SQF Food Safety Audit Edition 8.1

Steuben Foods, Inc - Steuben Foods, Inc

Summary

AUDIT DECISION
CERTIFIED

CERTIFICATION NUMBER
8279 | 128344

AUDIT RATING

Excellent

DECISION DATE
05/04/2021

AUDIT TYPE
RECERTIFICATION

RECERTIFICATION DATE
03/31/2022

AUDIT DATES
03/22/2021 - 03/25/2021

EXPIRATION DATE
06/14/2022

ISSUE DATE
05/05/2021

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 Manufacture

Products:
Exclusions: None

Scope of Certification:
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: Lateef, Shahid (131774)
Technical Reviewer: Mazariegos, Alfonso (123419)

Hours Spent on Site: 32
Hours of ICT Activities: 0
Hours Spent Writing Report: 8

Non-Conforming

11.2.7 Dust, Insect, and Pest Proofing

External windows, doors and other openings were observed during facility tours to be properly sealed to prevent any pest infestation or dust coming into the facility. External personnel doors were observed to be self-closing and sealed to prevent dust and pest ingress. All external doors and dock doors were sealed to prevent infestation. Electric insect devices, and interior and exterior rodent stations are located so the product is not at risk for contamination. Rodenticide bait is only used on the outside of the facility. Electric insect lights and devices were observed to follow the code requirements. Minor: Doors and other external openings were observed sealed and proofed, there was one observation for shipping receiving dock door #09 was observed with 2cmx4cm opening at the bottom right side of the door observed not sealed when closed.

11.2.7.1 All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against dust, vermin and other pests.

RESPONSE: MINOR

EVIDENCE: Doors and other external openings were observed sealed and proofed, there was one observation for shipping receiving dock door #09 was observed with 2cmx4cm opening at the bottom right side of the door observed not sealed when closed.

ROOT CAUSE: n/a

CORRECTIVE ACTION: Dock door #9 was repaired by maintenance after the observation was reported. Steuben Foods, Inc. will hire a Millwright that will be responsible for the observation and maintenance of facility doors. Evidence: Job Description: Mechanic Grade 1 - Mill Wright, photos 1.1-1.3

VERIFICATION OF CLOSEOUT: Correctice action was completed during the audit duration, provided records cor complition and pictures is acceptable.

COMPLETION DATE: 03/25/2021 **CLOSEOUT DATE:** 04/08/2021

11.2.10 Premises and Equipment Maintenance

Maintenance-Plant, equipment & building repair procedure VIII-2 dated 03/16/21 was documented for equipment's and other areas of the facility including building and structures was under the facilities department and maintained by the maintenance supervisor, Facilities were monitored for any damages and preventative control tasks were recorded on the work order being completed for any PM performed per the schedule maintained in an online PM program that would generate the required PM task to be completed as set in the program, Reviewed completed work order #CM034903 dated 02/26/21 for on gable line, The person completing the task will fill in all tasks performed for that area observed completed as per the instructions. Preventative maintenance management system documented online for equipment and other areas of the plant, observed scheduled weekly, monthly, quarterly and annually. The maintenance manager maintained the program. Reviewed PM work orders Won-13-0034914 dated 01/23/21 for case packer observed verified and completed as per the requirements. Master LIST for equipment was maintained online by the equipment maintenance supervisor. When repairs and maintenance work are completed, personnel complete the work order and the line operator would follow up on cleaning the area and removing the tools and would document on the reference work order reviewed completed 01/28/21 filler operator log combi block 02/11/20 observed verified by the supervisor. Maintenance personnel are trained in good manufacturing practices and food safety. Periodic inspections are completed to ensure loose parts and other materials are not potential contaminants and recorded on monthly internal inspection data base reviewed completed 03/17/21. Machinery, conveyers and other equipment over or near food or food contact surfaces are lubricated with food grade materials. The food grade lubricants were noted to be stored separately and labeled properly in maintenance area secured cabinets. Paint is not used on food contact surfaces and any paint in processing areas was noted to be in good condition. Premises and Equipment Maintenance" documents the methods and responsibility for the maintenance and repair of food storage areas, equipment, and buildings. Approved contractors were used for equipment or building repair where required. Maintenance procedures were established for the facility and equipment. Maintenance staff and contractors were provided GMPs training and observed following the policy. Supervisors were notified when maintenance work was to be conducted in their areas. Contractors were to sign in after reading the GMPs policy before starting their work by the respective department manager. Each area operator complete the appropriate hygiene and sanitation prior to the commencement of operations and was recorded on the area start-up checklist reviewed completed combi block dated 02/11/21. Minor: Paint used on walls and doors was observed to be maintained except observation was recorded in blend room C where some peeling off pain was observed on the wall beside the blend tank, that was not maintained in good shape.

11.2.10.11 Paint used in a food handling or contact zone shall be suitable for use, in good condition and shall not be used on any product contact surface.

RESPONSE: MINOR

EVIDENCE: Paint used on walls and doors was observed to be maintained except observation was recorded in blend room C where some peeling off pain was observed on the wall beside the blend tank, that was not maintained in good shape.

ROOT CAUSE: n/a

CORRECTIVE ACTION: Lehigh has been contracted to make repairs to the walls of Blend Room C. Work is planned to begin July 2, 2021 during a plant shutdown. Evidence: Lehigh Proposal, Lehigh PO

VERIFICATION OF CLOSEOUT: Correctice action was completed during the audit duration, provided records cor work order and pictures is acceptable.

COMPLETION DATE: 04/06/2021 **CLOSEOUT DATE:** 04/08/2021

11.2.13 Cleaning and Sanitation

Sanitation standard operating procedure V-8 dated 12/29/20 including CIP and master sanitation schedule dated 01/23/21 including (daily, weekly , monthly) for all areas was documented defining all process cleaning and sanitation requirements. Sanitation procedures define cleaning procedures for each area observed covering the processing, storage, outside areas with instructions and chemical used for each section of the facility. Restroom Cleaning program SP-075 dated 08/12/20 including the staff amenities and toilets was documented with verification activities documented for each area specific sanitation sheet reviewed completed as warehouse 6 office inspection log reviewed completed 02/11/21 observed verified. Frequencies and responsibilities for cleaning and sanitation as per procedures for each area including person responsible for cleaning was documented. Effectiveness of cleaning methods was performed by the area supervisor verifying each section completing the respective area cleaning report reviewed completed for daily master sanitation filling room#3 for the week starting 02/21/21 and GNS processing area (weekly) reviewed completed for the week 02/24/21, warehouse monthly cycle reviewed completed 02/12/21 observed verified by the supervisor. Employee areas including lunch room and toilets was completed on daily janitorial check list reviewed completed daily Warehouse 6 office area for the week starting 02/21/21 observed verified by the sanitation supervisor. Cleaning check sheet for each area covering all areas of the facility was documented. Cleaning materials are stored securely and properly labeled with SDS information available to all employees. Chemicals soaps were observed to be included on a list of approved chemicals, labeled consistent with regulations and had SDS on hand. Chemicals were tested for concentration by the trained operator of each area reviewed 3 speed filler completed 03/08/21 with acid and caustic results. Sanitation team members were properly by the SQF practitioner in cleaning methods and plant GMPs. Pre-operational inspections were performed by the area operators by performing visual inspection at the end of cleaning cycle and before the start of the start of the run would record all information on long turn checklist reviewed completed for A-3 speed filler dated 03/08/21, pre-operational checks were performed after every CIP cleaning and before the start of the next run that including the visual inspections and the cap last run water evaluation for the allergen and also ATP test performed by the QA documented online reviewed completed 01/01-30/21 for the combi block fillers observed in compliance with the cleaning requirements, operator would also perform cleaning and inspection for the area that includes facility and employees hygiene documented on the master sanitation program reviewed completed filling room-2 after completing the task 03/08/21 observed verified by the area supervisor before the start of the next operations reviewed completed daily including production area, employee areas were monitored and recorded on lunch room inspection log reviewed completed for the week 02/21/21 locker room inspection log completed for the week 02/21/21, Empty chemical containers were rinsed and recycled per the regulatory requirements. CIP was performed at this site, concentration check documented on the reference department run form reviewed completed for Combi block CBS Turn form reviewed completed 03/08/21. Verification of CIP cleaning was performed through ATP testing reviewed completed and documented CIP Combi bloc CBS turn form reviewed completed 01/01-30/21 with all pass results in compliance of the requirements. Minor: Areas around the facility were inspected and observed maintained except there was observation recorded of cobweb development in the warehouse beside the dock door observed not cleaned.

11.2.13.5	Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities and sanitary facilities and other essential areas are clean before the commencement of production. Pre-operational inspections shall be conducted by qualified personnel. **RESPONSE:** MINOR **EVIDENCE:** Areas around the facility were inspected and observed maintained except there was observation recorded of cobweb development in the warehouse beside the dock door observed not cleaned. **ROOT CAUSE:** n/a **CORRECTIVE ACTION:** Cobwebs beside the dock door were removed after the observation was reported. Ehrlich, the Pest Control Company contracted by Steuben Foods, Inc. was informed of the finding when the observation was reported. The monthly Master Sanitation Plan for the Ingredients Warehouse was updated to include “Inspect for cobweb/dust buildup and clean” Evidence: Monthly Ingredients Warehouse MSP, photos 3.1-3.8 **VERIFICATION OF CLOSEOUT:** Correctice action was completed during the audit duration, provided records cor work order and pictures is acceptable. **COMPLETION DATE:** 04/01/2021 **CLOSEOUT DATE:** 04/08/2021

Audit Statements

SQF Practitioner Name	Name the designated SQF Practitioner **RESPONSE:** Matt Depew
SQF Practitioner Email	Email of the designated SQF Practitioner **RESPONSE:** mdepew@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:** Julis Senko: President, Ken Stanley: VP operations, Steve Crescents: VP QA, : Brian Nolan: Director of safety, Steven Depew: General Manager, Matt Depew: Compliance coordinator/SQF Practitioner, Alyssa cook: Compliance coordinator, Bill Cooleg: warehouse, Nick. Eisensmith: QA Manager, Bill Cogwin: VP Maintenance, Jack Lockwood: Director Quality Assurance, , Andrea Scanzusa: Director HR,
Facility Description	Auditor Description of Facility (Please provide facility description include # of employees, size, production schedule, general layout, and any additional pertinent details **RESPONSE:** March 2021 was Announced re certification audit at this site with process categories FSC 15, 19 and 00 (quality). Site has 06 written food safety plans and 03 food quality plans, the site produces Milk, Flavored Milk, Broth, Gravy, Beverages, Fruit Beverages, Plant Based beverages, Nutritional beverages, Soups, Grain and Seed Powders, juices were packed aseptic packaging or , combi blocks stored and shipped at ambient conditions, milk packed in jugs gets stored and distributed at refrigeration conditions and paper board gable packaging materials used for soy milk also get stored and shipped refrigerated, Raw materials were received in totes or drums (frozen bases for soups and broths), bulk tanker (milk, liquid sucrose, liquid soy base) and bags (ingredients) stored at ambient sand some ingredients including flavors is stored refrigerated storage. Some grains were received those gets converted into liquid and then dehydrated to powders (process of dehydration or powder making from liquid was performed at contract manufacturing. All finished product produced at this site was own brand as well as private label brands. Finished product was packed in , plastic (bottles and Aseptic packaging stored at ambient temperature conditions. This site store and distribute products manufactured at this site only. Facility structures were build with appropriate solid metal frame and safe materials. The company started operations in 1985 at this location and since then has expansions performed at this location. This site is around 550,000 sq. ft (processing and storage/distribution areas). The facility operates 24 hour 07 days a week all year round with 03 shifts. The site operates with approximately 650 full time employees production and operations. The site is in the suburbs of a small town. This company operates only one facility and follows its own food safety program, there has been no corporate audit performed at this time.
Closing Meeting	People Present at the Closing Meeting (Please list names and roles in the following format Name: Role separated by commas) **RESPONSE:** Ken Stanley: VP operations, Steve Crescents: VP QA, : Steven Depew: General Manager, Matt Depew: Compliance coordinator/SQF Practitioner, Alyssa cook: Compliance coordinator, Bill Cooleg: warehouse, Nick. Eisensmith: QA Manager, Bill Cogwin: VP Maintenance, Jack Lockwood: Director Quality Assurance.
Auditor Recommendation	Auditor Recommendation **RESPONSE:** Issue certificate on successful completion of the Non conformances.

Section Responses

2.1.1 Food Safety Policy (Mandatory)

Food Safety and quality policy statement dated 02/27/20 signed by the CEO. The Policy statement covers customer and regulatory requirements, the use of continuous improvement of the system and the review of food safety objectives. The Policy is written in English language and is communicated to the facility's staff by posting at the Employee boards beside every employee entrance.

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines as a minimum the: i. The site's commitment to supply safe food; ii. Methods used to comply with its customer and regulatory requirements and continually improve its food safety management system; and iii. The site's commitment to establish and review food safety objectives.

RESPONSE: COMPLIANT

2.1.1.2 The policy statement shall be: i. Signed by senior site management; ii. Made available in language understood by all staff; iii. Displayed in a prominent position; and iv. Effectively communicated to all staff.

RESPONSE: COMPLIANT

2.1.2 Management Responsibility (Mandatory)

Management organization chart dated 12/02/20, QA organization chart dated 12/02/20 and quality manufacturing procedures WII dated 11/12/20 was documented defining the reporting structure with all department heads including the responsibilities was maintained by the SQF practitioner. The chart and the procedures outlines the structure of staff having responsibility for food safety. Major personal reviewed including the CEO, VP of Operations, General manager and VP of quality. , Senior management has communicated this to the organization and provide the resources for implementation of the food safety and quality through employee training and implementation of the policy statement. Compliance coordinator manager/SQF practitioner with VP Quality /SQF practitioner as back up have been appointed, they are full-time employees of the company, has formal HACCP training completed 05/15/20 through HACCP Alliance certified training provider, has Implementing SQF certificate completed 08/10/17 also completed online PCQI (FSPCA) completed 05/28/16. SQF practitioner was responsible for the development, implementation and maintenance of the SQF System. Organization role register dated 12/01/20 was documented and maintained by the SQF Practitioner reviewed for compliance coordinator, /SQF Practitioner, Production Shift Manager and staff responsible for food safety and quality with coverage for absenteeism was maintained online by the sqf practitioner for all job categories. Senior site management has designed internal objectives those were monitored by the food safety team during operational SQF monthly management meetings and continuously improving the food safety program. Resources were provided where required by the management. Plant staff is required to report food safety/quality issues to management, as evidenced by the relevant job description and interviews with employees in production, shipping/receiving and packaging operators. Change in personal and back up was documented in organization chart for each position. Designated blackout periods were defined in the program communicated by the facility SQF practitioner where required.

2.1.2.1 The reporting structure describing those who have responsibility for food safety shall be identified and communicated within the site.

RESPONSE: COMPLIANT

2.1.2.2 The senior site management shall make provision to ensure food safety practices and all applicable requirements of the SQF System are adopted and maintained.

RESPONSE: COMPLIANT

2.1.2.3 The senior site management shall ensure adequate resources are available to achieve food safety objectives and support the development, implementation, maintenance and ongoing improvement of the SQF System.

RESPONSE: COMPLIANT

2.1.2.4 Senior site management shall designate an SQF practitioner for each site with responsibility and authority to: i. Oversee the development, implementation, review and maintenance of the SQF System, including good manufacturing practices outlined in 2.4.2, and the food safety plan outlined in 2.4.3. 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

2.1.2.5 The SQF practitioner shall: i. Be employed by the site as a company employee on a full-time basis; ii. Hold a position of responsibility in relation 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 for Manufacturing and the requirements to implement and maintain an SQF System relevant to the site's scope of certification.

RESPONSE: COMPLIANT

2.1.2.6	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 have met the required competencies to carry out those functions affecting the legality and safety of food products. **RESPONSE:** COMPLIANT
2.1.2.7	Senior site management shall ensure that all staff are informed of their food safety and regulatory responsibilities, are aware of their role in meeting the requirements of the SQF Food Safety Code for Manufacturing, and are informed of their responsibility to report food safety problems to personnel with authority to initiate action. **RESPONSE:** COMPLIANT
2.1.2.8	Job descriptions for those responsible for food safety shall be documented and include a provision to cover for the absence of key personnel. **RESPONSE:** COMPLIANT
2.1.2.9	Senior site management shall establish processes to improve the effectiveness of the SQF System to demonstrate continuous improvement. **RESPONSE:** COMPLIANT
2.1.2.10	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
2.1.2.11	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
2.1.3	**Management Review (Mandatory)** Quality manufacturing procedures VII-29 dated 11/12/20 was documented, it defines the procedures for the annual review performed through the internal audit checklist covering all areas of the SQF system. Management review completed for Customer complaints section dated 02/18/20 observed completed for the entire SQF system during the year. Included sections of the SQF code reviewed monthly recorded as SQF food safety and quality checklist. The minutes would include the reference program review. quality management review completed 03/19/21. The review meeting participants included the SQF Practitioner, VP Operations and the VP of quality. The SQF practitioner updated management about the changes or updates impacting the SQF system during monthly management meetings attended by the SQF practitioner, General manager recorded as monthly management meeting food safety and quality committee monthly meeting conducted 02/23/21 was conducted by the SQF Practitioner including communication for all food safety concerns, all communication performed through management meeting reviewed completed was recorded in the monthly meeting minutes. Annual management review meeting conducted by the sqf practitioner and the food safety team for the SQF system completed for food safety manuals, the investigations and resolutions of corrective actions and customer complaints with investigations and trends. Food safety fundamentals and the food safety plans were reviewed by management when any changes are made in products and systems. Food quality and safety annual management review meeting participated by the VP of QA, VP of operations, compliance coordinator/SQF practitioner was documented reviewed completed 03/19/21 along with minutes communicated during the meeting, management review notes included the review of programs required when change happens in the program, that was recorded on change log with revision history and reason for change observed verified.
2.1.3.1	The senior site management shall be responsible for reviewing the SQF System and documenting the review procedure. Reviews shall include: i. The policy manual; ii. Internal and external audit findings; iii. Corrective actions and their investigations and resolution; iv. Customer complaints and their resolution and investigation; v. Hazard and risk management system; and vi. Follow-up action items from previous management review. **RESPONSE:** COMPLIANT
2.1.3.2	The SQF practitioner (s) shall update senior site management on a (minimum) monthly basis on matters impacting the implementation and maintenance of the SQF System. The updates and management responses shall be documented. The SQF System in its entirety shall be reviewed at least annually. **RESPONSE:** COMPLIANT

2.1.3.3 Food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be reviewed and updated as needed when any potential changes implemented have an impact on the site's ability to deliver safe food.

RESPONSE: COMPLIANT

2.1.3.4 Records of all management reviews and updates shall be maintained.

RESPONSE: COMPLIANT

2.1.4 Complaint Management (Mandatory)

The site's has documented as Complaint handling procedures VII-13 dated 02/09/21 was documented. SQF practitioner would manage the including the corrective actions and records kept of each complaint and resolution. Records of complaints log were reviewed for 2021 recorded with 16 complaints recorded for since the start of this year observed related to the quality issues received by the QA regulatory coordinator who would share with the plant QA with details, root cause analysis and investigation was performed by the plant QA and corrective actions procedures were in place and documented for all food safety and quality complaint reviewed completed with investigation and root cause analysis. Trending of complaints was documented by the corporate customer QA, observed to have been documented the procedures for the corrective actions was implemented including investigation and root cause analysis for all the food safety and quality related complaints including the trend analysis reviewed completed with 05 complaints related to the taste and texture., complaints with corrective actions including the preventive action.

2.1.4.1 The methods and responsibility for handling and investigating the cause and resolution of complaints from customers and authorities, arising from products manufactured or handled on site, shall be documented and implemented.

RESPONSE: COMPLIANT

2.1.4.2 Trends of customer complaint data shall be investigated and analyzed by personnel knowledgeable about the incidents.

RESPONSE: COMPLIANT

2.1.4.3 Corrective action shall be implemented based on the seriousness of the incident and as outlined in 2.5.3.

RESPONSE: COMPLIANT

2.1.4.4 Records of customer complaints and their investigations shall be maintained.

RESPONSE: COMPLIANT

2.1.5 Crisis Management Planning

Plant disaster contingency plan I-6 dated 02/16/21 was documented. The plan has been implemented and addresses known threats to the interruption of the business. SQF practitioner and plant manager oversight of the plan and a crisis management team has been identified and trained. The Plan includes responses to an extended business interruption, isolating and identifying affected product and a current crisis alert list. The crisis plan includes internal/external communications and sources of legal and expert advice. A test of the plan was conducted on 02/11/21 involving a scenario where a cooling tower from the roof collapse in fresh milk receiving area damaging the milk storage silo causing the production stop.. Plan was completed and verified by the food safety team. Records for the test conducted 02/11/21 was review and observed verified.

2.1.5.1 A crisis management plan that is based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, or other severe weather or regional events such as warfare or civil unrest) 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.

RESPONSE: COMPLIANT

2.1.5.2 The crisis management plan shall include as 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 a response does 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

2.1.5.3 The crisis management plan shall be reviewed, tested and verified at least annually.

RESPONSE: COMPLIANT

2.1.5.4 Records of reviews of the crisis management plan shall be maintained.

RESPONSE: COMPLIANT

2.2.1 Food Safety Management System (Mandatory)

QMP binders dated 02/16/21 has been developed and maintained electronically by the SQF practitioner. The plan contains the scope of the certification, a list of products in the scope, the organizational chart and food safety policies, programs and procedures that make up the site's SQF System. It is made available to all relevant staff through SQF practitioner. Changes made in the plan were validated or justified explaining the change for each document and food safety plan completed by the SQF practitioner recorded on the each document.

2.2.1.1 A food safety management system shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the site will use to meet the requirements of the SQF Food Safety Code for Manufacturing, 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 scope of certification; iv. A list of the products covered under the scope of certification; v. Food safety procedures, pre-requisite programs, food safety plans; and vi. Other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.

RESPONSE: COMPLIANT

2.2.1.2 All changes made to food safety plans, Good Manufacturing Practices and other aspects of the SQF System shall be validated or justified.

RESPONSE: COMPLIANT

2.2.2 Document Control (Mandatory)

Change control and document management program VII-4 01/29/21 was documented. Documents were found during the audit to be readily accessible and properly stored. Procedures were observed to be maintained securely and documents were accessible to the relevant staff. QC database master list document register with updates was maintained online by the SQF practitioner, observed to be current with all changes and updates recorded on change control database reviewed for document management program dated 01/29/21 with update procedures. All documents were stored by the SQF practitioner and were available as required and would be verified to be current.

2.2.2.1 The methods and responsibility for maintaining document control and ensuring staff have access to current documents shall be documented and implemented.

RESPONSE: COMPLIANT

2.2.2.2 A register of current SQF System documents and amendments to documents shall be maintained.

RESPONSE: COMPLIANT

2.2.2.3 Documents shall be safely stored and readily accessible.

RESPONSE: COMPLIANT

2.2.3 Records (Mandatory)

GMP documentation requirements program VII-07 dated 11/25/20, record storage and retention program VII dated 02/29/21 was implemented that describes the monitoring, verifying and retaining records. It define the procedures for recording, verification of records as well as the proper correcting and initialing of errors. These are based on customer, company and regulatory requirements. Records were observed to be readily accessible, legibly filled out, securely stored to prevent damage and have documented retention times. Records reviewed during the audit including combi product specification completed 02/19/21, quality system final review sheet completed 02/18/21, Finished goods testing sheet completed 02/18/21, hourly sample collection record completed 02/18/21, qc post production sensory review log completed 02/19/21 was observed to be monitored and verified, documents were readily accessible, securely stored for 04 years as per the Customer requirement for each record/documented retention times.

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

RESPONSE: COMPLIANT

2.2.3.2 All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed.

RESPONSE: COMPLIANT

2.2.3.3 Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and shall be retained in accordance with periods specified by a customer or regulations.

RESPONSE: COMPLIANT

2.3.1 Product Development and Realization

New product introduction and commercialization program dated 12/24/19 was documented defining the methods and responsibilities for commercialization of new products. Any product development would be performed by the product development team including the R&D trials at the pilot plant and then the plant trials reviewed completed for the as required. The facility is a co packer and majority of the product development was performed by the customers and they bring in the product with instructions for the processing and the specifications. There was own brand that facility R&D team will perform shelf life trials or manufacturing trials. Reviewed shelf life trials completed 02/20/21 for oat creamer (Elmhurst brand) recorded as shelf life study data collection sheet. The food safety team checks the formulations and processes with production trials, shelf-life evaluation trials and product testing as per the corporate R&D team. The shelf-life evaluations was used to establish "best by" dates, handling & storage requirements. The food safety plan would be validated by the food safety team and verified for each new product and process by the SQF practitioner. This review includes changes to distribution and ingredients. The facility maintains records of all steps of the product development cycle including process development, shelf-life and the facility trials reviewed completed for new product Ghost cereal milk completed 01/21/21 observed verified by the SQF Practitioner.

2.3.1.1 The methods and responsibility for designing, developing and converting product concepts to commercial realization shall be documented and implemented.

RESPONSE: COMPLIANT

2.3.1.2 Product formulation, manufacturing processes and the fulfillment of product requirements shall be validated by site trials, shelf life trials and product testing.

RESPONSE: COMPLIANT

2.3.1.3 Shelf life trials where necessary shall be conducted to establish and validate a product's: i. Handling and storage requirements including the establishment of "use by" or "best before dates"; ii. Microbiological criteria; and iii. Consumer preparation, storage and handling requirements.

RESPONSE: COMPLIANT

2.3.1.4 A food safety plan shall be validated and verified 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

2.3.1.5 Records of all product design, process development, shelf life trials and approvals shall be maintained.

RESPONSE: COMPLIANT

2.3.2 Raw and Packaging Materials

Specifications were maintained for all materials and procedures for quality management system defines SQF practitioner responsible for approving and developing detailed raw material, ingredient, and packaging specifications. The register for all specifications for ingredients, packaging, chemicals and other process aid was documented online by the QA who maintained approved raw and chemical materials for the facility. Reviewed for the natural chicken broth maintained a technical data sheet updated 03/06/18 observed accessible by the SQF practitioner including specification limits for the micro criteria, packaging instructions, shelf life, storage requirements. There was register of approved product and labels maintained by the SQF practitioner online. Specification was reviewed for soy base dated 02/20/20 observed including requirements for gluten, suds, vegan , fat, pH, protein, solids and appearance was verified through COA. Letters of guarantee, Certificates of compliance and/or certificates of analysis were required and maintained from each suppliers reviewed for the food contact packaging suppler (Combi bloc) dated 02/20/20 observed conforming to fulfill regulatory requirements. Chemicals were reviewed and observed with required SDS sheets including product labels were approved by the management and reviewed by the SQF practitioner recorded for each batch through verification with the reference labels maintained by the SQF practitioner.

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

RESPONSE: COMPLIANT

2.3.2.2 All raw and packaging materials and ingredients shall comply with the relevant legislation in the country of manufacture and country of destination, if known.

RESPONSE: COMPLIANT

2.3.2.3 The methods and responsibility for developing and approving detailed raw material, ingredient, and packaging specifications shall be documented.

RESPONSE: COMPLIANT

2.3.2.4 Raw and packaging materials and ingredients shall be validated to ensure product safety is not compromised and the material is fit for its intended purpose. Verification of raw materials and ingredients shall include certificates of conformance, certificate of analysis, or sampling and testing.

RESPONSE: COMPLIANT

2.3.2.5 Verification of packaging materials shall include: i. Certification that 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. ii. In the absence of a certificate of conformance, certificate of analysis, or letter of guarantee, tests and analyses to confirm the absence of potential chemical migration from the packaging to the food contents shall be conducted and records maintained.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

2.3.2.7 A register of raw and packaging material specifications and labels shall be maintained and kept current.

RESPONSE: COMPLIANT

2.3.3 Contract Service Providers

Contractor register 06/29/20 was documented defining all contract service providers specifications and requirements. Approved Contractor Statement with all current contract service providers was documented with specifications was maintained and found to include uniform services, pest control services, calibration and maintenance management services. Contract arrangements reviewed during the audit and found to be satisfactory.

2.3.3.1 Specifications for contract services that have an impact on product safety shall be documented, current, include a full description of the service to be provided and detail relevant training requirements of all contract personnel.

RESPONSE: COMPLIANT

2.3.3.2 A register of all contract service specifications shall be maintained.

RESPONSE: COMPLIANT

2.3.4 Contract Manufacturers

Contract manufacturers were used for spray drying liquid grains for this site, agreements specify the food safety requirements, including the specifications for each product documented in the dryer requirements dated 01/23/21 signed of by the manufacturer 01/30/21, including any change to be approved by both the parties. The facility status was required to have SQF or related food safety program compliance reviewed SQF certificate expiring 09/09/21.

2.3.4.1 The methods and responsibility for ensuring all agreements relating to food safety and customer product requirements and its realization and delivery are specified and agreed shall be documented and implemented.

RESPONSE: COMPLIANT

2.3.4.2 The site shall: i. Verify compliance with the SQF Food Safety Code for Manufacturing and that all customer requirements are being met at all times. Products and/or processes of co-manufacturers that are considered high risk shall be required to undergo an audit by the site or other third-party agency to confirm compliance to the SQF Food Safety Code for Manufacturing and agreed arrangements; and ii. Ensure changes to contractual agreements are approved by both parties and communicated to relevant personnel.

RESPONSE: COMPLIANT

2.3.4.3 Records of all contract reviews and changes to contractual agreements and their approvals shall be maintained.

RESPONSE: COMPLIANT

2.3.5 Finished Product Specifications

Tetra filling control program dated 02/16/21 and QC Formula Spec Matrix was maintained for each finished product was documented observed current. All finished product specifications approved by the customer and the site QA team. Finished product specifications reviewed for the macadamia unsweetened product specification dated 03/02/21 including sensory, microbiological targets pH, brix, coadding and the shelf life, customer requirements and labeling requirements. A register of all current finished product specifications based upon the individual product groups were maintained by the SQF practitioner reviewed for the Macadamia vanilla creamer 500 ml dated 02/19/21. Finished product specifications for all products were reviewed during the audit and found to be complete as per customer requirements.

2.3.5.1 Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and may include: i. Microbiological and chemical limits; and ii. Labeling and packaging requirements.

RESPONSE: COMPLIANT

2.3.5.2 A register of finished product specifications shall be maintained.

RESPONSE: COMPLIANT

2.4.1 Food Legislation (Mandatory)

Food legislation procedure VII-31 dated 11/12/20 was documented defining the legislative requirements followed by the SQF practitioner, the facility registered with FDA. VP of quality take care of the regulatory requirements and updates in the regulations from FDA or USDA also connected to industrial association. SQF practitioner also get communicated through USDA inspectors during the USDA product run. Methods and responsibilities defines the procedures that. Food produced was intended for local US markets and arrangements were made to comply with all legislations pertaining to the states where product was sold. The program defines that the certification body and SQF will be notified within 24 hours if a food safety event requiring public notification occurs. The facility complies with FSMA requirements through updating program based upon the preventative control FSMA requirements and SQF practitioner was trained on preventative control including FSPCA certified representative and observed to updated the food safety plan based upon preventive control requirements.

2.4.1.1 The site shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of use or 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 in the event of a regulatory warning. Notification to SQFI shall be by email to foodsafetycrisis@sqfi.com.

RESPONSE: COMPLIANT

2.4.2 Good Manufacturing Practices (Mandatory)

Property, buildings and equipment are located, constructed and designed to ensure food is manufactured in a safe, hygienic environment. No exemptions were recorded in the program. The site has documented and implemented as Personal hygiene practices procedures V-2 dated 04/30/20 defining all applicable requirements to the scope of this certification was documented. The policy covers food safety pre-requisite programs and good manufacturing practices as required by the scope. The effectiveness of the pre-requisite programs has been verified based on a schedule as per the documented program.

2.4.2.1 The site shall ensure the Good Manufacturing Practices described in modules 3, 4, 9, 10 or 11 (as applicable) 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 to ensure that food safety is not compromised.

RESPONSE: COMPLIANT

2.4.2.2 The Good Manufacturing Practices applicable to the scope of certification that outline 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 Food Safety Plans documented as Plan 1-1(ESL (Extended shelf life (all milk products)) dated 06/05/20 with CCP1 (Ultra-Pasteurization including the critical limit as 280 F for 02 seconds (dairy) (2.6 seconds for non dairy), Plan 1-2 (Tetra, Low acid Aseptic) dated 06/05/20 including the CCP 1 with critical limits set for the exit temperature (hold tube) >290 F for (infusion 3 machine) and CCP-2 (filling loss verification with critical limit peroxide temperature at filling >80F, air knife temperature >135F , Sterile air temperature >330 F, monitored 30 minutes . Plan 1-11 (Raw dairy) dated 06/05/20 including CCP1 (pasteurization) with CCP limit set as 163F(120 gallon/minute for 17 seconds. Plan 1-12 (Bottle line) dated 06/05/20 with CCP1 (ultra pasteurization with limits defined as temperature >282F hold tube exit temperature, Hold time >52 seconds, max. flow < 40 Gal/min.) and CCP-2 (Filling) with limits defined as HPV item. 265 F, Tracing temperature >220F, peroxide concentration >32%), Plan-1-14 Combi bloc dated 01/28/21 with CCP1 (Ultra pasteurization with limits set as Max. flow 27.0 Gal/minute, hold tube exit temperature >281F- CCP-2 (filling with critical limits set as temperature >250, H2O2 temperature >250C Pre-heating temperature 125C drying temperature >115 .115 C CCP#3 high acid products (pH) <4.6 as critical limit. Plan 1-15 (GNS (grains,nuts and seeds) dated 06/05/20 with 0 CCP identified in the plan, The finished product from GNS process becomes ingredient that gets stored into a refrigerated storage silo. The Plans observed including list of all products in the scope of the certification a complete product description, intended product use and flow diagram for each process including all input and output steps in the process. The process flow has been verified by the food safety team for each plan. The food safety team has analyzed all hazards including biological, physical and chemical including radiological hazards for each process step, ingredient and packaging material. Control measures are in place to eliminate or reduce the food safety risk to acceptable levels. Line leads and QC techs monitoring the CCPs were able to explain the monitoring and deviation procedures. Any deviations found in monitoring of established control limits are documented and investigated, with proper disposal of involved products. The plans are verified as part of the SQF system and reviewed annually or when changes occur by the food safety team with the last review date on 06/05/20. The organization scope of certification was defined including list of raw material and finished product with intended use were documented. Product requirements for destination states and countries were followed per the customer guidelines. Food safety plans were updated based upon the FSMA /HARPC observed as per the requirements.

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. Feed manufacturers may utilize a HACCP-based reference food safety plan developed by a responsible authority.

RESPONSE: COMPLIANT

2.4.3.2 The food safety plan shall be effectively implemented, maintained and outline the means by which 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

2.4.3.3 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 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

2.4.3.4 The scope of each food safety plan shall be developed and documented including the start and end-point of the processes under consideration and all relevant inputs and outputs.

RESPONSE: COMPLIANT

2.4.3.5 Product descriptions shall be developed and documented for all products included in the scope of the food safety plans. This shall reference the finished product specifications (refer to 2.3.5.1) plus any additional information relevant to product safety, such as pH, water activity, and/or composition.

RESPONSE: COMPLIANT

2.4.3.6 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 use of the product.

RESPONSE: COMPLIANT

2.4.3.7	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 material, packaging material, service inputs (e.g. water, steam, gasses as appropriate), scheduled process delays, and all process outputs including waste and rework. Each flow diagram shall be confirmed by the food safety team during all stages and hours of operation. **RESPONSE:** COMPLIANT
2.4.3.8	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
2.4.3.9	The food safety team shall conduct a hazard analysis for every identified hazard to identify which hazards are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure food safety. The methodology for determining hazard significance shall be documented and used consistently to assess all potential hazards. **RESPONSE:** COMPLIANT
2.4.3.10	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
2.4.3.11	Based on the results of the hazard analysis (refer to 2.4.3.9), 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
2.4.3.12	For each identified CCP, the food safety team shall identify and document the limits that separate safe from unsafe product. The food safety team shall validate the critical limits to ensure the designated 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
2.4.3.13	The food safety team shall develop and document procedures to monitor CCPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency. **RESPONSE:** COMPLIANT
2.4.3.14	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
2.4.3.15	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
2.4.3.16	Implemented food safety plans shall be verified as part of SQF System verification (refer to 2.5). **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 Approved Supplier Program (Mandatory)

Supplier approval program VII-11 dated 11/24/20 has been documented and implemented. It covers the procedures for approving suppliers of raw materials and ingredients, packaging materials and services. SQF Practitioners and food safety team would approve all material suppliers and co pack customers based materials were approved by the customers and approved list was updated with every change to the facility QA as per the policy, the facility purchasing team or would order based upon the approved suppliers data base and they can not purchase anything if the supplier name is not in the list, and receivers can not receive any materials if the suppliers is not in the data base. The SQF practitioner would follow the suppliers for this site, emergency use of non-approved appliers was not required as customers would arrange the materials in any emergency and QA would verify the materials received based upon the program. . The policy includes a review of the specifications of products, the supplier's food safety controls, procedures for granting and monitoring approved suppliers, the level of risk of products to the site and details of requirements for certificate of conformance. Approved supplier performance and status is monitored through supplier product quality and safety based upon the rating for the material supplied evaluating the performance. Supplier 3rd party audit certification for an approved scheme was required for all suppliers reviewed for ground basil supplier letter of guarantee dated 01/01/19, and supplier 3rd party reference food safety audit was required reviewed for the food contact salt supplier FSSC-22000 certificate expiring 06/21/21 was maintained. Materials were not received from any sister facilities. It was observed that the food security program dated 02/16/21 and VII-27 economically motivated adulteration management program dated 06/24/20 define the risk associated with the incoming materials. A register is maintained of all current approved suppliers by the SQF practitioner which was reviewed during the audit and found to be acceptable including the suppliers for food gable packaging and salt. Raw materials including packaging materials supplier found in the storage warehouse were verified to have come from suppliers on the approved supplier list. Ingredient hazard analysis completed for all ingredients reviewed during the audit observed completed in food safety plans. Continuing letter of guarantee and statement of compliance for the food contact gable packaging supplier reviewed dated 03/02/21 was part of the supplier approval program. Register of all approved suppliers was maintained online for each approved supplier accessible by the purchase only and reviewed by the SQF Practitioner.

2.4.4.1 Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall meet the agreed specification (refer to 2.3.2) and be supplied by an approved supplier.

RESPONSE: COMPLIANT

2.4.4.2 The receipt of raw materials, ingredients, and packaging materials received from non-approved suppliers shall be acceptable only in an emergency situation, and provided they are inspected or analyzed before use.

RESPONSE: COMPLIANT

2.4.4.3 The responsibility and procedure for selecting, evaluating, approving and monitoring an approved supplier shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.4.4 The site's food defense plan (refer to 2.7.1.1) shall include measures to secure incoming materials and ingredients and protect them from deliberate act of sabotage or terrorist-like incidents.

RESPONSE: COMPLIANT

2.4.4.5 The site's food fraud vulnerability assessment (refer to 2.7.2.1) shall include the site's susceptibility to raw material or ingredient substitution, mislabeling, dilution or counterfeiting which may adversely impact food safety.

RESPONSE: COMPLIANT

2.4.4.6 The food fraud mitigation plan (refer to 2.7.2.2) shall include methods by which the identified food safety vulnerabilities from ingredients and materials shall be controlled.

RESPONSE: COMPLIANT

2.4.4.7 Raw materials, ingredients, and packaging materials received from other sites under the same corporate ownership shall be subject to the same specification requirements (refer to 2.3.2) and approved supplier requirements as all other material providers.

RESPONSE: COMPLIANT

2.4.4.8 The approved supplier program shall be based on the prior performance of a supplier and the risk level of the raw materials ingredients, packaging materials, and services supplied, and shall contain as a minimum: i. Agreed specifications (refer to 2.3.2); ii. Reference to the rating of the level of risk applied to a raw material, ingredients, packaging materials and services and 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

2.4.4.9	Supplier audits shall be based on risk and shall be conducted by individuals knowledgeable of applicable regulatory and food safety requirements and trained in auditing techniques. **RESPONSE:** COMPLIANT
2.4.4.10	A register of approved supplier and records of inspections and audits of approved suppliers shall be maintained. **RESPONSE:** COMPLIANT

2.4.5 Non-conforming Product or Equipment

Product hold program IV-8 dated 12/29/20 was documented defining the procedures for withholding non-conforming products, raw materials, work-in-progress, ingredients and packaging, which was found to be properly implemented in the facility. Methods to segregate, identify, handle and dispose of product have been identified including placing the hold tag on it for any material put on hold. Nonconforming products or equipment is identified, segregated or disposed of, with records maintained by the SQF practitioner. This was observed during the audit by a review of the nonconformance recorded online holds log reviewed for hold incidence for the period of 2021 observed with total of 13 incidents recorded and closed including the corrective action completed, SQF practitioner was responsible for completion non conformances was interviewed could explain the hold procedures. Appropriate corrective action was completed and recorded by the SQF practitioner reviewed verified in an online program including the trend analysis for the non conformances. Trending for the reason of hold was reviewed for the period 2021 observed 99% for the packaging integrity reason and corrective actions were performed by the respective department. The log also included any equipment non conformance with corrective actions recorded on the reference work order.

2.4.5.1	The responsibility and methods outlining how non-conforming product, raw material, ingredient, work-in-progress, packaging or equipment detected during receipt, storage, processing, handling or delivery is handled shall be documented and implemented. The methods applied shall ensure: i. Non-conforming product is quarantined, identified, handled and disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; ii. Non-conforming equipment is effectively repaired or disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product; and iii. All relevant staff are aware of the organization's quarantine and release requirements applicable to equipment or product placed under quarantine status. **RESPONSE:** COMPLIANT
2.4.5.2	Quarantine records, and records of the handling, corrective action, or disposal of non-conforming product or equipment shall be maintained. **RESPONSE:** COMPLIANT

2.4.6 Product Rework

Rework for reprocessing program IV-VII-B dated 01/29/21 was documented and it defines that rework procedures was adopted as required for re packaging of the goods from one box to a different box or changing the labels only where required recorded on batch report reviewed completed 02/26/21 for walnut beverage with dates and quantity added from the older lot.

2.4.6.1	The responsibility and methods outlining how ingredients, packaging materials, or products are reworked shall be documented and implemented. The methods applied shall ensure: i. Reworking operations are supervised by qualified personnel; ii. Reworked product is clearly identified and traceable; iii. Each batch of reworked product is inspected or analyzed as required before release; iv. Inspections and analyses shall conform to the requirements outlined in element 2.5.4.1; and v. Release of reworked product shall conform to element 2.4.7. **RESPONSE:** COMPLIANT
2.4.6.2	Records of all reworking operations shall be maintained. **RESPONSE:** COMPLIANT

2.4.7 Product Release (Mandatory)

Product positive release program VI-1 dated 07/17/20 was used to document all inspections explain every product produced gets hold status in the online inventory program that was used to ship the product, and product can not be shipped until it has been changed the status in the online program as released, only QA can change the status to release after reviewing all the inspections including CCP monitoring records were verified to the specification standards following the regulatory requirements throughout the production cycle and verifying all steps were in compliance and recorded indicating the product meets the requirements and would release in inventory program monitored and documented by the QA department and change the product status for each pallet to released, reviewed completed 02/16/21 including all verifications by the supervisor.

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: i. By authorized personnel; and ii. Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.

RESPONSE: COMPLIANT

2.4.7.2 Records of all product release shall be maintained.

RESPONSE: COMPLIANT

2.4.8 Environmental Monitoring

The site has implemented and documented Environmental monitoring Program NY1450 dated 11/03/20. The program was based upon the risk assessment. There was no manufacturing performed for pet food products at this site. Corrective actions were implemented in case of any non-conformance. Swabbing locations and zoning chart defines Schedule and sampling locations as defined in the program including 120 samples weekly for listeria and salmonella EB count for Zone 03. Record reviewed including listeria saps, salmonella results date 01/21/21 with some trend observed for the listeria in one of the blend area observed to have appropriate corrective action performed with ultimately negative results.

2.4.8.1 A risk-based environmental monitoring program shall be in place for all food and pet food manufacturing processes.

RESPONSE: COMPLIANT

2.4.8.2 The responsibility and methods for the environmental monitoring program shall be documented and implemented.

RESPONSE: COMPLIANT

2.4.8.3 An environmental sampling and testing schedule shall be prepared, detailing the applicable pathogens or indicator organisms to test for that industry, the number of samples to be taken and the frequency of sampling.

RESPONSE: COMPLIANT

2.4.8.4 Environmental testing results shall be monitored and corrective actions (refer to 2.5.3.1) implemented where unsatisfactory trends are observed.

RESPONSE: COMPLIANT

2.5.1 Validation and Effectiveness (Mandatory)

SQF program effectiveness was performed per quality system auditing program VI-32 dated 11/02/20. SQF review schedule 2021 was documented defining the evaluation of effectiveness for each part of the SQF program applicable to the SQF code requirements. Effectiveness was reviewed as per the schedule defined in the program. Critical food safety limits were validated and revalidated annually for 02 CCPs in process (pH and finished product label)with last review completed 01/15/21 using process authority reference standards. Effectiveness of HACCP food safety programs performed per the schedule including review of customer complaints and other food safety parameters, that includes the GMPs and rest of the defined prerequisite program. Validation records completed as part of the effectiveness viewed completed for the HACCP program dated 06/10/20 and sanitation section completed 06/10/20 including customer complaints and process flow /hazard verification. Methods to ensure that procedure or process changes are still effective in controlling food safety are in place and verified at least annually by system review and using reference regulatory or industrial updates. Records of effectiveness of the SQF system were maintained by the SQF practitioner reviewed completed with validation checks and customer complaints and self inspection for each element. the audit.

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 ensure that: i. Good Manufacturing Practices are confirmed to ensure they achieve the required result; ii. Critical food safety limits are validated, and re-validated annually; iii. Changes to the processes or procedures are assessed to ensure controls are still effective; and iv. All applicable elements of the SQF Program are implemented and effective.

RESPONSE: COMPLIANT

2.5.1.2 Records of all validation activities shall be maintained.

RESPONSE: COMPLIANT

2.5.2 Verification Activities (Mandatory)

SQF Food process verification program dated 01/21/21 and HACCP process chart section dated 05 20/19 was documented that describes procedures for monitoring and verifying Good Manufacturing Practices, other food safety controls and regulatory compliance include utilizing authorized personnel to verify all monitoring activities. Record for verification of monitoring activities including quality systems final reviewed completed for ESL release for shipment completed 003/09/21 downtime log completed 03/11/21, production activity report completed 03/09/21, end of the run ELL completed 03/10/21, ESL finished product startup checklist completed 03/08/21, QA laboratory testing manual for pH determination completed 03/11/21, Combi 5 filler records dated 03/09/21, combi bloc turn sheet completed 03/11/21, pasteurizer electronics charts completed 03/11/21 observed verified daily by the supervisor and the quality team members for the area being monitored.

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

RESPONSE: COMPLIANT

2.5.2.2 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

2.5.2.3 Records of the verification of monitoring activities shall be maintained.

RESPONSE: COMPLIANT

2.5.3 Corrective and Preventative Action (Mandatory)

Corrective and preventative Action Program VII-16 dated 11/24/20 was documented including the investigation and corrective action performed for all food safety deviations. Program including CAPA database reviewed completed for 2021 with 05 corrective actions completed related to the process in scope that included the process of undertaking the correction activities for all non conformances. The policy was provided and outlined investigation and resolution of noncompliance of food quality and food safety issues. Internal online (CAPA) corrective action report was used to documents root cause analysis and corrective action performed reviewed completed with no specific trend observed among the 05 actions reviewed. Corrective actions observed to include investigation with and appropriate training as needed.

2.5.3.1 The responsibility and methods outlining how corrections and corrective actions are determined, implemented and verified, including the identification of the root cause and resolution of non-compliance of critical food safety limits and deviations from food safety requirements, shall be documented and implemented.

RESPONSE: COMPLIANT

2.5.3.2 Records of all investigation and resolution of non-conformities including their corrections and corrective action shall be maintained.

RESPONSE: COMPLIANT

2.5.4 Product Sampling, Inspection and Analysis

Post production inspection program IV-6 dated 03/16/20, sensory evaluation program dated 10/13/20 and Ingredient receipt program II-1 dated 07/17/20 was documented and defines the procedures for inspecting and analyzing materials at different stages during processing. The raw material was received from the approved suppliers and was received with COAs and samples were collected for some ingredients get sampled at the receiving and tested for sensory and ACC testing recorded on inbound material sensory evaluation sheet reviewed completed 03/10/21 for all the milk tankers received that day, In process sampling was performed as per the product requirement reviewed completed 03/10/21 for PT1 raw tank, sample was brought to the lab and tested for acidity, pH and temperature. Finished product gets sampled and was evaluated for sensory, and analytical at the lab for acidity or micro testing as needed. Each finished product batch was micro tested for spec in the lab. QA technician would perform the evaluations as per the specification. Inspections and analysis are scheduled at regular intervals to agreed specifications, regulatory requirements and true to labeling statements. All analysis are conducted to nationally recognized methods by the food safety team. Employee performing testing observed to have been trained in performing the reference tests. Site a lab manager perform the proficiency testing annually for each lab employee performing testing by receiving thru pre tested samples from the LGC and running the same testes by each of the lab employees and results for the acidity were shared. reviewed the results for total solids last test completed 02/19/21 observed all readings within with acceptable range.

2.5.4.1	The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work-in-progress shall be documented and implemented. The methods applied shall ensure: i. Inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements; ii. Inspections are conducted to ensure raw materials, work in process and finished products comply with the relevant specification, regulatory requirements and are true to label; and iii. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods. **RESPONSE:** COMPLIANT
2.5.4.2	On-site personnel that conduct environmental or product testing shall participate in an applicable proficiency testing program at least annually to ensure accuracy of results. **RESPONSE:** COMPLIANT
2.5.4.3	Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard and shall be included on the site's contract service specifications register (refer to 2.3.3.1). **RESPONSE:** COMPLIANT
2.5.4.4	Records of all inspections and analyses shall be maintained. **RESPONSE:** COMPLIANT

2.5.5 Internal Audits and Inspections (Mandatory)

The site's procedure for scheduling and conducting internal audits to assess the effectiveness of the SQF system has been documented and implemented per quality systems auditing VII-32 dated 07/01/20. SQF review schedule 2021 was used as part of the program that includes all areas of the SQF including the GMPs requirements reviewed last monthly audit completed 03/17/21 for the raw area section. The Internal Audit Program is maintained by the SQF practitioner. Food safety team rate internal auditor performs annual internal audit at this site. Facility and equipment inspections are conducted to ensure Good Manufacturing Practices are implemented per the schedule. Internal audits performed viewed completed for module 2 SQF code completed 08/19/20 recorded on food safety and quality checklist observed verified. Food safety team performs internal audits observed trained. All applicable SQF Code requirements viewed completed as part of the SQF internal GMPs audit program completed per the schedule. SQF practitioner is responsible to see that corrective actions are implemented and verified. SQF practitioner was responsible to review the program. All internal audits performed by the designated food safety team member observed independent of their functions being audited. Records of internal audits for food safety plan in the facility reviewed completed 08/19/20 as per the schedule.

2.5.5.1	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 at least annually. The methods applied shall ensure: i. All applicable requirements of the SQF Food Safety Code for Manufacturing are audited as per the SQF audit checklist or similar tool; ii. Correction and corrective action of deficiencies identified during the internal audits are undertaken; and iii. Audit results are communicated to relevant management personnel and staff responsible for implementing and verifying corrective actions. **RESPONSE:** COMPLIANT
2.5.5.2	Staff conducting internal audits shall be trained and competent in internal audit procedures. **RESPONSE:** COMPLIANT
2.5.5.3	Regular inspections of the site and equipment shall be planned and carried out to verify Good Manufacturing Practices and building/equipment maintenance is compliant to the SQF Food Safety Code for Manufacturing. The site shall: i. Take corrections or corrective and preventative action; and ii. Maintain records of inspections and any corrective action taken. **RESPONSE:** COMPLIANT
2.5.5.4	Where practical staff conducting internal audits shall be independent of the function being audited. **RESPONSE:** COMPLIANT
2.5.5.5	Records of internal audits and inspections and any corrections and corrective action taken as a result of internal audits shall be maintained. **RESPONSE:** COMPLIANT

2.6.1 Product Identification (Mandatory)

Coding procedures IV-4 dated 12/29/20 was documented Packaging material label verification procedures IV-11 dated 10/24/20 were documented. Each pallet of raw and packaging material received gets identification pallet tag that get scanned for the storage location, receiver documents supplier lot code name of raw material or packaging material with quantity and date received on the receiving records and also enter that information in online inventory program. Material transfer during processing was documented on blend sheet during the production process. Finished product every pallet receive a pallet sticker that gets scanned to the inventory system before loading into the truck as per the customer and regulatory requirements. filler PLE start up checklist was used for each packaging line for each product stat up reviewed completed for the combi bloc dated 03/10/21 was completed for each line and each product start up and every product change. The identification system ensures that all finished goods are clearly identified at all stages of their process. All records related to product identification including the pallet identification label, shipping and receiving logs, production sheets were maintained and reviewed for finished product packaging check completed 03/11/21 observed completed as per the program.

2.6.1.1 The methods and responsibility for identifying raw materials, ingredients, packaging materials, work-in -progress, process inputs and finished products during all stages of production and storage shall be documented and implemented. The product identification system shall be implemented to ensure: i. Raw materials, ingredients, packaging materials, 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 identification records shall be maintained.

RESPONSE: COMPLIANT

2.6.1.3 Product start up and changeover procedures during packing 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.

RESPONSE: COMPLIANT

2.6.2 Product Trace (Mandatory)

Mock / Actual recall/ traceability program VII-09 dated 08/24/20 was used as control point for lot identification throughout the process, it defines the responsibility and methods used to trace a product, SQFP has identified those responsible for initiating, managing the trace system. The procedure was also used to test the trace system one up and one back. Rework was performed as per the procedures. Effectiveness of the trace system is conducted at least annually. The facility conducts trace exercise as mock recall. Last exercise conducted 10/20/20 product (mushroom extract #VV20.47 with total quantity produced 6468 lbs. 18771 cases) (07 cases were destroyed and rest got shipped out to the customers. traced 100% with all shipping documents (one up) to the customers and 100% traced one back for the ingredient 100% traced (one back), food contact packaging Prisma paper was traced 100%. Exercise was completed in 01 hour and 35 minutes using online inventory program. Product trace exercise including all records of shipments to the customers and through the process to the suppliers of ingredient/packaging with date of receipt of materials were maintained. Records were available for review including incoming materials with date of receipt was maintained.

2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure: i. Finished product is traceable to the customer (one up) and provides traceability through the process to the manufacturing supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back); ii. Traceability is maintained where product is reworked; and iii. The effectiveness of the product trace system shall be reviewed at least annually as part of the product recall and withdrawal review (refer to 2.6.3.3).

RESPONSE: COMPLIANT

2.6.2.2 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 program 1X-1 dated 02/26/20 was documented defining the methods and responsibilities for withdrawing and recalling product if necessary. A recall team has been designated and is led by the CEO of the company and managed by the VP of quality at the head office of the company. The policy includes the requirement to investigate a recall and determine the root cause of a recall/withdrawal with a corrective action. It also includes a communication plan to notify consumers, regulatory authorities and other essential bodies. Program explains that SQFI and the Certification Body who must be notified within 24 hours in writing of any food safety event requiring public notification. Investigation into the root cause of any product recall, mock recall or product withdrawal, with actions taken, was observed to be documented. Mock recall was conducted at least annually. Last exercise conducted on 10/20/20 product (mushroom extract #VV20.47 with total quantity produced 6468 lbs. 18771 cases) (07 cases were destroyed and rest got shipped out to the customers. traced 100% with all shipping documents (one up) to the customers and 100% traced one back for the ingredient 100% traced (one back), food contact packaging Prisma paper was traced 100%. Exercise was completed in 01 hour and 35 minutes using online inventory program. Product trace exercise including all records of shipments to the customers and through the process to the suppliers of ingredient/packaging with date of receipt of materials were maintained. Records were available for review including incoming materials with date of receipt was maintained. There has been no actual recall recorded since the last audit.

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; and iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident; iv. SQFI, the certification body, and the appropriate regulatory authority shall be listed as an essential body 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 Investigation shall be undertaken to determine the root cause of a withdrawal, mock recall or recall and details of investigations and any action taken shall be documented.

RESPONSE: COMPLIANT

2.6.3.3 The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually. Testing shall include incoming materials (one back) and finished product (one up).

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

2.6.3.5 Records of all product withdrawals, recalls and mock recalls shall be maintained.

RESPONSE: COMPLIANT

2.7.1 Food Defense Plan (Mandatory)

The site has food security program XI-1 dated 02/16/21 was documented, that defines the procedures, responsibilities and criteria for preventing deliberate food adulteration have been documented and implemented. A food defense protocol includes names of management team and SQF practitioner, SQF practitioner responsible for food defense has completed food defense training. The program defines methods to allow access to the site only for authorized personnel, designated access points, the secured storage of materials and hazardous chemicals and the control of access to contractors and visitors. The plan was reviewed as management review last completed 02/16/21 and challenged annually or when any changes happen at this facility with last reviewed and challenge completed 06/15/20 including a real happening of suspicious activity where an employee was trying to access the restricted area who got stopped by the guards for behaving suspiciously , the test was observed completed with corrective actions verified by the SQF Practitioner. Product receiving, shipping and storage inside the building was documented and implemented. Corrective action program in place and annual review of food defense plan will be performed as per the program.

2.7.1.1 The methods, responsibility and criteria for preventing food adulteration caused by a deliberate act of sabotage or terrorist-like incident shall be documented, implemented and maintained.

RESPONSE: COMPLIANT

2.7.1.2 A food defense plan shall include: i. The name of the senior site management person responsible for food defense; ii. The methods implemented to ensure only authorized personnel have access to production equipment and vehicles, manufacturing and storage areas through designated access points; iii. The methods implemented to protect sensitive processing points from intentional adulteration; iv. The measures taken to ensure the secure receipt and storage of raw materials, packaging, equipment and hazardous chemicals; v. The measures implemented to ensure raw materials, ingredients, packaging materials, work-in progress, process inputs and finished products are held under secure storage and transportation conditions; and vi. The methods implemented to record and control access to the premises by employees, contractors, and visitors.

RESPONSE: COMPLIANT

2.7.1.3 The food defense plan shall be reviewed and challenged at least annually.

RESPONSE: COMPLIANT

2.7.1.4 Records of reviews of the food defense plan shall be maintained.

RESPONSE: COMPLIANT

2.7.2 Food Fraud

The site has Economically motivated adulteration management program VII-27 dated 06/24/20 was documented explaining the site's susceptibility to fraudulent and economic gain. Vulnerability assessment for each material along with the security measures to avoid food fraud. Mitigation strategies as part of the procedure including the assessment table was documented and risk assessment was performed. The process included assessment based upon the employees, customers and suppliers covering the vulnerabilities assessed by the site. The plan would be reviewed annually with last review completed 06/24/20 was verified by the sqf practitioner, no food fraud incidence was reported since the last audit.

2.7.2.1 The methods, responsibility and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety.

RESPONSE: COMPLIANT

2.7.2.2 A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled.

RESPONSE: COMPLIANT

2.7.2.3 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually.

RESPONSE: COMPLIANT

2.7.2.4 Records of reviews of the food fraud vulnerability assessment and mitigation plan shall be maintained.

RESPONSE: COMPLIANT

2.8.1 Allergen Management for Food Manufacturing (Mandatory)

Allergens control program II-5 dated 10/13/20 was documented and implemented. SQF practitioner was responsible for the implementation. Allergens of concern were wheat, milk, soy, tree nut(coconut, walnut, cashews, almonds, hazelnut, macadamia nut) fish, Gluten, sulphites and Sesame (based upon the category of products being processed at this site. Coding procedures defines the label verification at all stages of production including the verification of correct allergen declaration and destruction of obsolete labels. Program defines the changeover for each run verified through approved test kits from Neogen for each allergen run recorded on aseptic allergen testing record reviewed for UHT-1 for Soy and coconut completed 03/15/21 with no detection of allergen for both rinse water and the product run after the allergen. All FDA and destination countries declared allergens were part of the employee training list. Workplace allergens from locations such as lunchrooms, locker rooms and vending machines were found to be included in the allergen program for employee training and awareness. The site was found to have list of allergens available to site personnel. The allergens are part of the hazard analysis and each allergen has a designated color coding applied to each pallet. Product labeling procedures were adopted per the regulatory requirements. Rework of allergens was performed as per the program. Validation was reviewed documented performed each allergen run testing rinse water and the product run after the allergen tested for specific allergen run before the change over using 3M Elution Neogen(test kit for each allergen processed at this site. for coconut and soy reviewed completed 03/15/21 observed all 70 (60 rinse water and 10 products) samples test results with below detectable limits. All allergens validation was completed throughout the year. The operation was found to have a product identification system that includes clear identification of all product at all stages. The product trace system ensures the complete trace of ingredients. The procedures define the mitigation of unintentional chance of contamination through visitor's policy and employee training program.

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 from locker rooms, vending machines, lunch-rooms, and visitors; iii. A register of allergens which is applicable in the country of manufacture and the country (ies) of destination if known; iv. A list of allergens which is accessible by relevant staff. v. The hazards associated with allergens and their control incorporated into the food safety plan. vi. A management plan for control of identified allergens. The allergen management program shall include the identification, management, and labelling of products containing gluten, where applicable. **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 containing allergens. **RESPONSE:** COMPLIANT
2.8.1.3	Provision 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 is 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 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 shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured. **RESPONSE:** COMPLIANT
2.8.1.8	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 is true to label with regard to allergens. Such 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
2.8.1.9	The product trace system shall take into consideration the conditions under which allergen containing foods are manufactured and ensure full trace back of all ingredients and processing aids used. **RESPONSE:** COMPLIANT
2.8.1.10	Re-working of product containing food allergens shall be conducted under conditions that ensure product safety and integrity is 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 introducing unintended allergens through supplier, contract manufacturer, employee and visitor activities. **RESPONSE:** COMPLIANT

2.8.2 Allergen Management for Pet Food Manufacturing

Pet food was not processed at this site.

2.8.2.1 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 inputs and processing aids, including food grade lubricants, that contain food allergens; ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch-rooms, and visitors; iii. A list of allergens which is accessible by relevant staff; and iv. The hazards associated with allergens and their control incorporated into the food safety plan.

RESPONSE: NOT APPLICABLE

2.8.2.2 Product labeling, in accordance with regulatory requirements, shall include allergens where risks from cross-contact have been identified.

RESPONSE: NOT APPLICABLE

2.8.3 Allergen Management for Manufacturers of Animal Feed

Animal feed was not processed at this site.

2.8.3.1 Sites that exclusively manufacture animal feed and do not manufacture, handle or store food or pet food products are not required to implement an allergen management plan unless required by regulation or customer requirement.

RESPONSE: NOT APPLICABLE

2.8.3.2 Where an allergen management plan is required by regulation or customer specification, the requirements of 2.8.2 shall apply.

RESPONSE: NOT APPLICABLE

2.9.1 Training Requirements

Training of personnel Procedures VII-18 dated 02/12/21 was documented for plant personnel for all tasks to ensure the effective implementation of the SQF system. Training program defines new hire and annual refresher training maintained by the SQF practitioner. This was evidenced in the facility by interviews with plant employees including production operators, receiving shipping supervisor. Training program included the GMPs, employee specific job, work instructions and refresher training.

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.

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)

Training of personnel Procedures VII-18 dated 02/12/21 was documented for all tasks to ensure the effective implementation of the SQF system. This was evidenced in the facility by interviews with plant employees including production operators, receiving shipping supervisor. Training program included the GMPs, employee specific job (quality check monitors/CCP monitors, line leads), work instructions, food safety plan and refresher training.

2.9.2.1 An employee training program shall be documented and implemented. It shall outline the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with: i. Developing and applying Good Manufacturing Practices; ii. Applying food regulatory requirements; iii. Steps identified by the hazard analysis and/or other instructions as critical to effective implementation of the food safety plan and the maintenance of food safety; and iv. Tasks identified as critical to meeting the effective implementation and maintenance of the SQF System.

RESPONSE: COMPLIANT

2.9.3 Instructions

Training of personnel Procedures VII-18 dated 02/12/21 was documented and implemented, it defines work instructions, it explains how tasks critical to maintaining food safety are performed viewed completed for annual CCP instructions completed 11/04/20 for all 03 CCPs observed verified by the supervisor. The site uses English language and all training material and signs were available and verified.

2.9.3.1 Instructions shall be available in the languages relevant to the staff, explaining how all tasks critical to meeting regulatory compliance, the maintenance of food safety, and process efficiency are to be performed.

RESPONSE: COMPLIANT

2.9.4 HACCP Training Requirements

Training of personnel Procedures VII-18 dated 02/12/21 was documented for personnel involved in the development and maintaining the food safety plan is administered completed as part of annual refresher dated 11/30/20 through SQF Practitioner to all the employees. Food safety team members go through the HACCP refresher training through certified training provider.

2.9.4.1 HACCP training shall be provided for staff involved in developing and maintaining food safety plans.

RESPONSE: COMPLIANT

2.9.5 Language

The training language and materials used are understood by all plant personnel. English language was used in training program, employees interviewed could explain the food safety knowledge and trainings received.

2.9.5.1 Training materials and the delivery of training shall be provided in language understood by staff.

RESPONSE: COMPLIANT

2.9.6 Refresher Training

Refresher training was identified in the training program. All personnel receive refresher training at least annually or when required. The last refresher training was conducted 03/02-04/21 for all the filler operation employees. The training covers the GMPs and all food safety requirements, observed signed by all the employees.

2.9.6.1 The training program shall include provision for identifying and implementing the refresher training needs of the organization.

RESPONSE: COMPLIANT

2.9.7 Training Skills Register

Training Matrix dated 03/15/21 including each section of the process areas was maintained by the training department, all trainings were provided by a the trained Food safety team members or training department who have the professional training from an recognized training institute, register was maintained online for all individuals working at this site. Each training employee pass the short quiz after completing the SQF and HACCP training and was verified by the SQF Practitioner. The training index include name of employee with department and the training requirement with frequency. CCP monitor training form viewed completed as HACCP training reviewed completed 03/02-04/21 including all Tetra operation monitors. Training records would include the name of the trainer, person training completed and subject training provided and supervisors initials that the training has been completed viewed for production department with short quiz reviewed completed dated 03/02/21 for the filler operators recorded on training summery record. Plant employees interviewed on the production floor including warehouse supervisors and line operators were found to have current training records on the register. Training verification was performed by the respective department supervisor.

2.9.7.1 A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the: i. Participant name; ii. Skills description; iii. Description of the training provided; iv. Date training completed; v. Trainer or training provider; and vi. Supervisor's verification that the training was completed, and that the trainee is competent to complete the required tasks.

RESPONSE: COMPLIANT

11.1.1 Premises Location and Approval

The site's buildings, property and surroundings were observed during the audit to not pose a food safety risk to products. Measures have been established to maintain a suitable external environment and adjoining buildings observed to have no food safety risk for the site. The site maintains the required approvals for their ongoing operations observed in compliance with the regulations, the operations observed to have annual food processing license from New York State department of agriculture dated 11/14/20. Site is also FDA and USDA registered facility including the warehouse. Site was located in a small town about half an hour from the major city.

11.1.1.1 The location of the premises shall be such that adjacent and adjoining buildings, operations and land use do not interfere with safe and hygienic operations.

RESPONSE: COMPLIANT

11.1.1.2 The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

RESPONSE: COMPLIANT

11.2.1 Materials and Surfaces

Product contact surfaces, surfaces not in contact with food and storage areas are constructed of suitable materials including stainless steel equipment, food grade plastic buckets, concrete smooth floors and insulated walls. They were observed during the audit to be properly maintained so that food safety is not compromised.

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

RESPONSE: COMPLIANT

11.2.2 Floors, Drains, and Waste Traps

Floors are constructed of smooth and dense impact resistant material and properly graded for effective drainage of overflow or waste water. Waste water during the audit was observed to be properly discharged. Drains were observed to be located and constructed for ease of cleaning and inspection. Waste water from around the facility drains was directed outside of the building through the drains where pH gets tested continually through an online program that would alarm the management in cases pH gets out of the required municipality range, and it get adjusted by adding chemicals in the waste line and from there the waste water gets discharged to the town sewage system. Waste water from the employee areas was directed to the city sewage system without entering into the facility drainage system. Waste traps were installed outside the building where all effluents get collected by the authorized contractor on regular bases.

11.2.2.1 Floors shall be constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

RESPONSE: COMPLIANT

11.2.2.2 Floors shall be sloped to floor drains at gradients suitable to allow the effective removal of all overflow or wastewater under normal working conditions.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.2.2.4 Waste trap system shall be located away from any food handling area or entrance to the premises.

RESPONSE: COMPLIANT

11.2.3 Walls, Partitions, Doors and Ceilings

Walls, ceilings and doors are of durable construction with smooth and light colored surfaces. These areas were observed to be clean during the audit tours. Wall to wall and wall to floor junctures were observed to be sealed and free of debris. Ducting, piping and conduit conveying services were observed to be properly designed and installed to prevent contamination and for ease of cleaning. Doors, windows and frames in product areas were observed to be properly constructed of materials with the same functional requirements as internal walls and partitions. The ceilings in all food processing and handling areas are constructed of insulated material, which are easily cleaned and prevent product contamination. Drop ceilings were observed in blending areas and office areas that was part of pest monitoring program. N/A: Overhead waste water pipe were not used.

11.2.3.1	Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious with a light-colored finish and shall be kept clean (refer to 11.2.13.1). **RESPONSE:** COMPLIANT
11.2.3.2	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
11.2.3.3	Ducting, conduit and pipes that convey 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. **RESPONSE:** COMPLIANT
11.2.3.4	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. **RESPONSE:** NOT APPLICABLE
11.2.3.5	Doors, hatches and windows and their frames in food processing, handing or storage areas shall be of a material and construction which 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
11.2.3.6	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. **RESPONSE:** COMPLIANT
11.2.3.7	Drop ceilings shall be constructed to enable monitoring for pest activity, facilitate cleaning and provide access to utilities. **RESPONSE:** COMPLIANT
11.2.4	**Stairs, Catwalks and Platforms** Stairs, catwalks and platforms were designed and used to protect product from contamination.
11.2.4.1	Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.13.1). **RESPONSE:** COMPLIANT
11.2.5	**Lightings and Light Fittings** Lighting was of the appropriate intensity for employees to carry out their tasks efficiently. Light fittings in food handling areas were observed to be protected or with shatterproof covering. Structures were protected from accidental damages. Periodic inspections are completed for each area included in the glass inventory register, observed monitored as per the program with last checks completed 02/26/21 observed with no damages in any area.
11.2.5.1	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. **RESPONSE:** COMPLIANT
11.2.5.2	Light fittings 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 fittings cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials and addressed in the cleaning and sanitation program. **RESPONSE:** COMPLIANT
11.2.5.3	Light fittings in warehouses and other areas where the product is protected shall be designed such as to prevent breakage and product contamination. **RESPONSE:** COMPLIANT

11.2.6 Inspection / Quality Control Area

Inspection areas were provided beside the packaging areas (Tetra, Combi Pac and Gable) for net weight, seal integrity testing was observed maintained, with sufficient lighting and hand wash facilities. There was no open product tested within the production areas.

11.2.6.1 A suitable area shall be provided for the inspection of the product if required.

RESPONSE: COMPLIANT

11.2.6.2 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 hand washing facilities; ii. Have appropriate waste handling and removal; and iii. Be kept clean to prevent product contamination.

RESPONSE: COMPLIANT

11.2.7 Dust, Insect, and Pest Proofing

External windows, doors and other openings were observed during facility tours to be properly sealed to prevent any pest infestation or dust coming into the facility. External personnel doors were observed to be self-closing and sealed to prevent dust and pest ingress. All external doors and dock doors were sealed to prevent infestation. Electric insect devices, and interior and exterior rodent stations are located so the product is not at risk for contamination. Rodenticide bait is only used on the outside of the facility. Electric insect lights and devices were observed to follow the code requirements. Minor: Doors and other external openings were observed sealed and proofed, there was one observation for shipping receiving dock door #09 was observed with 2cmx4cm opening at the bottom right side of the door observed not sealed when closed.

11.2.7.1 All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against dust, vermin and other pests.

RESPONSE: MINOR

EVIDENCE: Doors and other external openings were observed sealed and proofed, there was one observation for shipping receiving dock door #09 was observed with 2cmx4cm opening at the bottom right side of the door observed not sealed when closed.

ROOT CAUSE: n/a

CORRECTIVE ACTION: Dock door #9 was repaired by maintenance after the observation was reported. Steuben Foods, Inc. will hire a Millwright that will be responsible for the observation and maintenance of facility doors. Evidence: Job Description: Mechanic Grade 1 - Mill Wright, photos 1.1-1.3

VERIFICATION OF CLOSEOUT: Correctice action was completed during the audit duration, provided records cor complition and pictures is acceptable.

COMPLETION DATE: 03/25/2021 **CLOSEOUT DATE:** 04/08/2021

11.2.7.2 External personnel access doors shall be provided. They shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against ingress of dust, vermin and other pests.

RESPONSE: COMPLIANT

11.2.7.3 External doors, including overhead dock doors in food handling areas used for product, pedestrian or truck access shall be insect-proofed by at least one or a combination of the following methods: i. A self-closing device; ii. An effective air curtain; iii. An insect-proof screen; iv. An insect-proof annex; v. Adequate sealing around trucks in docking areas.

RESPONSE: COMPLIANT

11.2.7.4 Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Poison rodenticide bait shall not be used inside ingredient or product storage areas or processing areas.

RESPONSE: COMPLIANT

11.2.8 Ventilation

Adequate ventilation was available, where needed, in enclosed processing and food areas. Ventilation exhaust pipes going outside the roof from the exhaust and pasteurizer were seen to be adequately sealed and cleaned, insect-proofed and located to not pose a risk of contamination. Ventilation was observed to be adequate around the facility including the refrigerated room and no condensation was noted. Positive air pressure was maintained only filler rooms and monitoring was not required.

11.2.8.1	Adequate ventilation shall be provided in enclosed processing and food handling areas. **RESPONSE:** COMPLIANT
11.2.8.2	All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.12, to prevent unsanitary conditions. **RESPONSE:** COMPLIANT
11.2.8.3	Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam is generated and shall have the following features: i. 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); ii. Fans and exhaust vents shall be insect-proofed and located so as not to pose a contamination risk; and iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination. **RESPONSE:** COMPLIANT

11.2.9 Equipment, Utensils, and Protective Clothing

Site requirements and construction program V-14 dated 02/26/21 and sanatory design procedures V-1 dated 12/10/20, was documented defining purchasing equipment and utensils, including tables are designed, constructed and installed to meet regulatory requirements and prevent risks of contamination of the product. These items were found to be cleaned and stored properly after use to prevent cross contamination. Equipment surfaces were observed to be smooth, impervious and free from cracks and crevices. Equipment's are made of non-toxic materials. Water used for cleaning is discharged to the floor drainage system and meets requirements. Clothing required to be kept in clean and in good condition and appropriate handling and storage facilities were provided sourced through approved protective clothing company. Protective clothing meets documented specifications, is easily cleaned, and is made of material that will not contaminate food including the gloves. Employees store protective clothing on racks adjacent to access points when going on breaks. All equipment, utensils and protective clothing are cleaned at appropriate frequencies and are properly stored to prevent contamination.

11.2.9.1	Specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment shall be documented and implemented. **RESPONSE:** COMPLIANT
11.2.9.2	Equipment and utensils shall be designed, constructed, installed, operated and maintained to meet any applicable regulatory requirements and not to pose a contamination threat to products. **RESPONSE:** COMPLIANT
11.2.9.3	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
11.2.9.4	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 11.2.13. Bins used for inedible material shall be clearly identified. **RESPONSE:** COMPLIANT
11.2.9.5	Waste and overflow water from tubs, tanks and other equipment shall be discharged direct to the floor drainage system, and to meet local regulatory requirements. **RESPONSE:** COMPLIANT
11.2.9.6	Protective clothing shall be manufactured from material that will not contaminate food and is easily cleaned. **RESPONSE:** COMPLIANT
11.2.9.7	Racks shall be provided for the temporary storage of protective clothing when staff leave the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities. **RESPONSE:** COMPLIANT
11.2.9.8	All equipment, utensils and 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

11.2.10 Premises and Equipment Maintenance

Maintenance-Plant, equipment & building repair procedure VIII-2 dated 03/16/21 was documented for equipment's and other areas of the facility including building and structures was under the facilities department and maintained by the maintenance supervisor, Facilities were monitored for any damages and preventative control tasks were recorded on the work order being completed for any PM performed per the schedule maintained in an online PM program that would generate the required PM task to be completed as set in the program, Reviewed completed work order #CM034903 dated 02/26/21 for on gable line, The person completing the task will fill in all tasks performed for that area observed completed as per the instructions. Preventative maintenance management system documented online for equipment and other areas of the plant, observed scheduled weekly, monthly, quarterly and annually. The maintenance manager maintained the program. Reviewed PM work orders Won-13-0034914 dated 01/23/21 for case packer observed verified and completed as per the requirements. Master LIST for equipment was maintained online by the equipment maintenance supervisor. When repairs and maintenance work are completed, personnel complete the work order and the line operator would follow up on cleaning the area and removing the tools and would document on the reference work order reviewed completed 01/28/21 filler operator log combi block 02/11/20 observed verified by the supervisor. Maintenance personnel are trained in good manufacturing practices and food safety. Periodic inspections are completed to ensure loose parts and other materials are not potential contaminants and recorded on monthly internal inspection data base reviewed completed 03/17/21. Machinery, conveyers and other equipment over or near food or food contact surfaces are lubricated with food grade materials. The food grade lubricants were noted to be stored separately and labeled properly in maintenance area secured cabinets. Paint is not used on food contact surfaces and any paint in processing areas was noted to be in good condition. Premises and Equipment Maintenance" documents the methods and responsibility for the maintenance and repair of food storage areas, equipment, and buildings. Approved contractors were used for equipment or building repair where required. Maintenance procedures were established for the facility and equipment. Maintenance staff and contractors were provided GMPs training and observed following the policy. Supervisors were notified when maintenance work was to be conducted in their areas. Contractors were to sign in after reading the GMPs policy before starting their work by the respective department manager. Each area operator complete the appropriate hygiene and sanitation prior to the commencement of operations and was recorded on the area start-up checklist reviewed completed combi block dated 02/11/21. Minor: Paint used on walls and doors was observed to be maintained except observation was recorded in blend room C where some peeling off pain was observed on the wall beside the blend tank, that was not maintained in good shape.

11.2.10.1 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

11.2.10.2 Routine maintenance of plant and equipment in any food processing, handling or storage area shall be performed according to a maintenance-control schedule and recorded. The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality.

RESPONSE: COMPLIANT

11.2.10.3 Failures of plant and equipment in any food processing, handling or storage area shall be documented, reviewed and their repair incorporated into the maintenance control schedule.

RESPONSE: COMPLIANT

11.2.10.4 Maintenance staff and contractors shall comply with the site’s personnel and process hygiene requirements (refer to 11.3.1, 11.3.2, 11.3.3, 11.3.4).

RESPONSE: COMPLIANT

11.2.10.5 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

11.2.10.6 Site supervisors shall be notified when maintenance or repairs are to be undertaken in any processing, handling or storage area.

RESPONSE: COMPLIANT

11.2.10.7 The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside processing times.

RESPONSE: COMPLIANT

11.2.10.8 Temporary repairs, where required shall not pose a food safety risk and shall be included in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions.

RESPONSE: COMPLIANT

11.2.10.9 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 completed and a pre-operational inspection conducted prior to the commencement of site operations.

RESPONSE: COMPLIANT

11.2.10.10 Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product.

RESPONSE: COMPLIANT

11.2.10.11 Paint used in a food handling or contact zone shall be suitable for use, in good condition and shall not be used on any product contact surface.

RESPONSE: MINOR

EVIDENCE: Paint used on walls and doors was observed to be maintained except observation was recorded in blend room C where some peeling off pain was observed on the wall beside the blend tank, that was not maintained in good shape.

ROOT CAUSE: n/a

CORRECTIVE ACTION: Lehigh has been contracted to make repairs to the walls of Blend Room C. Work is planned to begin July 2, 2021 during a plant shutdown. Evidence: Lehigh Proposal, Lehigh PO

VERIFICATION OF CLOSEOUT: Correctice action was completed during the audit duration, provided records cor work order and pictures is acceptable.

COMPLETION DATE: 04/06/2021 **CLOSEOUT DATE:** 04/08/2021

11.2.11 Calibration

Calibration / maintenance program VIII-3 dated 03/02/21 and calibration schedule dated 12/18/20 was documented explaining the calibration schedule including with all equipment list requiring calibration. The frequency of inspections was based on the manufacturer's recommendations or customer requirements. A review of the calibration records for the listed equipment's confirms the schedule is being followed. Calibration procedures for individual equipment address the disposition of any affected product should inspection equipment found to be out of calibration. Calibration records viewed for HTST 1 (milk) performed by the New York State department dated 10/16/20, RTD calibrated 06/06/20, cold storage thermometer calibrated 10/14/20, scales were calibrated through a certified technician reviewed last completed 02/11/21, mass flow meters calibrated through the manufacturer annually with last test completed 01/19/21 by a certified technician. Lab equipment including salt titrator completed 01/16/21, CEM (total solid testing equipment) completed 01/21/21 , chart recorders (CIP) completed 10/29/20. Calibration procedures define the disposal of products in case of any equipment is found to be out of calibration, Inspected equipment was protected from damage or unauthorized use as it was only calibrated by authorized trained employees only authorized personal have access of use. Equipment is calibrated against national or international standards as described in the reviewed certificates.

11.2.11.1 The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in pre-requisite programs and food safety plans, or to demonstrate compliance with customer specifications shall be documented and implemented. Software used for such activities shall be validated as appropriate.

RESPONSE: COMPLIANT

11.2.11.2 Procedures shall be documented and implemented to address the disposition of potentially affected products should measuring, test and inspection equipment be found to be out of calibration state.

RESPONSE: COMPLIANT

11.2.11.3 Calibrated measuring, test and inspected equipment shall be protected from damage and unauthorized adjustment.

RESPONSE: COMPLIANT

11.2.11.4 Equipment shall be calibrated against national or international reference standards and methods or to 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

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

RESPONSE: COMPLIANT

11.2.11.6 Calibration records shall be maintained.

RESPONSE: COMPLIANT

11.2.12 Pest Prevention

Pest Control policy V-07 dated 07/02/20/07/19 was documented, licensed pest contractor has been appointed for pest prevention and an updated scope of service agreement dated 08/06/19 defines the methods of pest prevention, the frequency of interior weekly and exterior (monthly) inspections and targeted pests. A current site map is accurate showing the location (inside and outside) for each device dated 03/16/21 for this processing site. A pesticide application log gives details and dates of all chemical usage last completed 03/18/31. Licenses of the Pest control services with expiration 09/30/21 from Sate of New York was current and indicate employees are trained and competent with service technician license expiring 09/21/22 from State of New York was current. A list of chemicals used by the pest contractor with SDS information was on file. Inspection activity service reports viewed for 03/18/23/21 with only some flies finding in the its. The maps for all areas of the site were kept current and verified. Every visit report gets signed by a management representative after visits, all reports reviewed for the period found to be completed as scheduled. Any observations or issues noted by the Pest Contractor was addressed and documented by the site. The trending of the pest activity frequency is documented and reviewed for 2020 observed no specific findings. N/A: Pest control chemicals were not stored at the facility and disposed off by the contractor. .

11.2.12.1 The methods and responsibility for pest prevention shall be documented and effectively implemented. The premises, its surrounding areas, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin.

RESPONSE: COMPLIANT

11.2.12.2 Identified pest activity shall not present a risk of contamination to food products, raw materials or packaging.

RESPONSE: COMPLIANT

11.2.12.3 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 investigated and resolved. Records shall be kept of the disposal, investigation, and resolution.

RESPONSE: COMPLIANT

11.2.12.4 The pest prevention program 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; v. Outline the frequency with which pest status is to be checked; vi. Include on a site map the identification, location, number and type of bait stations set; vii. List the chemicals used (they 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.

RESPONSE: COMPLIANT

11.2.12.5 Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present.

RESPONSE: COMPLIANT

11.2.12.6 Records of all pest control applications shall be maintained.

RESPONSE: COMPLIANT

11.2.12.7 Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 11.6.4 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food and food contact surfaces.

RESPONSE: NOT APPLICABLE

11.2.12.8 Pest contractors shall be: i. 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 2.3.3) which will include and maintain 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; and vi. Provide a written report of their findings and the inspections and treatments applied.

RESPONSE: COMPLIANT

11.2.12.9 The site shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that: i. Empty chemical containers are not reused; ii. Empty containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor.

RESPONSE: NOT APPLICABLE

11.2.13 Cleaning and Sanitation

Sanitation standard operating procedure V-8 dated 12/29/20 including CIP and master sanitation schedule dated 01/23/21 including (daily, weekly , monthly) for all areas was documented defining all process cleaning and sanitation requirements. Sanitation procedures define cleaning procedures for each area observed covering the processing, storage, outside areas with instructions and chemical used for each section of the facility. Restroom Cleaning program SP-075 dated 08/12/20 including the staff amenities and toilets was documented with verification activities documented for each area specific sanitation sheet reviewed completed as warehouse 6 office inspection log reviewed completed 02/11/21 observed verified. Frequencies and responsibilities for cleaning and sanitation as per procedures for each area including person responsible for cleaning was documented. Effectiveness of cleaning methods was performed by the area supervisor verifying each section completing the respective area cleaning report reviewed completed for daily master sanitation filling room#3 for the week starting 02/21/21 and GNS processing area (weekly) reviewed completed for the week 02/24/21, warehouse monthly cycle reviewed completed 02/12/21 observed verified by the supervisor. Employee areas including lunch room and toilets was completed on daily janitorial check list reviewed completed daily Warehouse 6 office area for the week starting 02/21/21 observed verified by the sanitation supervisor. Cleaning check sheet for each area covering all areas of the facility was documented. Cleaning materials are stored securely and properly labeled with SDS information available to all employees. Chemicals soaps were observed to be included on a list of approved chemicals, labeled consistent with regulations and had SDS on hand. Chemicals were tested for concentration by the trained operator of each area reviewed 3 speed filler completed 03/08/21 with acid and caustic results. Sanitation team members were properly by the SQF practitioner in cleaning methods and plant GMPs. Pre-operational inspections were performed by the area operators by performing visual inspection at the end of cleaning cycle and before the start of the start of the run would record all information on long turn checklist reviewed completed for A-3 speed filler dated 03/08/21, pre-operational checks were performed after every CIP cleaning and before the start of the next run that including the visual inspections and the cap last run water evaluation for the allergen and also ATP test performed by the QA documented online reviewed completed 01/01-30/21 for the combi block fillers observed in compliance with the cleaning requirements, operator would also perform cleaning and inspection for the area that includes facility and employees hygiene documented on the master sanitation program reviewed completed filling room-2 after completing the task 03/08/21 observed verified by the area supervisor before the start of the next operations reviewed completed daily including production area, employee areas were monitored and recorded on lunch room inspection log reviewed completed for the week 02/21/21 locker room inspection log completed for the week 02/21/21, Empty chemical containers were rinsed and recycled per the regulatory requirements. CIP was performed at this site, concentration check documented on the reference department run form reviewed completed for Combi block CBS Turn form reviewed completed 03/08/21. Verification of CIP cleaning was performed through ATP testing reviewed completed and documented CIP Combi bloc CBS turn form reviewed completed 01/01-30/21 with all pass results in compliance of the requirements. Minor: Areas around the facility were inspected and observed maintained except there was observation recorded of cobweb development in the warehouse beside the dock door observed not cleaned.

11.2.13.1 The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities 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. Methods used to confirm the correct concentrations of detergents and sanitizers, and vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

RESPONSE: COMPLIANT

11.2.13.2 Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing.

RESPONSE: COMPLIANT

11.2.13.3 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards and other utensils and for cleaning of protective clothing used by staff. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. Racks and containers for storing cleaned utensils shall be provided as required.

RESPONSE: COMPLIANT

11.2.13.4 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 modifications to CIP equipment shall be validated. Personnel engaged in CIP activities shall be effectively trained.

RESPONSE: COMPLIANT

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

RESPONSE: MINOR

EVIDENCE: Areas around the facility were inspected and observed maintained except there was observation recorded of cobweb development in the warehouse beside the dock door observed not cleaned.

ROOT CAUSE: n/a

CORRECTIVE ACTION: Cobwebs beside the dock door were removed after the observation was reported. Ehrlich, the Pest Control Company contracted by Steuben Foods, Inc. was informed of the finding when the observation was reported. The monthly Master Sanitation Plan for the Ingredients Warehouse was updated to include “Inspect for cobweb/dust buildup and clean” Evidence: Monthly Ingredients Warehouse MSP, photos 3.1-3.8

VERIFICATION OF CLOSEOUT: Correctice action was completed during the audit duration, provided records cor work order and pictures is acceptable.

COMPLETION DATE: 04/01/2021 **CLOSEOUT DATE:** 04/08/2021

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

RESPONSE: COMPLIANT

11.2.13.7 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.

RESPONSE: COMPLIANT

11.2.13.8 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 chemicals purchased and used shall be 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 handles sanitizers and detergents.

RESPONSE: COMPLIANT

11.2.13.9 Detergents and sanitizers that have been mixed for use shall be correctly mixed according to manufacturers’ instructions, stored in containers that are suitable for use, and clearly identified. Mix concentrations shall be verified and records maintained.

RESPONSE: COMPLIANT

11.2.13.10 The site shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that: i. Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use; ii. Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and iii. Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor.

RESPONSE: COMPLIANT

11.2.13.11 A record of pre-operational hygiene inspections, cleaning and sanitation activities, and verification activities shall be maintained.

RESPONSE: COMPLIANT

11.3.1 Personnel

Personal hygiene practices policy V-2 dated 04/30/20 was documented and implemented. Employees are prohibited from working in food handling or open food storage areas who are suffering from, or who are or were carriers of, an infectious disease that may be passed through food. The site has documented measures to prevent contact of product materials with bodily fluids and respond appropriately to any bodily fluid spillage. The policy includes the prohibition of any food handling activity for persons with exposed cuts, sores or lesions and requires that minor cuts or abrasions be covered with a waterproof, metal detectable, colored bandage. The policy prohibits smoking, eating, drinking or spitting in the facility. Smoking is permitted only in designated areas outside the building. Employee interviews confirmed that employees are trained in good manufacturing practices and are knowledgeable of the requirements.

11.3.1.1 Personnel who are carriers or are known to have been 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.

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 from open wounds, coughing, sneezing, spitting, or any other means. In the event of an injury which causes spillage of bodily fluid, a properly trained employee 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 disposed of.

RESPONSE: COMPLIANT

11.3.1.3 Personnel with exposed cuts, sores or lesions shall not engage in handling or processing products or handling primary packaging materials or food contact surfaces. Minor cuts or abrasions on exposed parts of the body shall be covered with a colored bandage containing a metal strip or an alternative suitable waterproof and colored dressing.

RESPONSE: COMPLIANT

11.3.1.4 Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. Drinking of 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 or equipment.

RESPONSE: COMPLIANT

11.3.2 Hand Washing

Personal hygiene practices policy V-2 dated 04/30/20 has been documented and implemented. Hand wash basins are located at appropriate employee access points to processing areas. Hand wash sinks are made of non-corrosive materials and supplied with tempered potable water. Soap in a fixed dispenser, paper towels and waste containers are available. Hands-free operated taps and hand sanitizers are available in all areas of the site. Signs are posted English reminding employees to wash their hands before returning to work. Signs are posted at hand wash stations and in bathrooms. Employees are required to wash hands when wearing gloves. Interviews conducted with line operators in packaging and mixing areas during the audit demonstrated that employees understand the hand washing requirements. Employees were observed to wash their hands properly during the audit and to use proper glove procedures. Hand washing stations were provided with hands free tap operations and the sanitizer was provided.

11.3.2.1 Hand wash basins shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

RESPONSE: COMPLIANT

11.3.2.2 Hand wash basins shall be constructed of stainless steel or similar non-corrosive material and as 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

11.3.2.3 The following additional facilities shall be provided in high risk areas: i. Hands free operated taps; and ii. Hand sanitizers.

RESPONSE: COMPLIANT

11.3.2.4 A sign instructing people to wash their hands, and in appropriate languages, shall be provided in a prominent position.

RESPONSE: COMPLIANT

11.3.2.5 Personnel shall have clean hands and hands shall be washed by all personnel, including 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, dropped product or contaminated material.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3 Clothing

A policy, based on a documented risk assessment, found in Personal hygiene practices policy V-2 dated 04/30/20 was documented, that defines the site's clothing requirements and been implemented based upon the risk assessment. Clothing including shoes are required to be clean at the commencement of the shift and changed or replaced if excessively soiled. Disposable gloves are to be changed when soiled or damaged. Employees were observed to comply with the clothing requirements of the facility.

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 as not to present a contamination risk to products.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.3.4 Excessively soiled uniforms shall be changed or replaced where 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 designated sealed containers in personnel lockers and not on packaging, ingredients, product or equipment.

RESPONSE: COMPLIANT

11.3.4 Jewelry and Personal Effects

Personal hygiene practices policy V-2 dated 04/30/20 was documented and implemented. Jewelry and other loose objects are prohibited in food processing and handling areas. Employees were observed to follow the jewelry policy during the audit tours. Medical alert bracelets are allowed by policy when approved by management.

11.3.4.1 Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or any area where food is exposed. The wearing of plain bands with no stones and prescribed medical alert bracelets can be permitted, however the site will need to consider their customer requirements and the applicable food legislation.

RESPONSE: COMPLIANT

11.3.5 Visitors

A policy defining visitor and contractor requirements found in Good manufacturing practices GMP-OS0083 policy dated 12/11/19 was documented and implemented. The policy requires that visitors be trained in hygiene and food safety requirements before entering food processing or handling areas and be continually escorted while in food handling locations. The requirements for visitors in those areas include the proper use of access points, hand wash requirements, suitable protective clothing and footwear, removal of jewelry or other loose objects, and an absence of visible signs of illness and all visitors were required to sign in after reading the policy provided by the department head the person is visiting .

11.3.5.1 All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any food processing or handling area.

RESPONSE: COMPLIANT

11.3.5.2 All visitors shall be required to remove jewelry and other loose objects.

RESPONSE: COMPLIANT

11.3.5.3 Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled or processed.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.5.5 All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing or handling areas or shall be escorted at all times in food processing, handling and storage areas.

RESPONSE: COMPLIANT

11.3.6 Staff Amenities

Employee bathrooms and break rooms were observed to be appropriately lit and ventilated and available for all personnel at the facility.

11.3.6.1 Staff amenities supplied with appropriate lighting and ventilation shall be made available for the use of all persons engaged in the handling and processing of product.

RESPONSE: COMPLIANT

11.3.7 Change Rooms

Change rooms were provided as per the company clothing policy those include lockers areas for storing outside stuff observed sufficient for all the employees. Staff come in clean clothes and use factory provided shirts, hair and hands coverings. Showers were not required but provided when required. High risk process areas considered GNS processing where color coded uniform with change room was provided to change outer covering as soiled or upon reentry into the area.

11.3.7.1 Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as required.

RESPONSE: COMPLIANT

11.3.7.2 Change rooms shall be provided for staff engaged in the processing of high risk foods or processing operations in which clothing can be soiled.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.3.8 Laundry

High risk processing areas were designated based upon the risk assessment marked as red areas on the facility map, Employees in those areas were required to follow additional precautions including changing the designated colored smocks and hair nets. at this site and soiled uniforms were required to be changed immediately into the clean ones provided by the contracted laundry services.

11.3.8.1 Provision shall be made for the laundering and storage of clothing worn by staff engaged in high risk processes and for staff engaged in processing operations in which clothing can be heavily soiled.

RESPONSE: COMPLIANT

11.3.9 Sanitary Facilities

Restrooms and washrooms were observed to be separate from food processing and handling areas and accessed via a separate room. An area has been provided for the storage of outer garments and other items while using the facilities. Sanitary facilities were observed to be sufficient in number for all employees and were cleaned and maintained on a scheduled basis. Site drawings and interview with the SQF practitioner, combined with onsite observations provided satisfactory evidence that sanitary drainage is separated from plant drainage and that it is disposed of in accordance with regulations. The sanitary facilities have hand wash sinks with signs in English were posted as per the requirements of the SQF Code.

11.3.9.1 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. Include an area inside or nearby, for storing protective clothing, outer garments and other items while using the facilities; and vi. Kept clean and tidy.

RESPONSE: COMPLIANT

11.3.9.2 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 in regulations.

RESPONSE: COMPLIANT

11.3.9.3 Hand wash basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.2.

RESPONSE: COMPLIANT

11.3.10 Lunch Rooms

There were 04 Lunch rooms provided based upon number of employees, those are properly separated from production are well lit, properly ventilated and are appropriately sized for the number of facility employees. Lunch rooms include hot and cold potable water, food storage areas, refrigerators with hand and utensil washing capabilities were provided. Signs in English reminding employees to wash their hands before returning to work were observed at the exit to lunch rooms. Lunch rooms were observed to be clean and well-maintained during the audit tours. Outside eating areas were maintained as used during the season by the sanitation team.

11.3.10.1 Separate lunch-room facilities shall be provided away from a food contact/handling zone.

RESPONSE: COMPLIANT

11.3.10.2 Lunch-room facilities 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 them 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

11.3.10.3 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 introduction of contamination including pests to the site.

RESPONSE: COMPLIANT

11.3.10.4 Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in lunch-rooms, at lunch-room exits and in outside eating areas if applicable.

RESPONSE: COMPLIANT

11.4.1 Staff Engaged in Food Handling and Processing Operations

Personal hygiene practices policy V-2 dated 04/30/20 was documented that defines food handling procedures for all employees. Personnel are required to access the processing areas through personnel doors only and doors were observed closed. False fingernails or fingernail polish, long nails, false or extended eyelashes are prohibited per the GMPs policy and no violations were noted. Hair restraints were observed to be worn where the product is exposed. Ingredients were in appropriate, labeled containers and kept off the floor. Product attributes including dimensions, net weight and labelling is conduction in areas that were well lit and appropriately equipped for that purpose. Wash down hoses were observed to be properly stored on racks when not in use. N/A: Sensory evaluations was not conducted inside the processing areas.

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 left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required; iii. Packaging material, 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; v. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2; vi. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food; and vii. Hair restraints are used where product is exposed.

RESPONSE: COMPLIANT

11.4.1.2 In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone the site shall implement proper 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 separate from processing equipment.

RESPONSE: NOT APPLICABLE

11.4.1.3 All wash down hoses shall be stored on hose racks after use and not left on the floor.

RESPONSE: COMPLIANT

11.5.1 Water Supply

Water is sourced from town of Elma used in processing, hand washing and cleaning purposes. Water received from the city is potable. Sufficient supply of hot and cold water observed around the facility washing stations. System was designed to not to contaminate the clean water storage tank before the carbon filtration and the RO treatment (only bottle line) observed to follow safe food handling practices. N/A: Non-potable water is not used at this site.

11.5.1.1 Adequate supplies of potable water drawn from a known clean source shall be provided for use during processing operations, as an ingredient and for cleaning the premises and equipment.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.1.3 The delivery of water within the premises shall ensure potable water is not contaminated.

RESPONSE: COMPLIANT

11.5.1.4 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 back flow or back siphonage.

RESPONSE: NOT APPLICABLE

11.5.1.5 Where water is stored on site, storage facilities shall be adequately designed, constructed and maintained to prevent contamination.

RESPONSE: COMPLIANT

11.5.2 Water Treatment

Water was treated through RO treatment at this site (only for the bottle line as per customer requirement), equipment was observed to have been designed for the safe processing and was maintained as per the manufacturer instructions including the UV light intensity by the Maintenance personnel.. Treated water was regularly monitored by taking monthly samples sending to an outside laboratory tested for coliforms, free Chlorine level reviewed completed 03/08/21 including coliform, HPC results as no detectable limits and free Cl <0.1.

11.5.2.1 Water treatment methods, equipment and materials, if required, shall be designed, installed and operated to ensure water receives an effective treatment.

RESPONSE: COMPLIANT

11.5.2.2 Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

RESPONSE: COMPLIANT

11.5.2.3 Treated water shall be regularly monitored to ensure it meets the indicators specified.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.5.3 Ice Supply

Ice was not used for any processing step.

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

RESPONSE: NOT APPLICABLE

11.5.3.2 Ice rooms and receptacles shall be constructed of materials as outlined in elements 11.2.1, 11.2.2 and 11.2.3 and designed to minimize contamination of the ice during storage and distribution.

RESPONSE: NOT APPLICABLE

11.5.4 Water Quality

Water used for in process, cleaning and handwashing is monitored for potability. The site collect water sample around the facility after the RO treatment was collected and sent out to an accredited laboratory tested for HPC, Coliform and Free Cl. on monthly bases with last test reviewed completed 01/12/21 observed all results conforming to the potability requirements, appropriate corrective action was performed when needed. All analytical results observed to have been performed using national recognized standards.

11.5.4.1 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. to convey food; iv. as 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 used to heat water that will come in contact with food.

RESPONSE: COMPLIANT

11.5.4.2 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

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

RESPONSE: COMPLIANT

11.5.5 The Quality of Air and Other Gasses

Compressed air was not used on any product or product contact surfaces. Nitrogen gas was used on some food contact areas was received with COA for food use reviewed the COA by the supplier dated 12/17/19 approving the clean gas. There was no other gas used.

11.5.5.1 Compressed air or other gases (e.g. nitrogen, carbon dioxide) that contacts 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 used in the manufacturing process that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards.

RESPONSE: COMPLIANT

11.6.1 Storage and Handling of Goods

The site has documented storage control program II-2 dated 07/17/20 defining the storage of raw materials, ingredients, packaging, equipment, refrigerated and ambient storage including the chemicals. The program was used to ensure that all materials, including rework are used within their designated shelf-life and appropriate stock rotation. First expired first out process was used to control the materials. Approved outside storage distribution centers were used to store products based upon customer needs those were approved and audited by the QA team and also they are approved storage facilities go through annual 3rd party food safety program. N/A: Temporary storage facility was not used.

11.6.1.1 The site shall document and implement an effective storage plan that allows for the safe, hygienic storage of raw materials (i.e. frozen, chilled, and ambient), ingredients, packaging materials, equipment, and chemicals.

RESPONSE: COMPLIANT

11.6.1.2 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented.

RESPONSE: COMPLIANT

11.6.1.3 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

11.6.1.4 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers.

RESPONSE: COMPLIANT

11.6.1.5 Where goods described in 11.6.2 to 11.6.4 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 is no risk to the integrity of those goods or contamination or adverse effect on food safety.

RESPONSE: NOT APPLICABLE

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

RESPONSE: NOT APPLICABLE

11.6.2 Cold Storage, Freezing and Chilling of Foods

Storage control program II-2 dated 07/17/20 was documented, the site use one cold storage areas for storage of raw materials and some finished products. The room was fitted with the temperature monitoring devices and physical monitoring was performed on twice daily bases recorded on the refrigerated warehouse temperature records reviewed completed for 03/08/21 with all readings conforming to the requirements. The units were observed to have discharge outside the trailer and no condensation was observed. The warehouse observed to have sufficient capacity for the required product.

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

RESPONSE: COMPLIANT

11.6.2.4 Freezing, chilling and cold storage rooms shall be fitted with temperature monitoring equipment and located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible.

RESPONSE: COMPLIANT

11.6.2.5 Loading and unloading docks shall be designed to protect the product during loading and unloading.

RESPONSE: COMPLIANT

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

Storage areas for dry good material and finished goods storage tanks were observed to be located away from any wet areas, clean and well maintained. The product is protected from contamination, deterioration and pest harborage. Racking is designed and constructed from impervious materials and located so storage areas can be cleaned and inspected. Forklifts and other vehicles in processing areas and storage areas were observed to not present a food hazard.

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.

RESPONSE: COMPLIANT

11.6.3.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

All hazardous chemicals were observed to be properly stored and labeled and did not appear to present a hazard to personnel or food products. No processing utensils or packaging were stored next to chemicals. Chemical storage areas were observed to be locked and had instructions on handling hazardous chemicals, an up-to-date inventory of all chemicals, available first aid and spill containment equipment. Daily supplies of chemicals were properly stored. All stored chemicals have current SDS information on file at the facility observed supplied by the approved supplier. SDS and the label declaration and approval for the chemical's intended use were reviewed for (Detergent and sanitizer, CC-200(CIP low foaming cleaner), all food grade lubricants observed to be following applicable legislations with no allergen observed. N/A: Pesticides were not stored at the site.

11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be stored so as not to present a hazard to staff, product, packaging, product handling equipment or areas in which the product is handled, stored or transported.

RESPONSE: COMPLIANT

11.6.4.2 Processing utensils and packaging shall not be stored in areas used to store hazardous chemicals and toxic substances.

RESPONSE: COMPLIANT

11.6.4.3 Daily supplies of chemicals used for continuous sanitizing of water or as a processing aid, or for emergency cleaning of food processing equipment or 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 authorized personnel.

RESPONSE: COMPLIANT

11.6.4.4 Pesticides, rodenticides, fumigants and insecticides shall be stored separate from sanitizers and detergents. All chemicals shall be stored in their original containers, or in clearly labelled and suitable secondary containers if allowed by applicable legislation.

RESPONSE: NOT APPLICABLE

11.6.4.5 Hazardous chemical and toxic substance storage facilities shall: i. Be compliant with national and local legislation and designed such that there is no cross-contamination between chemicals; ii. Be adequately ventilated; iii. Be provided with appropriate signage indicating the area is a hazardous storage area; iv. Be secure and lockable to restrict access only to those personnel with formal training in the handling and use of hazardous chemicals and toxic substances; v. Have instructions on the safe handling of hazardous chemicals and toxic substances readily accessible to staff; vi. Be equipped with a detailed and up-to-date inventory of all chemicals contained in the storage facility; vii. Have suitable first aid equipment and protective clothing available close to the storage area; viii. In the event of a hazardous spill, be designed such that spillage and drainage from the area is contained; and ix. Be equipped with spillage kits and cleaning equipment.

RESPONSE: COMPLIANT

11.6.5 Loading, Transport, and Unloading Practices

A policy defining the practices for receiving was documented as storage control program II-2 dated 07/17/20 and procedures for trailer inspection WSOP0002 dated 07/24/13 was documented defining the requirements for loading, unloading and transportation requirements. It was observed during the audit tours that food is unloaded, stored and loaded under conditions that prevent cross contamination.

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

11.6.6 Loading

The site's storage control program II-2 dated 07/17/20 and warehouse shipping program MFSOP-0004 dated 04/26/11 requires that all trailers be inspected for cleanliness, infestation, odors, damage, etc. before loading and that vehicles be secured from tampering by use of seal or other agreed method. Documentation was reviewed recorded as trailer inspection form reviewed completed for 3/09/21 with all the inspection performed before the loading. It was observed during the audit tours that loading practices do not expose products to detrimental conditions. Trailers and vehicles used for transport were observed to be properly secured from tampering.

11.6.6.1 Vehicles (e.g. trucks/vans/containers) used for transporting food 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

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

RESPONSE: COMPLIANT

11.6.6.3 Vehicles (e.g. trucks/vans/containers) shall be secured from tampering using a seal or other agreed upon and acceptable device or system.

RESPONSE: COMPLIANT

11.6.7 Transport

Storage control program II-2 dated 07/17/20 defines the refrigerated transport was used for some of the outgoing products, units were monitored for the temperature settings and shipping will not load the product until the required temperature was reached and recorded on trailer inspection form reviewed completed 03/08/21 with all readings conforming to the requirements. The receiving customer monitors the temperature at receiving and inform the facility QA if there is any deviation.

11.6.7.1 Refrigerated units shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and product temperatures recorded at regular intervals during loading as appropriate.

RESPONSE: COMPLIANT

11.6.7.2 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

11.6.8 Unloading

Storage control program II-2 dated 07/17/20 was documented defining refrigerated transport was used for some ingredients, units were checked before unloading the product and temperature recorded on the receiving trailer inspection report reviewed completed 03/11/21. Unloading procedures were observed to have no risk to the materials.

11.6.8.1 Prior to opening the doors, the 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 commencement of unloading and at regular intervals during unloading.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.7.1 Process Flow

The process flow was observed to be logical, with a continuous flow and designed to prevent cross contamination. It was observed during audit tours that the flow of employees is such that any cross contamination is minimal.

11.7.1.1 The process flow shall be designed to prevent cross-contamination and organized so there is a continuous flow of product through the process. The flow of personnel shall be managed such that the potential for contamination is minimized.

RESPONSE: COMPLIANT

11.7.2 Receipt of Raw and Packaging Materials and Ingredients

Dry ingredients were observed to be stored separately from unprocessed raw materials and frozen items. Packaging material was not used for any product.

11.7.2.1 Dry ingredients and packaging shall be received and stored separately from frozen and chilled raw materials to ensure there is no cross-contamination. Unprocessed raw materials shall be received and segregated to ensure there is no cross-contamination.

RESPONSE: COMPLIANT

11.7.3 Thawing of Food

Some of the frozen ingredients are thawed by placing the material in the refrigerator and then used. N/A: Water thawing was not used. N/A: Air thawing was not used at this site. Practices were designed to dispose of the packaging in a way to minimize any cross contamination.

11.7.3.1 Thawing of food shall be undertaken in equipment and rooms appropriate for the purpose.

RESPONSE: COMPLIANT

11.7.3.2 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.

RESPONSE: NOT APPLICABLE

11.7.3.3 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

11.7.3.4 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

11.7.4 High Risk Processes

Site has conducted a risk assessment and has defined the areas with high risk as red zones in the facility layout. GNS area considered high risk for cross contamination of allergens, required changing outer garments into a specified color for that area including the shoe covers rest to wear the smocks on top of the uniforms. Only designated employees were allowed in that area.

11.7.4.1 The processing of high risk food shall be conducted under controlled conditions such that sensitive areas in which 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

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

RESPONSE: COMPLIANT

11.7.4.3 Staff access points shall be located, designed and equipped to enable staff to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination.

RESPONSE: COMPLIANT

11.7.4.4 Staff engaged in high risk areas shall change into clean clothing or temporary protective outerwear when entering high risk areas.

RESPONSE: COMPLIANT

11.7.4.5 Product transfer points shall be located and designed so as not to compromise high risk segregation and to minimize the risk of cross-contamination.

RESPONSE: COMPLIANT

11.7.5 Control of Foreign Matter Contamination

Sanitary design program V-1 dated 02/26/20, Inline strainer/magnet post production policy dated 04/23/19, Glass replacement and breakage policy MFSOP-0013 dated 11/23/18 and brush and equipment color coding program dated 02/26/20 was documented. Procedures define the responsibility and methods used in controlling the physical contaminants. The food safety team perform the regular inspections on monthly bases and record on the plant inspection checklist reviewed completed 03/17/21 and monthly checks for glass and brittle plastic registry reviewed completed 02/02/21 observed to have been completed for all areas of the plant and equipment verified as per the procedures with one observation of missing glass cover at row D in filler room and appropriate corrective action was observed completed as per the investigation. Loose metal objects and any covering would be removed from the storage area as per the foreign mater control procedures and was controlled by the supervisor regular inspections. The policy defines inspections and monitoring of pallets for safe food use for wooden pallets and utensils. Knife and cutting instrument verification program dated 07/12/20 defines the secure use of knives and monitored during pre operational inspections during each shift.

11.7.5.1 The responsibility and methods used to prevent foreign matter contamination of the product shall be documented, implemented and communicated to all staff.

RESPONSE: COMPLIANT

11.7.5.2 Inspections shall be performed to ensure plant and equipment remain in good condition, equipment has not become detached or deteriorated and is free from potential contaminants.

RESPONSE: COMPLIANT

11.7.5.3 All glass objects or similar material in food handling/contact zones shall be listed in a glass register including details of their location.

RESPONSE: COMPLIANT

11.7.5.4 Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where the product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers required under regulation) shall not be permitted in food processing /contact zones.

RESPONSE: COMPLIANT

11.7.5.5 Regular inspections of food handling/contact zones shall be conducted 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 register.

RESPONSE: COMPLIANT

11.7.5.6 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

11.7.5.7 Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition shall be subject to regular inspection.11.7.5.8 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

11.7.5.8 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

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

RESPONSE: COMPLIANT

11.7.6 Detection of Foreign Objects

Strainer and magnet program dated 04/23/19 was documented. Line operators were interviewed performing the task as strainer integrity for each run recorded as inline strainer/magnet post production report reviewed completed 03/09/21, observed all checks with safe limits and no deviation recorded, operators and technicians monitoring devices were interviewed and they were able to explain the procedures and what would they do if they will come across any nonconformance. , no other device was used for foreign material control. All records observed to have been maintained and verified by the SQF practitioner.

11.7.6.1 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

11.7.6.2 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

11.7.6.3 Records shall be maintained of the inspection of foreign object detection devices and of any products rejected or removed by them. Records shall include any corrective actions resulting from the inspections.

RESPONSE: COMPLIANT

11.7.7 Managing Foreign Matter Contamination Incidents

Glass replacement and breakage policy MFSOP-0013 dated 11/23/18 was documented that requires that any product affected by foreign material contamination be isolated, inspected, reworked or disposed of. The glass policy requires that a thorough cleanup and inspection (including cleaning of equipment and footwear) upon any glass breakage occurrence. SQF practitioner or supervisor is required to inspect the affected area before the restarting of production. Food safety supervisors and production employees interviewed during the audit were able to explain their understanding about the policies and procedures about foreign material contamination handling.

11.7.7.1 In all cases of foreign matter contamination the affected batch or item shall be isolated, inspected, reworked or disposed.

RESPONSE: COMPLIANT

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

RESPONSE: COMPLIANT

11.8.1 Location

Onsite laboratory was used at this site for testing microbiological and chemical profile of the products. it was observed separate from the processing areas. Micro waste after autoclaving was disposed of to the outside garbage bin rest of the lab waste was contained and disposed of to the main garbage bin outside the premises. Waste water from the lab was directed to the outside city sewage system. Signage in English was posted outside the lab indicating the restricted area and access was granted only with the authorized key.

11.8.1.1 On site laboratories conducting chemical and microbiological analysis 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.

RESPONSE: COMPLIANT

11.8.1.2 Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory wastewater outlet shall as a minimum be down stream of drains that service food processing and handling areas.

RESPONSE: COMPLIANT

11.8.1.3 Signage shall be displayed identifying the laboratory area as a restricted area accessible only by authorized personnel.

RESPONSE: COMPLIANT

11.9.1 Dry and Liquid Waste Disposal

A policy defining the methods and responsibilities for handling dry, wet and liquid waste has been documented and implemented as environmental consideration program V-3 dated 12/03/20 was documented. Waste was observed to be removed on a scheduled basis and is documented daily on the master sanitation program reviewed completed 03/02-05/20. Waste containers, hoppers, bins and storage areas on the interior and exterior of the facility were observed to be well-maintained and clean. Solid waste from processing was observed to be properly disposed of. Waste water is discharged to plant drains to outside city sewage system. All waste from the rest rooms and lunch rooms was discharged to the city sewage system directly outside the premises. daily master sanitation form reviewed completed for the week 02/21/21 for combi bloc area. Process was documented explaining requirements for trademarked material disposal by providing the customer with destruction information.

11.9.1.1 The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented.

RESPONSE: COMPLIANT

11.9.1.2 Waste shall be removed on a regular basis and not 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

11.9.1.3 Trolleys, vehicles waste disposal equipment, collection bins and storage areas shall be maintained in a serviceable condition, cleaned and sanitized regularly so as not to attract pests and other vermin.

RESPONSE: COMPLIANT

11.9.1.4 Adequate provision shall be made for the disposal of all solid processing waste including trimmings, inedible material and used packaging.

RESPONSE: COMPLIANT

11.9.1.5 Where applicable, a documented procedure shall be in place for the controlled disposal of trademarked materials. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

RESPONSE: COMPLIANT

11.9.1.6 Inedible waste designated for animal feed shall be stored and handled so as to not cause a risk to the animal or to further processing.

RESPONSE: COMPLIANT

11.9.1.7 Waste held on site prior to disposal shall be stored in a separate storage facility and suitably insect proofed and contained so as not to present a hazard.

RESPONSE: COMPLIANT

11.9.1.8 Adequate provision shall be made for the disposal of all liquid waste from processing and food handling areas. Liquid waste shall be either removed from the processing environment continuously or held in a designated storage area in lidded containers prior to disposal so as not to present a hazard.

RESPONSE: COMPLIANT

11.9.1.9 Reviews of the effectiveness of waste management will form part of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports.

RESPONSE: COMPLIANT

11.10.1 Grounds and Roadways

The site's buildings, property and surroundings were observed during the audit to not pose a food safety risk to products. Surrounding were observed to have other businesses no risk was observed for the facility. Measures have been established to maintain a suitable external environment and the facility hire a contractor to monitor and maintain external environment per the requirements. Monitoring was recorded on monthly walk database conducted between April to November reviewed last inspection record completed 11/20/20 observed verified by the management. The site maintains the pathways to have safe walk around.

11.10.1.1 Measures shall be established to maintain a suitable external environment, and the effectiveness of the established measures shall be monitored and periodically reviewed.

RESPONSE: COMPLIANT

11.10.1.2	The grounds and area surrounding the premises shall be maintained to minimize dust and kept free of waste, accumulated debris or standing water so as not to attract pests and vermin. **RESPONSE:** COMPLIANT
11.10.1.3	Paths, roadways and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operation of the premises. **RESPONSE:** COMPLIANT
11.10.1.4	Paths, roadways, loading and unloading areas shall be adequately drained to prevent ponding of water. Drains shall be separate from the site drainage system and regularly cleared of debris. **RESPONSE:** COMPLIANT
11.10.1.5	Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises. **RESPONSE:** COMPLIANT
11.10.1.6	Paths from amenities leading to site entrances are required to be effectively sealed. **RESPONSE:** COMPLIANT