top seals due to operator error; dt. Feb 26, 2022 faded code print issue due to malfunctioning of code printer were reviewed.

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

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

2.4.6 Product Rework

Rework for reprocessing dt. Jan 7, 2022 was implemented by the site. Site rework like into like products only. Reworked product lot is not carried forward to another rework to ensure reworked product is not going through multiple rework cycle. Rework was authorized by Quality Systems group, a rework allocation report was generated. Site do not rework if contains are damaged, product expired, or product is outside of acceptable pH range. Product reworked was traced by adding suffix REW to original lot and recording of REW lot and quantity. All records were verified by QS group and records were maintained. Rework record dated Feb 8, 2022 was reviewed for 2% lactose free milk.

2.4.6.1 The responsibility and methods outlining how ingredients, packaging, or products are reworked shall be documented and implemented. The methods applied shall ensure: i. Reworking operations are overseen by qualified personnel; ii. Reworked product is clearly identified and traceable; iii. Reworked product is processed in accordance with the site's food safety plan; iv. Each batch of reworked product is inspected or analyzed as required before release; v. Inspections and analyses conform to the requirements outlined in element 2.4.4.1; vi. Release of reworked product conforms to element 2.4.7; and vii. Reworked product does not affect the safety or integrity of the finished product. Records of all reworking operations shall be maintained.

RESPONSE: COMPLIANT

2.4.7 Product Release (Mandatory)

Product Positive Release procedure dt. Sept 17, 2021 outlined product release procedure implemented at the site. QS Analysts were responsible to release product from inspect status after reviewing CCPs, label checks, and micro results. Product release included procedure to confirm product labels compliance with relevant legislation. Each production lot was tested for microbiological parameters and product was only released by QS group after review of acceptable results. Quality systems final review for product release records dt. Dec 6, 2021; Mar 8, 2022; and Mar 23, 2022 were reviewed.

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

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

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

2.4.8 Environmental Monitoring

The site implemented a risk-based Environment Pathogen Monitoring dated Nov 3, 2020 which identified Food Contact Surfaces (FCS) and Non Food Contact Surfaces (NFCS). Site uses zoning concept and divided surfaces in zone-1, zone-2, zone-3, and zone-4 for environmental monitoring. Sites identified, number of samples, frequency, and organism to be tested and acceptance criteria thereof. Zone-1 was not tested for pathogens except in GNS area. ATP used for direct food contact surface in zone-1; whereas Listeria, Salmonella, and EB were tested for zone 2, zone 3, and zone 4. Methods to handle unsatisfactory or elevated results were listed in the program. ATP test results from Mar 1, 2022; Mar 9, 2022; and Mar 21, 2022 were reviewed. Environmental micro results from Feb 22, 2022 and Mar 21, 2022 were reviewed.

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

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

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

2.5.1 Validation and Effectiveness (Mandatory)

Food safety and HACCP program review dt. Jun 2, 2021 was implemented by the site that outlined frequency and methods for validation and assigned responsibility to SQF Practitioner. SQF review schedule was prepared defining the evaluation of effectiveness for each part of the SQF food safety and quality system component applicable to SQF code requirements. Changes to process or procedure were validation before implementation. Critical food safety limits were validated and revalidated annually. CCP validation records dt. Nov 5, 2021; Allergen validation records Nov 9, 2021; Pest control validation records dt. July 9, 2021; and Sanitation program validation records dt. Dec 17, 2021 were available.

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

2.5.2 Verification Activities (Mandatory)

Food safety and HACCP program review dt. Jun 2, 2021 implemented by the site included methods and responsibilities for verification activity for Good Manufacturing Practices, critical control points, regulatory compliance, and other food safety controls. Verification schedule was prepared and implemented. Verification of monitoring activity was done by plant floor supervisors and QA. Verification included authorize each verified record by verifier. Verification records dt. Dec 6, 2021; Jan 7, 2022; Jan 12, 2022; Feb 22, 2022; Mar 17, 2022; and Mar 19, 2022 were reviewed.

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

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

2.5.3 Corrective and Preventative Action (Mandatory)

Corrective and Preventive Action dt. Nov 23, 2021 outlined responsibility and methods for corrective and preventive actions and root cause investigation for nonconformances resulting due to deviations from food safety requirements; monitoring activities; customer and consumer complaints; internal and external audits; or any other food safety or product quality issues. CAPA was requested by QS group and respective department was responsible to complete investigation and resolution of non-compliance and return to QS group. Corrective action log was maintained with pertinent details. Records reviewed dated Jan 4, 2022 for package quality issue due to a equipment failure; dt. Jan 18, 2022 for watery texture; dt. Feb 7, 2022 for burnt marks through top seals due to operator error; dt. Feb 26, 2022 faded code print issue due to malfunctioning of code printer; dt. Mar 3, 2022 for a foreign material; and dt. Mar 4, 2022 for off flavored product were reviewed.

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

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: COMPLIANT

2.5.4 Internal Audits and Inspections (Mandatory)

Internal audit and Quality Monitoring Scheme dt. Mar 24, 2021 outlined sites requirement to audit all applicable requirements of SQF food safety and quality system. Evidences were recorded, corrective and preventive actions were implemented, and findings were communicated to site management and those responsible for investigation and corrective actions. Frequency for internal auditing of all aspects of SQF food safety and quality system was identified as at least annual. Internal Auditor's training record from May 2021 was reviewed. Monthly GMP inspections were completed by SQFP and records dated dt. Aug 12, 2021; Nov 12, 2021; and Jan 18, 2022 were on file. Internal audit record dated Dec 17, 2022 was on file and included corrective actions for non-compliances.

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

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

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

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

2.6.1 Product Identification (Mandatory)

Ingredient and packaging receipt dt. July 16, 2021; Ingredient and packaging usage dt. July 16, 2021; Coding procedure dt. Mar 22, 2022; and Quality Monitoring Scheme dt. Mar 24, 2022 outlined procedure for identification of products at all stages of receiving, production, and storage. Raw materials were uniquely identified using product codes, description, and lot codes. In-process materials were identified with product codes, description, and lot codes. Finished products were identified with product codes, description, finished product labels, lot codes, and best by dates. Receiving, batching, processing, filling, and shipping records were maintained identifying products and corresponding lot numbers. Work in progress materials and finished product labels were verified at begging of shift, every hours, change of shift, and every time packaging changed. Label verification was part of Ingredient and packaging usage dt. July 16, 2021. Product Design Number (PDN) was verified by Filler Operator against specification sheet to ensure accuracy of finished product labels. Site maintains product changeover documents to record label verification and verify removal of packaging materials from previous production runs. Personnel interviewed during site tours were knowledgeable of site's protocols. Records dt. Jan 6, 2022; Jan 11, 2022; Feb 10, 2022; Feb 22, 2022; Mar 16, 2022; and Mar 19, 2022 were available.

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

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

2.6.2 Product Trace (Mandatory)

Product Traceability procedure dated Apr 27, 2021 outlined methods used for tracing ingredient, packaging materials, work-in-progress materials, and finished products from receiving to the production and shipping. Site uses ERP system (Proteam) for tracing materials handled at the site. All raw materials, work-in-progress materials, and finished products were logged in with lot number and resource number. raw materials were identified and logged with supplier lot numbers. Lot numbers of ingredients were recorded on blend sheets with quantities used of each lot. Work-in-progress blends were traced by unique resource number and lot number. Lot number format used were customer driven and majority of customers uses best by date or best before which was included in individual finished product specifications. The program required trace exercise at least on annual basis and acceptance criteria was set as 100% trace of finished product in 4 hours and 95-100% of raw materials (ingredient and packaging) in 4 hours. Finished product trace exercise and mock recall summary dt. Jan 26, 2022 was reviewed. Product selected was Non-GMO Beef Broth Lot# 1364Y1. A total of 16,692 cases were produced. Total cases shipped 11,970 and cases in inventory 4,721 with an inventory Adjustment of 1 case. Total cases accounted 16,692 which was amounting to 100% accounted and total time taken recorded as 1 hour and 45 minutes. Mock trace exercise conducted on Mar 30, 2022 for a primary packaging flat carton sleeve item# CP00689V3 used in finished product code 851770008402 Organic Chocolate Drink Ci17 24 Ct. A total of 516,240 cartons were received (444,240 on Nov 17, 2021 and 72,000 on Dec 1, 2021) with Lot# 8/28/2021. A total of 576,000 were used between Dec 7, 2021 and Dec 23, 2021 and a total of -59,760 inventory adjustment. Inventory adjustment investigation was undertaken by QA and QS group as confirmed by QA Director and SQFP. A total of 100% was accounted for in 3 hours.

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

2.6.3 Product Withdrawal and Recall (Mandatory)

Product Recall Plan dt. Apr 29, 2021 implemented at the site outlined requirements for product withdrawal and recall. Recall coordinator was Vice-President QA and recall team members were listed in the program. The program included communication plan, sources of legal and expert advise, and contact details of SQFI and certification body. Recall effectiveness checks were also included. The product withdrawal and recall system was reviewed and tested on Jan 26, 2022 for finished product Non-GMO Beef Broth Lot# 1364Y1 (ref: 2.6.2). After hour contacts were also verified and found satisfactory. Communication was prepared including customer contact details. Records were maintained and available for review. There was no product recall or withdrawal in past 12 months involving product produced at the site. Requirement to notify SQFI (at email foodsafetycrisis@sqfi.com) and certification body (AIB) within 24 hours in writing in case of food safety event requiring public notification was included in the program.

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

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

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

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

2.6.4 Crisis Management Planning

Plant Disaster Contingency Plan dated Feb 21, 2022 implemented at the site was based on understanding of known potential dangers. Site identified scenarios including flood, fire, explosion, industrial accident, acts of terrorism, and natural catastrophe. A crisis management team was identified which included senior management and assigned responsibility to Vice-President QA and assigned VP-Operations as back-up. Plant Disaster Contingency Plan included communication plan, legal counsel, regulatory contacts, and requirement to notify regulatory agencies, SQFI (email: foodsafetycrisis@sqfi.com), and certification body (AIB). Measures to isolate and identify product affected by a response to a crisis was identified; product to be held and disposal determined by crisis management team and final product disposition was by QA. Crisis Management plan was last reviewed, tested, and verified on Feb 21, 2022 for a scenario of fire in a boiler room.

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

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

2.7.1 Food Defense Plan (Mandatory)

Food defense threat assessment was completed by the site on Mar 21, 2022 to identify potential threats that can be caused by a deliberate act of sabotage or terrorist-like incident. Food security program ft. Feb 24, 2022 documented sites food defense plan and listed mitigation for identified vulnerabilities. SQFP was assigned as Food Defense Coordinator and responsible for the program. The site uses external lighting, interior and exterior camera, employee training, fencing, gate, armed guards, patrol guards, restricted access, visitor controls, secured load, used of approved suppliers, controlled access to chemicals, and restricted driver entrance. Only authorized personnel were allowed access to the site through designated access points. Food defense training was provided to all relevant staff dt. Mar 3, 2022. Food defense annual challenge test was last conducted on Sept 29, 2021 for a scenario of unauthorized employee entering the building and records were maintained.

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

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

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

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

2.7.2 Food Fraud (Mandatory)

Economically Motivated Adulteration Management dated Sept 14, 2021 was implemented at the site that that included methods, responsibility, and criteria for identifying the site’s vulnerability to food fraud. Vulnerability Assessment included supplier relationship, supply chain audits, IP certifications, supplier history, geopolitical considerations, fraud history, and economic anomalies. Food fraud mitigation plan was developed based on identified vulnerability. Mitigation strategies included of use of approved suppliers, supplier history, lot control, GFSI audits of supplier sites, Identity preserved certifications, ingredient CoA for incoming lots, inspection of incoming ingredients, temper evidence, and secured loads. Food fraud mitigation plan's training was completed on Mar 3, 2022. Food fraud vulnerability assessment was last review on Mar 14, 2022.

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

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

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

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

2.8.1 Allergen Management (Mandatory)

Allergen Control Program dated Oct 14, 2021 outlined method used for allergen management at the site. The program included raw material specifications and allergen checklists and allergen risk analysis of incoming materials, ingredient, and lubricants. Assessment of workplace related allergens from visitors, employees, vending machines, and service providers was completed. Ingredient receiving controls, segregation of allergen containing ingredient during storage, brush and equipment color coding, color coded sticker for allergen containing ingredients, CIP between product changeovers, rinse water testing, use of air lock system, allergen spill clean-up procedures, distinctive hairnet and uniform, production scheduling, and allergen testing of finished product were implemented to minimize cross contact. Site identified following allergen handled at the site: Wheat, Milk, Egg, Treenuts, Coconut, Sesame, Soy, Fish, and Sulphites. Site included ingredient allergen hazard in the food safety plan. List of allergens was made accessible to relevant staff and employee training was completed on Mar 1, 2022. Upon receiving ingredient containing allergens were visual inspected for spills or damages, labels were verified against specification, allergen specific labels were placed, and allergen containing ingredient were stored in designated storage area by receiving staff. Allergen cleaning verification record for Tetra line dated Mar 6, 2022; ESL line dt. Mar 12, 2022; and Combi bloc filler line dt. Mar 21, 2022 were reviewed. Reconciliation during packaging and verification of correct label during in-line packaging checks were recorded. Site's traceability requirements included tracing allergen containing ingredient and work-in-progress materials. Rework was allowed only like-into-like products only and recorded on production records. Allergen cleaning verifications for Mar 24, 2022 for Tetra filler were reviewed. Allergen program validation records dt. Nov 9, 2021 were reviewed.

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

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

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

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

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

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

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

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

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

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

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

2.9.1 Training Requirements

Training of personnel dt. Feb 1, 2022 outlined training needs of the organization's personnel engaged in food handling, processing, and other functions affecting product safety and quality. Appropriate training were 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 and training matrix was maintained. Site tours, program review, and employee interviews exhibited understanding of site's food safety procedure, SQF system, and GMPs. SQF Practitioner's Implementing SQF Systems training certificate from Apr 2021 and substitute SQF Practitioner's Implementing SQF Systems training certificate from May 2008 were on file.

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

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

2.9.2 Training Program (Mandatory)

A training program dt. Feb 1, 2022 was implemented by the site and a training Matrix was maintained. Employees were provided relevant training at least on annual basis. Employee onboarding training was required prior to employee start working in food processing or handling areas. Annual refresher training included GMP & personnel hygiene, HACCP and SQF overview, allergen control, pest control, chemical handling, and food defense. Staff responsible or monitoring and verification of CCP, CQP, preventive controls, product sampling and inspection, environmental monitoring, and cleaning and sanitation was provided relevant training. Job specific training was provided on the job. Training materials, delivery of training, and procedures on all tasks critical to food safety were in English which was understood by staff employed at the site. SQF Practitioner and substitute practitioner were trained in HACCP, SQF Implementation, and Internal audits. QA Manager was also trained in food defense, and better process control and was also PCQI. Training records were maintained and included; Participant name, Skills description, Description of the training provided, Training date, Trainer, and Training verification. Training records dt. Mar 1, 2022 and Mar 3, 2022 for chemical handling; environmental monitoring; allergen control; label verification; GMP; CCP; and CQP were available.

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

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

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

11.1.1 Premises Location and Approval

The site completed risk analysis of site environment and identified no risks to site's products from local activities. Site requirement and construction dt. Mar 1, 2022 was documented. Site is located in outskirts of Elma, New York. Buildings and surroundings observed during audit tours do not pose food safety risk to products. The site maintained applicable approvals for ongoing operations and current FDA registration with exp. date Dec 31, 2022 and Milk Dealer License with expiry date July 31, 2022; and NY State Food Processing License exp. date Nov 14, 2022 was on file.

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

11.1.2 Building Materials

Floors were observed to be maintained with no issues noted of standing water. Drains appeared clean and did not present any hazard. No issues observed with drain during site tours, drains were located so as to not pose contamination hazard. Waste trap was located away plant entrances and main building. Ceilings and doors were of durable construction. There was no issue observed in wall-to-wall and wall-to-floor junctions. A risk analysis was completed by food safety team did not reveal any cross contamination risks from pipes carrying water, steam, and bulk ingredients. Sanitary waste or wastewater lines were not located directly over product or storage areas. Doors were of solid construction and windows were made of shatterproof materials. There were no issues noted with stairs, catwalks or platforms.

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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

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

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: NOT APPLICABLE

EVIDENCE: Sanitary waste or wastewater lines were not located directly over product or storage areas.

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: COMPLIANT

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

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

11.1.3 Lightings and Light Fittings

Lighting in food processing and handling areas was observed to be of appropriate intensity. Light fixtures in processing areas, ingredient and packaging storage areas, and all areas where the product is exposed was shatter- proof or protected from breakage. Light fixtures in the warehouse was designed to prevent breakage and product contamination.

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

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

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

11.1.4 Inspection/ Quality Control Area

Inspection stations were provided adjacent to processing lines for product inspections including package integrity checks. Inspection stations were provided with handwashing facilities, waste bins, and maintained clean to prevent product contamination. Waste bins were not overfilled.

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

11.1.5 Dust, Insect, and Pest Proofing

External windows, doors, and other openings were observed to be properly sealed to prevent pest infestations. Overhead dock doors were provided with adequate sealing around trucks. Fly lights, interior traps, and exterior bait station locations appeared to not pose contamination risk to products. Rodenticide bait was not used or stored inside facility. Minor: External door in Silo Hall 1 was observed without a functioning self-closing device.

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

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: MINOR

EVIDENCE: External door in Silo Hall 1 was observed without a functioning self-closing device.

ROOT CAUSE: Self-closing device was installed. Upon inspection the self closing device appeared to be damaged making it inoperable. The damage was not reported to maintenance to be repaired.

CORRECTIVE ACTION: Corrective: self-closing device was repaired by maintenance staff and is fully functional (see pictures). Preventive: Master sanitation program forms include reporting any damaged, unsanitary, or misplaced items to the area supervisor. An addendum was created and shared with production departments to outline specific items that should be inspected, including damage to exterior doors (see Master Sanitation Addendum).

VERIFICATION OF CLOSEOUT: Reviewed pictures and updated document submitted by the site.

COMPLETION DATE: 04/25/2022 **CLOSEOUT DATE:** 04/25/2022

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

11.1.6 Ventilation

Adequate ventilation was observed in processing and food handling areas. Positive air pressure was maintained in airlock room at the entrance of segreagated GNS area. Ventilation equipment, fans, and exhaust pipes were insect-proofed and located to not pose contamination risks. Extractor fans were provided and there was no observation of condensation buildup during site tours. Minor: Ventilation opening near boiler room in the hallway and near supervisor offices near ESL lines were observed inadequately cleaned.

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

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: MINOR

EVIDENCE: Ventilation opening near boiler room in the hallway and near supervisor offices near ESL lines were observed inadequately cleaned.

ROOT CAUSE: The fan and A/C unit noted as unsanitary was overlooked during cleaning by facility personnel and contracted service dedicated to ventilation cleaning.

CORRECTIVE ACTION: Corrective: The A/C unit was cleaned by sanitation personnel (see pictures). The fan was discarded and replaced due to the cleanliness issue and damage to the protective screen. Preventive: Master sanitation program forms include reporting any damaged, unsanitary, or misplaced items to the area supervisor. An addendum was created and shared with production departments to outline specific items that should be inspected, including ventilation (see Master Sanitation Addendum).

VERIFICATION OF CLOSEOUT: Reviewed pictures and updated document submitted by the site.

COMPLETION DATE: 04/25/2022 **CLOSEOUT DATE:** 04/25/2022

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

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

11.1.7 Equipment and Utensils

Sanitary Design Policy dt. Dec 8, 2021 documented requirement for construction and fabrication of equipment and purchasing requirement. Equipment product contact surfaces conditions appeared crack free and made of impervious materials. There were no observations of processing equipment that may be pose a potential food safety risks. Containers for edible and inedible materials were constructed from appropriate materials and properly identified. Product containers and bins used were appeared of materials that are suitable for food contact. Waste bins were clearly identified. There were no excessively soiled or unclean equipment or utensils. There were no issues noted with vehicles used in the handling areas. Equipment, utensils, and containers were constructed from stainless steel or food- grade synthetic materials. Non-conforming equipment segregation and disposal was covered under site's nonconformance procedure. Equipment destined for disposal were properly identified and tagged. Minor: Plastic straps curtains at the pallet conveyor to cold storage were observed broken and in unsanitary condition.

11.1.7.1 Specifications for equipment and utensils and procedures for purchasing equipment shall be documented and implemented.

RESPONSE: COMPLIANT

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

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: NOT APPLICABLE

EVIDENCE: There were no equipment storage rooms at the site.

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: MINOR

EVIDENCE: Plastic straps curtains at the pallet conveyor to cold storage were observed broken and in unsanitary condition.

ROOT CAUSE: The curtain was planned to be replaced but materials had not yet arrived.

CORRECTIVE ACTION: Corrective: The new curtain was installed (see pictures). Preventive: Master sanitation program forms include reporting any damaged, unsanitary, or misplaced items to the area supervisor. An addendum was created and shared with production departments to outline specific items that should be inspected, including conveyors (see Master Sanitation Addendum).

VERIFICATION OF CLOSEOUT: Reviewed pictures and updated document submitted by the site.

COMPLETION DATE: 04/25/2022 **CLOSEOUT DATE:** 04/25/2022

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

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

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

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

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

11.1.8 Grounds and Roadways

GMP inspections were conducted on monthly basis to verify site exterior and grounds. Pathways, roadways, loading or unloading areas were maintained clean and there were no issues noticed during the site tour. Exterior was observed free of waste, accumulated debris, or vegetation. Paths leading to site entrances were observed to be effectively sealed.

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

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

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

RESPONSE: COMPLIANT

11.2.1 Repairs and Maintenance

Maintenance repair procedure dated Mar 16, 2021 was documented for maintenance of plant, equipment and building repair. Preventive maintenance schedule was maintained electronically by maintenance department. Weekly task order list was prepared and assigned to maintenance mechanic. Breakdown of equipment's were recorded as corrective maintenance. Site uses Computerized Maintenance Management System (CMMS) manage preventive maintenance (PM) and corrective maintenance (CM) records. PM records dt. Jan 20, 2022 for filter replacement on Elopak; dt. Feb 2, 2022 for air compressor; and dt. Mar 20, 2022 for filter replacement were on file. CM records dt. Oct 21, 2021 for bottle filler line valve rebuild; dt. Nov 17, 2021 for repair work on case packer; and dt. Feb 18, 2022 for airline track fault on CB2 filler were on file. Maintenance staff and contractors were required to comply with the Site's GMP policies. Supervisors were informed when maintenance activities were performed in respective production areas. Reconciliation of tools and parts was confirmed by mechanics following completion of any task that may have affected a product zone or food contact surface and recorded on maintenance records. Inspections was conducted after cleaning followed by maintenance activities. Temporary repairs were not observed. Food contact equipment and equipment located over food contact equipment were lubricated with food-grade lubricant. Paint was not used on food contact surfaces.

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

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

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

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

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

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

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

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

11.2.2 Maintenance Staff and Contractors

Maintenance staff and contractors were trained to comply with site's GMP and personnel hygiene requirements. Maintenance staff and contractors were required to remove tools and debris after maintenance and inform supervisor. Sanitation was completed and pre-operational inspection was performed prior to restarting of operations when maintenance work done on food contact surfaces.

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

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

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

11.2.3 Calibration

Calibration policy dt. Mar 3, 2022 outlined methods and responsibility for calibration and re-calibration of measuring, testing, and inspection equipment at the site. Calibration was performed according to regulatory requirements or manufacturer recommendations. Policy outlined methods to handle affected product when equipment was found out of calibration. Calibrated equipment were observed to be protected from damage and unauthorized access. List of equipment requiring calibration was maintained that listed calibration, equipment ID and location, and calibration frequency. Calibration records were maintained. Records reviewed dt. Nov 9, 2021 for thermometer, dt. Dec 8, 2021 for RTD gauge; dt. Dec 8, 2021 for thermo couple; dt. Feb 18, 2022 for flow meters, and dt. Feb 22, 2022 for scales.

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

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

11.2.3.3 Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers' recommended schedule.

RESPONSE: COMPLIANT

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

11.2.3.5 Calibrated measuring, testing, and inspection equipment shall be protected from damage and unauthorized adjustment or use.

RESPONSE: COMPLIANT

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

11.2.4 Pest Prevention

Site uses licensed pest control operator for pest control services at the site. Weekly interior and exterior services were provided by contractor and reports were maintained. Pesticide Business Operator License with expiry dt. Sept 30, 2024 was on file issued by State of New York. Scope of service, list of approved pest control chemicals, and SDS were on file. Pest device map dt. Jun 1, 2021 was on file was reviewed. Monthly pest trend analysis was reviewed in food safety team meetings and records for trend analysis. No adverse trend reported in past one year. Service Technician's Exterminator license was on file with exp. dt. Dec 21, 2023. Service reports reviewed for Dec 2, 2021; Jan 27, 2022; Feb 17, 2022; and Mar 22, 2022. Pesticides were not stored on-site. Animals were not permitted on-site.

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

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

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

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

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

RESPONSE: NOT APPLICABLE

EVIDENCE: Pesticides were not stored on-site.

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

RESPONSE: COMPLIANT

11.2.5 Cleaning and Sanitation

Sanitation Standard Operating Procedures (SSOPs) were developed for effective cleaning of processing equipment, storage areas, and staff amenities. ESL processing line CIP; Tetra filler line CIP; and PHX#2 Sterile Tank CIP dated Mar 22, 2016; Combibloc Filler CIP dt. Nov 17, 2014; Silo and Pipe Cleaning SOP dt. Aug 26, 2017; Wall cleaning procedure dt. Apr 26, 2017; and Floor cleaning SOP dt. July 5, 2017 were reviewed. List of approved cleaning chemicals and SDS were maintained. Cleaning-in-place (CIP) parameters were defined, monitored, and chemical and concentration checked and recorded. CIP chemical contact time and temperature were monitored and recorded. Tetra filler CIP log for Feb-Mar 2022 and Tetra processing line CIP log for Feb-Mar 2022 were reviewed. Chemical titration chart dated Jun 11, 2021 listed CIP parameters for each CIP used at the site. Master cleaning schedule listed daily, weekly, monthly, quarterly, semi-annual, and annual frequencies. Weekly sanitation task sheet was generated from lectronic program and assigned to sanitation employees. All cleaning activities are verified by Supervisors. Staff amenities, sanitary facilities and other essential areas were included in pre-operational inspections. Spill cleaning instructions and spill containment kits were made available in chemical storage area and throughout facility. Cleaning chemical handling training was provided and record dt. Jun 12, 2021 was on file. Pre-op inspections were carried out and records were maintained. Visual inspection, ATP, allergen swabs, and micro swabs were used for cleaning verifications. Pre-op inspection records from Jan 6, 2022; Jan 11, 2022; Feb 10, 2022; and Mar 16, 2022 were reviewed. Listeria spp. results for FCS from Feb 22, 2022 were reviewed. ATP results from Mar 1, 2022; Mar 9, 2022; and Mar 21, 2022 were reviewed. Allergen swab results dt. Mar 6, 2022; Mar 12, 2022; and Mar 21, 2022 were reviewed.

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

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

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

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

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

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

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: COMPLIANT

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

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

11.3.1 Personnel Welfare

Personnel hygiene practices dt. Apr 22, 2021 outlined site's policy that prevented personnel exhibiting signs of illness to engage in food processing/handling. The policy also outlined measures to prevent raw materials, food contact surfaces, and finished products contamination and also included segregation and clean-up requirements. Documented procedures and training was in place to prevent contact of ingredients, food packaging, finished products, or food contact surfaces from bodily fluids from open wounds, coughing, sneezing, spitting, or any other means. Exposed cuts were covered using water proof blue colored bandage.

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

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

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

11.3.2 Handwashing

Handwashing stations were provided near personnel access points and throughout food handling and processing areas and site personnel were observed to wash their hands as required and follow site's glove policy. Handwashing stations were constructed of non-corrosive materials and provided with potable water, liquid soap, hands free paper towel, and waste bins. Hands-free operated taps and hand sanitizer was provided in GNS processing areas. Signs were posted in English in break rooms, toilets, plant entrance, and hand wash stations instructing people to wash hands prior to returning to work.

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

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

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

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

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

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

RESPONSE: COMPLIANT

11.3.3 Clothing and Personal Effects

Risk analysis dated Dec 21, 2021 included clothing and hair risk assessments. Hair and beard restraints were used by all employees. Sites GMP policy included controls for clothing and shoes cleanliness. Foam based boot sanitizing was used at plant entrance and entrances to each processing areas. There were no issued observed in regards to clothing or hair during site visit. Disposal gloves were used appropriately. Non-disposable gloves were not used. Aprons were cleaned by a approved laundering service provider. Employees were observed using the racks provided to store protective clothing prior to leaving the production/ open product areas. Site's jewelry policy prohibited loose objects and jewelry except plain wedding bands. There were no clothing, hair, or jewelry violation observed during audit tours.

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

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

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

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

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

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

11.3.4 Visitors

Site required visitors to read and sign visitors food safety and hygiene protocols before entering food processing and handling areas. Visitors were required to were appropriate clothing, remove jewelry and loose objects, be free from illness, use applicable hair restraints, and use proper entryways. Visitors exhibiting illness were not permitted in food processing and handing areas. There were no observations of visitors during site tour which were in violation of site's requirements.

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

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

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

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

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

Cleaning procedures for staff amenities were developed and implemented at the site. Cleaning records for staff amenities were maintained. Lunch room, change room, rest room, and locker room cleaning and inspection log dt. Jan 23 to Jan 29, 2021 was reviewed. Appropriate lighting and ventilation was provided in staff amenities. Adequate staff amenities were observed for use by all personnel. Change rooms were provided and observed to be clean during site tour. Staff appeared to change into distinctive clothing and hairnets while entering GNS processing area. Sufficient number of restrooms were provided separate from food processing and handling areas and accessed via a separate room. Showers were not required for this operation. Restrooms were observed to be clean and tidy. Sanitary drainage was separated from plant drainage. Restrooms have handwash stations with signs in English and observed to comply with requirements of current SQF Code. Break rooms were away from food contact/ handling zones, were in sufficient size and numbers for employees at the site, ventilated and well lit. Break rooms included hot and cold potable water, refrigerators, microwaves, and handwash sinks. There was no outside eating areas at the site.

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

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

11.3.5.3 High-risk change areas shall be provided for staff engaged in the processing of high-risk foods or processing operations in which clothing can be soiled.

RESPONSE: COMPLIANT

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

11.3.5.5 Where required, a sufficient number of showers shall be provided for use by staff.

RESPONSE: NOT APPLICABLE

EVIDENCE: Showers were not required at the site.

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

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

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

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

11.3.5.10 Where outside eating areas are provided, they should be kept clean and free from waste materials and maintained in a manner that minimizes the potential for the introduction of contamination, including pests to the site.

RESPONSE: NOT APPLICABLE

EVIDENCE: There was no outside eating areas at the site.

11.4.1 Staff Engaged in Food Handling and Processing Operations

Personnel entry to processing areas was through personnel access doors and no violations observed during site tour. Site's personnel were observed following site's Good Manufacturing Practices policy. Packaging, product, and ingredients were in appropriate containers and stored off the floor. There were no open doors observed during site tour. Waste was removed from processing areas regularly and there was no accumulated waste or overflowing waste containers. Hoses were installed from ceilings and kept off the floor while not in use. There were no staff observed eating or tasting products in food handling or processing area. Hair restrains were used properly by all employees. No observation of employees wearing false fingernails, false eyelashes, or nail polish. Smoking, chewing, eating, or spitting was not permitted in production, storage, or exposed product areas. Process flow was designed to prevent cross contamination of products. Sensory evaluations in processing areas was not permitted.

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

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

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

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: NOT APPLICABLE

EVIDENCE: Sensory evaluation was not permitted in a food handling/contact zones.

11.5.1 Water Supply

Site uses water as an ingredient, for cleaning of premises and equipment, for manufacturing of steam, and for hand washing. Site used water supplied by the town of Elma, New York. Supplies of hot and cold water was provided for effective cleaning of the premises and equipment. Contingency plan was covered in crisis plan in case water supply deemed to be contaminated. There was backflow system and the tests were completed on Nov 27, 2021. Site do not use any non-potable water. Water (derived from city source) was stored in a designated storage tank prior to RO treatment (for bottle line) to avoid cross contamination of treated water.

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

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

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

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

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: NOT APPLICABLE

EVIDENCE: Site do not use any non-potable water.

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

11.5.2 Water Treatment

Water used for bottle line was treated using Reverse Osmosis (RO) and equipment was maintained as per the manufacturer instructions. RO system was part of preventive maintenance. Water used as in ingredient and treated water was tested monthly at an external accredited laboratory for coliforms, E. coli, HPC, and free Chlorine. Water test report dt. Mar 10, 2022 was reviewed.

11.5.2.1 Water treatment methods, equipment, and materials, if required, shall be designed, installed, and operated to ensure water receives effective treatment. Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

RESPONSE: COMPLIANT

11.5.2.2 Water used as an ingredient in processing or for cleaning and sanitizing equipment shall be tested and, if required, treated to maintain potability (refer to 11.5.2.1).

RESPONSE: COMPLIANT

11.5.2.3 Treated water shall be regularly monitored to ensure it meets the specified indicators. Water treatment chemicals usage shall be monitored to ensure chemical residues are within acceptable limits. Records of testing results shall be kept.

RESPONSE: COMPLIANT

11.5.3 Water Quality

Site uses water as an ingredient, for cleaning of premises and equipment, for hand washing, and for manufacture of food contact steam. Site used water supplied by town of Elma, NY. Microbiological analysis of water was on monthly basis using reference standards at an external accredited laboratory. Results dt. Aug 17, 2021 were available. Ice was not used at the site.

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

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

11.5.3.3 Water and ice shall be analyzed using reference standards and methods.

RESPONSE: COMPLIANT

11.5.4 Ice Supply

There was no use of ice at the .

11.5.4.1 Ice provided for use during processing operations, as a processing aid, or an ingredient shall comply with 11.5.3.1.

RESPONSE: NOT APPLICABLE

EVIDENCE: There was no use of ice at the .

11.5.4.2 Ice that is purchased shall be from an approved supplier and included in the site's food safety risk assessment. Ice shall be supplied in containers that are appropriate for use, cleanable if reused, and tested as appropriate.

RESPONSE: NOT APPLICABLE

EVIDENCE: There was no use of ice at the .

11.5.4.3 Ice rooms and receptacles shall be constructed of materials as outlined in element 11.1.2 and designed to minimize contamination of the ice during storage, retrieval, and distribution.

RESPONSE: NOT APPLICABLE

EVIDENCE: There was no use of ice at the .

11.5.5 Air and Other Gasses

Site also uses compressed air nitrogen gas as food contact. Compressed air was tested at external laboratory and results dated Jan 29, 2022 were reviewed. Nitrogen generating unit was installed at the site and was verified by the supplier and a certificate of analysis validating quality of nitrogen gas was on file dated Feb 7, 2022. Site do not use any other gas.

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

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

11.6.1 Receipt, Storage and Handling of Goods

Site's procedures for effective and safe receiving and storage of raw materials, ingredient, chemicals, equipment, and packaging was outlined in Storage Policy dt. July 16, 2021 and Receiving Policy dt. Mar 3, 2020. Storage policy included effective stock rotation methods and responsibility. Site follows FIFO for stock rotation and use materials within stated sheflife. There was no observation of overaged or expired raw materials or finished products. Temporary or overflow conditions were not observed during audit and site do not use any temporary storage. There were no temporary or overflow storage practices at the site.

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

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

11.6.1.3 The responsibility and methods for ensuring effective stock rotation principles shall be documented and implemented.

RESPONSE: COMPLIANT

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

11.6.1.5 Where raw materials, ingredients, packaging, equipment, and chemicals are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there are no risks to the integrity of those goods, no potential for contamination or adverse effect on food safety.

RESPONSE: NOT APPLICABLE

EVIDENCE: Temporary or overflow conditions were not observed during audit and site do not use any temporary storage.

11.6.1.6 Records shall be available to verify the effectiveness of alternate or temporary control measures for the storage of raw materials, ingredients, packaging, equipment, chemicals, or finished products.

RESPONSE: NOT APPLICABLE

EVIDENCE: Alternative storage was not used by the site.

11.6.2 Cold Storage, Freezing and Chilling of Foods

Temperature of cooler was monitored and recorded every shift. Refrigerated storage appeared of sufficient capacity, operating efficiently, appeared clean, and there were no frosting or condensate issues. Documented procedure dated Jan 22, 2022 was in place for temperature monitoring and records were maintained. Daily plant wide temperature monitoring log dt. Jan 18, 2022 and Jan 22, 2022 were reviewed. Discharge from condensate and defrost was discharged into drainage.

11.6.2.1 The site shall provide confirmation of the effective operational performance of freezing, chilling, and cold storage facilities. Chillers, blast freezers, and cold storage rooms shall be designed and constructed to allow for the hygienic and efficient refrigeration of food and be easily accessible for inspection and cleaning.

RESPONSE: COMPLIANT

11.6.2.2 Sufficient refrigeration capacity shall be available to chill, freeze, store chilled, or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.

RESPONSE: COMPLIANT

11.6.2.3 The site shall have a written procedure for monitoring temperatures, including the frequency of checks, and corrective actions, if the temperature is out of specification. Freezing, chilling, and cold storage rooms shall be fitted with temperature monitoring equipment that is located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible. Records shall be kept of frozen, cold, and chilled storage room temperatures.

RESPONSE: COMPLIANT

11.6.2.4 Discharge from defrost and condensate lines shall be controlled and discharged into the drainage system.

RESPONSE: COMPLIANT

11.6.3 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods

Dry storage area was away from wet areas and product processing areas. Rackings were made of impervious materials and designated to enable cleaning and inspection of floors and behind racks. Storage areas were cleaned regularly. There were no accumulated debris or unsafe storage of materials observed during site tour.

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

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

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

Hazardous chemicals were clearly labelled and all chemicals were included on a list of chemicals. SDS for all chemicals were maintained on file. Hazardous chemicals were used in accordance with manufacturer instructions and controlled to prevent cross-contamination with raw and packaging material, work-in progress materials, or finished products. Chemicals were not used for sanitizing water. Access to the chemical storage was restricted to authorized personnel only and storage was well ventilated. Chemical storage did not appeared to pose contamination threat to processing utensils and packaging. Personnel who handle hazardous chemicals and cleaning chemicals were trained in chemical handling, were provided first aid equipment, and personnel protective equipment (PPE). Food grade and non-food grade chemicals were segregated and access controlled. Unused chemicals and empty chemical containers were disposed in accordance with requirements and primary containers were not reused. Empty bulk chemical containers were picked up by chemical supplier. Pesticides, rodenticides, fumigants, or insecticides were not stored on-site. Spill clean-up procedures, PPE, and spill containment kits were available at multiple location throughout the site.

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

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

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

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

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

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

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

11.6.5 Loading, Transport, and Unloading Practices

Shipping and Receiving Policy dt. Mar 3, 2020 and Procedure for trailer inspection dt. July 24, 2013 outlined loading, transport, and unloading practices at the site. Vehicles inspections for cleanliness, trailer integrity, infestation, odors, reefer operation, and foreign materials was recorded on Trailer Inspection Forms. Trucks seal numbers were verified and recorded. Truck temperature was verified before loading refrigerated products. Raw materials and Trailer temperatures were verified and recorded on Raw Material Temperature Receipt Log and Trailer Inspection Forms. There were no issues noted with the loading and unloading practices and docks. Refrigeration units operating condition was verified and temperature was recorded prior to unloading. Unloading was performed to minimize product and package integrity.

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

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: COMPLIANT

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

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

11.6.5.5 Refrigerated units shall maintain the product at the required temperature. The unit's temperature settings shall be set, checked, and recorded before loading, and the product temperature shall be recorded at regular intervals during loading, as applicable.

RESPONSE: COMPLIANT

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

11.6.5.7 On arrival, prior to opening the doors, the food transport vehicle's refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently, and product temperatures shall be recorded at the start of unloading and regular intervals during unloading.

RESPONSE: COMPLIANT

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

11.7.1 High-Risk Processes

Site identified GNS processing area as high risk zone and implemented several control measures. GNS processing area was segregated from other processes using an airlock room. Employees were dedicated for GNS area and were required to change in distinctive clothing and hair restraint when entering GNS processing area. Dedicated footwear or use of boot sleeves was required before entering GNS area. Air testing results from Mar 1, 2022 were reviewed. GNS area was segregated from other processing and storage area of the site to avoid risk of cross-contamination. GNS area also used dedicated receiving doors and storage area to avoid risk of cross-contamination.

11.7.1.1 The processing of high-risk food shall be conducted under controlled conditions, such that sensitive areas, in which the high-risk food has undergone a "kill" step, a "food safety intervention" or is subject to post-process handling, are protected/segregated from other processes, raw materials, or staff who handle raw materials, to ensure cross-contamination is minimized.

RESPONSE: COMPLIANT

11.7.1.2 Ambient air in high-risk areas shall be tested at least annually to confirm that it does not pose a risk to food safety.

RESPONSE: COMPLIANT

11.7.1.3 Areas in which high-risk processes are conducted shall only be serviced by staff dedicated to that function.

RESPONSE: COMPLIANT

11.7.1.4 Staff engaged in high-risk areas shall change into clean clothing and footwear or temporary protective outerwear when entering high-risk areas. Staff access points shall be located, designed, and equipped to enable staff to change into the distinctive protective clothing and practice a high standard of personal hygiene to prevent product contamination.

RESPONSE: COMPLIANT

11.7.1.5 Product transfer points shall be located and designed, so they do not compromise high-risk segregation and minimize the risk of cross-contamination.

RESPONSE: COMPLIANT

11.7.2 Thawing of Food

Site uses cold rooms for thawing of some frozen ingredients and monitors temperature of cold store rooms. Air thawing was not used by the site. Site do not use water thawing. Used cartons and packaging from thawed product was removed regularly and there was no product contamination risks observed during site tour. There was no excessive or accumulated used packaging or cartons from thawed product.

11.7.2.1 Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose. Equipment for water thawing shall be continuous flow to ensure the water exchange rate and temperature do not contribute to product deterioration or contamination. Water overflow shall be directed into the floor drainage system and not onto the floor or shall be appropriately plumbed.

RESPONSE: COMPLIANT

11.7.2.2 Air thawing facilities shall be designed to thaw food under controlled conditions at a rate and temperature that does not contribute to product deterioration or contamination.

RESPONSE: NOT APPLICABLE

EVIDENCE: Air thawing was not used by the site.

11.7.2.3 Provision is to be made for the containment and regular disposal of used cartons and packaging from thawed product so that there is no risk to the product.

RESPONSE: COMPLIANT

11.7.3 Control of Foreign Matter Contamination

Foreign material control procedure dt. Mar 3, 2022 was implemented at the site. The procedure outlined methods used to prevent foreign matter contamination of product processed and handled at the site. Containers, equipment, and other utensils made of glass, ceramics, or laboratory glassware were not permitted in food processing areas. Pre-operational inspections, preventive maintenance, glass and brittle plastics inspections, and monthly GMP inspections were used to ensure plant and equipment is free from potential contaminants. Pre-operational inspection for thermometers was completed and recorded. Glass replacement and breakage procedure dated Nov 13, 2018 required isolation, cleaning, and inspection prior to start of the operations in case of glass or brittle plastics breakage. Wooden utensils were not permitted at the site except wooden pallets for storage and transportation of product and packaging. Wooden pallets used at the site were dedicated for the purpose and observed in good condition during site tours. Pallets are inspected for cleanliness and damage prior to use. There were no observations of hazards for loose objects. Snap-off blades were not permitted, only company issued knives were allowed in product processing and handling areas. Gaskets were subject to inspection during preventive maintenance. Monthly glass and brittle plastics register verification records dt. Nov 19, 2021; Dec 27, 2021; Jan 18, 2022; and Feb 7, 2022 were reviewed. Gasket and rubber seals were monitored during sanitation and also during preventive maintenance.

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

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

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

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

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

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

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

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

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

11.7.4 Detection of Foreign Objects

Site uses inline strainer and magnets for foreign material detection. Strainer and magnet program and foreign material control program dated Mar 3, 2022 outlined responsibility, methods, and frequency for monitoring, maintaining, and verifying in-line strainer and magnets. Strainers to strain particles greater than 1/16 inch were used. Strainers and magnets were verified at the start of the production run and at the end of production run and records were maintained. Records dated Jan 7, 2022; Jan 12, 2022; Feb 10, 2022; Mar 16, 2022; and Mar 18, 2022 were reviewed.

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

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

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

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

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

11.8.1 Waste Disposal

Trash can cleaning SOP Oct 13, 2021 and Wet and Dry Compactor Bay SOP dt. July 5, 2017 outlined responsibility and methods used to collect and handle dry and liquid waste. Dedicated labelled containers were used for waste disposal. Waste containers were cleaned on daily basis and observed clean during site tours. Used packaging was removed throughout the shift. Obsolete labels and trademarked or printed packaging was placed on hold as per sites hold policy and destroyed to render it unusable prior to removal from the site by waste contractors. There were no inedible waste designated for animal feed at the site. Waste containers were not overflowing and did not present contamination issue. Site uses a contractor to remove waste form the site. Liquid waste generated from processes and sanitation of product processing equipment was discharged in site drainage. Monthly hygiene inspections were completed by QA department to reviews effectiveness of waste management. Daily checks are conducted as a part of pre-op inspections and recorded. Reviewed records dt. Jan 11, 2022; Jan 23, 2022; Feb 10, 2022; and Mar 16, 2022.

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

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

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

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

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

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

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: NOT APPLICABLE

EVIDENCE: There were no inedible waste designated for animal feed at the site.

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

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

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